# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## **FORM 10-Q/A**

(Amendment No. 1)

(Mark One)

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2017

or

□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-36740

# FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)

409 Illinois Street San Francisco, CA (Address of Principal Executive Offices) 77-0357827 (I.R.S. Employer Identification No.)

> 94158 (Zip Code)

(415) 978-1200

Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 🗵 No 🗆

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	$\boxtimes$	Accelerated filer	
Non-accelerated filer	$\Box$ (Do not check if a smaller reporting company)	Smaller reporting company	
		Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 🗆 No 🗵

The number of outstanding shares of the registrant's common stock as of November 30, 2017 was 82,197,479.

## EXPLANATORY NOTE

FibroGen, Inc. (the "Company") filed its Quarterly Report on Form 10-Q for the period ended September 30, 2017, on November 8, 2017 (the "Original Filing"). The Company is filing this Amendment No. 1 to the Quarterly Report on Form 10-Q/A ("Amendment No. 1") to file that certain Amended and Restated License, Development and Commercialization Agreement (for the US and Certain Other Territories), by and between the Company and AstraZeneca AB, dated as of October 16, 2014 and effective as of July 30, 2013 as Exhibit 10.16 thereto. This Amendment No. 1 does not reflect subsequent events occurring after the filing date of the Original Filing or modify or update any disclosures made in the Original Filing, except as described above.

## ITEM 6. EXHIBITS.

Exhibit	bit Incorporation				By Reference	
Number	Exhibit Description	Form	SEC File No.	<u>Exhibit</u>	Filing Date	
10.16*†	<u>Amended and Restated License, Development and Commercialization Agreement by</u> and between Registrant and AstraZeneca AB, effective as of July 30, 2013.	_	_	_	_	
31.1*	<u>Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule</u> <u>15d-14(a).</u>		_	_	_	
31.2*	<u>Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).</u>	_	_	_	_	

- \*
- Filed herewith Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission. t

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to be signed on its behalf by the undersigned thereunto duly authorized.

Date: December 13, 2017

Date: December 13, 2017

## FibroGen, Inc.

By: /s/ Thomas B. Neff

Thomas B. Neff Chairman of the Board and Chief Executive Officer (*Principal Executive Officer*)

By: /s/ Pat Cotroneo

Pat Cotroneo Vice President, Finance and Chief Financial Officer (*Principal Financial and Accounting Officer*)

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[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

Exhibit 10.16

## AMENDED AND RESTATED

## LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

(for the US and Certain Other Territories)

between

FIBROGEN, INC.

and

ASTRAZENECA AB

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.	

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.	

#### AMENDED AND RESTATED

#### LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

**THIS AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT** (the "*Agreement*") is entered into as of October 16, 2014 (the "*Execution Date*"), and effective as of July 30, 2013 (the "*Effective Date*") by and between **FIBROGEN, INC.**, a Delaware corporation having its principal place of business at 409 Illinois St., San Francisco, California 94158, United States ("*FibroGen*") and ASTRAZENECA AB, a company incorporated in Sweden under no. 556011-7482 with offices at Pepparedsleden 1, 431 83 Mölndal, Gothenburg, Sweden ("*AstraZeneca*"). FibroGen and AstraZeneca are sometimes referred to herein individually as a "*Party*" and collectively as the "*Parties*".

#### BACKGROUND

A. AstraZeneca is a fully-integrated, global pharmaceutical company with expertise in the research, development, manufacture and commercialization of human therapeutic products.

**B.** FibroGen is a biotechnology company with expertise in the discovery, research, development and manufacture of small molecule prolyl hydroxylase inhibitors that modulate hypoxia-inducible factor for the treatment of anemia.

**C.** FibroGen is developing certain of such compounds in collaboration with Astellas Pharma Inc. ("*Astellas*"), its exclusive licensee for Japan, Europe, the Commonwealth of Independent States (CIS), the Middle East and South Africa pursuant to certain collaboration agreements between FibroGen and Astellas (collectively, the "*Astellas Collaboration*").

**D.** AstraZeneca and FibroGen desire to establish as of Effective Date a collaboration for the joint continued development, including regulatory submission, and, if successful, commercialization of certain of such compounds in the U.S. and all countries of the world other than those subject to the existing Astellas Collaboration.

**E.** With respect to the collaboration between the Parties in China, the development and commercialization activities are governed by that certain License, Development and Commercialization Agreement (China) by and between FibroGen China Anemia Holdings, Ltd., Beijing FibroGen Medical Technology Development Co., Ltd., and FibroGen International (Hong Kong) Limited, Affiliates of FibroGen, and AstraZeneca, of even date herewith (the "*China Agreement*"), except that a portion of the governance structure for China shall be as set forth in this Agreement, and the Parties' activities with respect to all other countries not licensed to Astellas are governed by this Agreement.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

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## ARTICLE 1

#### DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1. Except where the context otherwise requires, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. In addition, the terms "includes," "including," "include" and derivative forms of them shall be deemed followed by the phrase "without limitation" (regardless of whether it is actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others)).

**1.1** "*Acquiror*" has the meaning set forth in Section 15.5.

**1.2** "*Affiliate*" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.3 "Alliance Manager" has the meaning set forth in Section 2.7.

1.4 "Annual Net Sales" means the Net Sales made during any given Calendar Year.

**1.5** "*Anti-Corruption Laws*" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.6 "Astellas" has the meaning set forth in Section C on the first page.

1.7 "Astellas Agreements" means the Astellas EU Agreement and the Astellas Japan Agreement.

1.8 "Astellas Collaboration" has the meaning set forth in Section C on the first page.

**1.9** "*Astellas EU Agreement*" means the Anemia License and Collaboration Agreement between FibroGen and Astellas with respect to the countries listed on **Exhibit A** (other than Japan) effective April 28, 2006, as amended from time to time.

**1.10** "Astellas Japan Agreement" means the Collaboration Agreement between FibroGen and Astellas with respect to Japan effective June 1, 2005, as amended from time to time.

1.11 "AstraZeneca Inventions" has the meaning set forth in Section 7.8(d).

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**1.12** "*AstraZeneca Know-How*" means all Information Controlled as of the Effective Date or thereafter during the Term by AstraZeneca and/or its Affiliate(s) that is reasonably necessary or useful for the research, development, manufacture, use, importation or sale of Products in the Field. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of or by AstraZeneca, except as provided in Section 15.5. For additional clarity, AstraZeneca Know-How shall exclude rights under any AstraZeneca Patents and AstraZeneca's interest in the Joint Patents and Joint Inventions.

**1.13** "*AstraZeneca Patents*" means all Patents that are Controlled as of the Effective Date or thereafter during the Term by AstraZeneca and/or its Affiliate(s) and that claim the composition of matter, manufacture or use of one or more Collaboration Compounds or Products or that would otherwise be infringed (or with respect to patent applications, would be infringed if issued or granted with the then-currently pending claims), absent a license, by the manufacture, use or sale of any Collaboration Compounds or Product. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of or by, AstraZeneca except as provided in Section 15.5.

**1.14** "*AstraZeneca Anti-Corruption Rules and Policies*" means the key principles from AstraZeneca's ABAC and External Interactions Policies regarding anti-bribery and corruption issues, attached as **Exhibit F** to this Agreement, as the same may be amended, modified or supplemented from time to time as notified by AstraZeneca to FibroGen.

**1.15** "*AstraZeneca Technology*" means the AstraZeneca Patents, AstraZeneca Know-How, and AstraZeneca's interest in Joint Patents and Joint Inventions.

**1.16** "*Bankrupt Party*" has the meaning set forth in Section 13.9(b).

1.17 "Business Day" means a day other than a Saturday, Sunday or bank or other public holiday in San Francisco, California, the UK or Sweden.

1.18 "Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.19 "Calendar Year" means each successive period of twelve (12) calendar months commencing on January 1.

1.20 "Carcinogenicity Studies" means the following carcinogenicity studies in rats and mice: (1) [\*].

**1.21** "China Agreement" has the meaning set forth in Section E on the first page.

**1.22** "*China Committee*" means the governing committee established under the China Agreement, and any successor or other committee or governing body that serves the same functions under the China Agreement.

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**1.23** "*CKD Indications*" means (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, and (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis.

1.24 "Clinical Trial" means any human clinical trial of a Product.

1.25 "Co-Commercialization Agreement" has the meaning set forth in Section 5.10.

**1.26** "*Collaboration*" has the meaning set forth in Section 2.1.

**1.27** "*Collaboration Compound*" means any of the following: (a) FG-4592, (b) any HIF Compound (other than FG-4592) that is added to this Agreement pursuant to Section 3.6, and (c) any salts, esters, complexes, chelates, crystalline and amorphous morphic forms, pegylated forms, enantiomers (excluding regioisomers), prodrugs, solvates, metabolites and catabolites of any of the foregoing ((a) or (b)).

1.28 "Collaboration Inventions" has the meaning set forth in Section 9.2.

**1.29** "*Combination Product*" means a Product that is comprised of or contains a Collaboration Compound as an active ingredient together with one (1) or more other active ingredients and is sold either as a fixed dose/unit or as separate doses/units in a single package.

**1.30** "*Commercialization*" means the commercial manufacture, marketing, promotion, sale and/or distribution of Products in the Territory. Commercialization includes commercial activities conducted in preparation for Product launch in each indication. "*Commercialize*" has a correlative meaning.

**1.31** "*Commercialization Costs*" means all costs incurred by or on behalf of FibroGen that are directly and reasonably allocable to the conduct of activities allocated to FibroGen under the U.S. Commercialization Plan or Co-Commercialization Agreement for the Commercialization of Products in the U.S.

**1.32** "*Commercially Reasonable Efforts*" means, with respect to a Party's obligations under this Agreement to Develop or Commercialize a Product, the carrying out of such obligations or tasks with a level of efforts and resources consistent with the commercially reasonable practices of (a) in the case of AstraZeneca, a pharmaceutical company the size and geographical scope of AstraZeneca and (b) in the case of FibroGen, a biotechnology company the size and geographical scope of FibroGen, in each case (a) and (b) for the development or commercialization of similarly situated pharmaceutical products as such Product and at a similar stage of development or commercialization, taking into consideration their safety and efficacy, their cost to develop, the nature and extent of their market exclusivity (including patent coverage and regulatory exclusivity), the likelihood of Regulatory Approval, their expected profitability, including the amounts of marketing and promotional expenditures with respect to such products and generic products, and the competitiveness of alternative compounds and products. Commercially Reasonable Efforts requires that the Party: (a) promptly assign responsibility for such obligations or tasks to specific employee(s) who are held accountable for progress and monitor such progress

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on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives. For the avoidance of doubt, the commitment to use "Commercially Reasonable Efforts" shall not preclude the suspension or discontinuance by AstraZeneca of any Product, if appropriate, based on the foregoing considerations.

**1.33** "*Committee*" means the Joint Steering Committee, Joint Development Committee, Joint Commercialization Committee or IP Committee, or any other subcommittee established under Article 2, as applicable.

1.34 "Compliance Audit" has the meaning set forth in Section 10.3(e).

**1.35** "*Confidential Information*" means, with respect to a Party, all Information of such Party that is disclosed to the other Party under this Agreement, which may include, without limitation, specifications, know-how, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, whether disclosed in oral, written, graphic, or electronic form. All confidential Information disclosed by either Party pursuant to the Existing Confidentiality Agreement shall be deemed to be Confidential Information of the disclosing Party hereunder (with the mutual understanding and agreement that any use or disclosure thereof that is authorized under Article 12 shall not be restricted by, or be deemed a violation of, such Existing Confidentiality Agreement).

**1.36** "*Control*" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns such material, Information, or intellectual property right, or (b) has a license or right to use to such material, Information, or intellectual property right, in each case with the ability to grant to the other Party access, a right to use, or a license, or a sublicense (as applicable) to such material, Information, or intellectual property right, or intellectual property right on the terms and conditions set forth herein, without violating the terms of any agreement or other arrangement with any Third Party.

**1.37** "*Core Indication*" means any of the following: (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis, (c) [\*]).

1.38 "Covenant Period 1" has the meaning set forth in Section 7.4(a)(ii).

1.39 "Covenant Period 2" has the meaning set forth in Section 7.4(a)(iii).

**1.40** "*CPI-U*" means the Consumer Price Index for All Urban Consumers (All Items), or any successor to such published measure, not seasonally adjusted, as published by the U.S. Department of Labor Bureau of Labor Statistics.

1.41 "Designated Indication" has the meaning set forth in Section 3.5(a).

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## 1.42 "Designated Product" has the meaning set forth in Section 8.4(a).

**1.43** "*Development*" means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of a Product for one or more indications or (b) developing the process for the manufacture of clinical and commercial quantities of drug substance or drug Product. This includes: (i) preclinical testing, toxicology and Clinical Trials; (ii) preparation, submission, review, statistical analysis, report writing and development of data or information for the purpose of submission to a governmental authority to obtain, maintain and/or expand Regulatory Approval of a Product, and outside counsel regulatory legal services related thereto; and (iii) manufacturing process development and scale-up for drug substance and drug product, test method development, packaging development, stability testing, qualification and validation, production of drug substance and drug product, in bulk for preclinical and clinical studies, and related quality assurance technical support activities; provided, however, that Development shall exclude Commercialization. For clarity, Development shall include those Phase 4 Clinical Trials that are included in clause (b) of the definition of Phase 4 Clinical Trials. "*Develop*" has a correlative meaning.

**1.44** "*Development Budget*" means the budget associated with the activities conducted under the Development Plan for the U.S., detailing the anticipated Development Costs.

**1.45** "*Development Costs*" means all costs incurred by or on behalf of FibroGen or AstraZeneca that are reasonably allocable to the Development of Products for the U.S. in accordance with the Development Plan, which shall equal the sum of (a) Personnel Costs, (b) the Fully Burdened Cost of Collaboration Compound or Product or comparator drug, concomitant drug, placebo or other materials used in any Clinical Trial or Nonclinical Studies, and (c) all other out-of-pocket costs, in each case for activities for the U.S.

**1.46** "*Development Data*" has the meaning set forth in Section 3.10(a).

**1.47** "*Development Plan*" means the plan for conducting collaborative Development of Products for approval and use in the U.S. and RoW, as set forth in Section 3.2(a).

**1.48** "*Development Sharing Period*" means the time period commencing on August 1, 2013 and ending on the date on which the Parties have incurred two hundred thirty-three million Dollars (\$233,000,000) in Development Costs.

1.49 "Development Strategy" has the meaning set forth in Section 3.2(c).

**1.50** "*DFCI Agreement*" means the License Agreement between FibroGen and the Dana-Farber Cancer Institute, Inc. ("*DFCI*"), dated March 29, 2006, a redacted copy of which is attached hereto as **Exhibit B**.

1.51 "Distributor" has the meaning set forth in Section 7.3(c).

1.52 "Dollar" or "\$" means United States dollar.

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**1.53** "*ESA Approved Indications*" means the following indications: (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis, (c) [\*].

**1.54** "*EU*" means all of the European Union member states as of the applicable time during the Term.

**1.55** "*Executive Officer*" means, in the case of AstraZeneca, AstraZeneca's Chief Executive Officer or any senior executive designated by and who reports directly to the Chief Executive Officer of AstraZeneca, and in the case of FibroGen, FibroGen's Chief Executive Officer.

**1.56** "*Existing Confidentiality Agreement*" means, collectively, the Non-Disclosure Agreement between FibroGen and AstraZeneca dated June 21, 2012, as amended February 7, 2013, and May 23, 2013, and the Non-Disclosure Agreement between FibroGen and AstraZeneca dated April 1, 2013.

1.57 "FCPA" means the U.S. Foreign Corrupt Practices Act of 1977, as amended, including the rules and regulations thereunder.

1.58 "FDA" means the United States Food and Drug Administration or its successor.

**1.59** "*FD&C Act*" means the United States Federal Food, Drug and Cosmetic Act, as amended.

1.60 "FG-4592" means the molecule with the chemical structure set forth on Exhibit C.

**1.61** "*FibroGen IPO*" means the initial public offering of its securities by FibroGen in any of the U.S., United Kingdom, Spain, France, Italy, Germany, Japan, China or Hong Kong.

**1.62** "*FibroGen Know-How*" means all Information Controlled as of the Effective Date or thereafter during the Term by FibroGen and/or its Affiliate(s) and reasonably necessary or useful for the development, manufacture, use, importation or sale of Collaboration Compounds or Products in the Field; including, without limitation, any such Information made or generated by or on behalf of FibroGen or its Affiliate in the course of performing FibroGen's obligations or exercising FibroGen's rights under this Agreement. The use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of FibroGen, except as provided in Section 15.5. FibroGen Know-How shall exclude (a) rights under any FibroGen Patents and FibroGen's interest in the Joint Patents and Joint Inventions and (b) any Third Party Information that is not included pursuant to Section 8.8(d).

**1.63** "*FibroGen Patents*" means (i) the Listed Patents and (ii) all other Patents (excluding any Joint Patents) that are Controlled as of the Effective Date or thereafter during the Term by FibroGen and/or its Affiliate(s) and that claim the composition of matter, manufacture or use of one or more Collaboration Compounds or Products in the Field or that would otherwise be infringed (or with respect to patent applications, would be infringed if issued or granted with the

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then-currently pending claims), absent a license, by the manufacture, use or sale of any Collaboration Compound or Product in the Field. The use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of FibroGen except as provided in Section 15.5. FibroGen Patents does not include Third Party Patents that are not included pursuant to Section 8.8(d).

1.64 "FibroGen Technology" means the FibroGen Patents, FibroGen Know-How, and FibroGen's interest in Joint Patents and Joint Inventions.

**1.65** "*Field*" means (a) the treatment of anemia in humans and non-human animals, which means any treatment intended to increase hemoglobin levels or utilization or to increase hematocrit, as measured by acceptable clinical parameters, including unit volume concentrations of hemoglobin, red blood cell volume, or red blood cell count, and (b) any Designated Indication added to the Field pursuant to Section 3.5. For the avoidance of doubt, the Core Indications, the ESA Approved Indications as well as the indications listed on **Exhibit D** are all included in clause (a) of the preceding sentence.

**1.66** "*First Commercial Sale*" means, with respect to a Product and country in the Territory, the first arm's length sale for monetary value by AstraZeneca, its Affiliates or its Sublicensees to a Third Party intended for end use or consumption by the general public (regardless of when actual consumption occurs) of such Product in such country after Regulatory Approval (and any pricing or reimbursement approvals, if reasonably necessary to commence regular commercial sales) has been obtained in such country. For the avoidance of doubt, sales prior to receipt of Regulatory Approvals necessary to commence regular commercial sales, such as so-called "treatment IND sales", "named patient sales" or "compassionate use sales", shall not be construed as a First Commercial Sale.

**1.67** "*Fully Burdened Cost*" means, with respect to a Product, all costs actually incurred by FibroGen or its Affiliates attributable and fairly allocable to produce, package and distribute the Product to AstraZeneca or its carrier [\*]) for the acquisition or sale of such Product, which costs to produce and package the Product will include the direct material and labor and indirect costs (fairly allocated) that are incurred by FibroGen or its Affiliates associated with the manufacture, filling, packaging, labeling, and preparation of product for shipment and/or other preparation of such Product, as applicable, including non-refundable and non-creditable Indirect Taxes, customs fees and customs duties. Fully Burdened Cost will be determined in accordance with U.S. GAAP and will include the attributable and fairly allocable costs of facilities, labor, purchasing, depreciation of equipment, materials, payments to Third Parties for any necessary contract work for the manufacture or testing of the Product, quality assurance, quality control and other testing (including validation studies), storage (if requested by AstraZeneca), shipping and costs for distribution, and a reasonable allocation of general and administrative overhead for the manufacturing operations attributable to Product distribution to AstraZeneca. These costs shall include capacity reservation charges paid to a Third Party, and the proportion of fixed overhead allocated to total available capacity reasonably reserved for the product, less the amount included in budgeted cost of goods (budgeted capacity); provided, that FibroGen shall use good faith efforts to utilize any such reserved but unused capacity. By way of example, if fifteen percent (15%) of the total site capacity is reasonably reserved for the production of the Product.

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and for the same period budgeted capacity is planned for only ten percent (10%) of the site, the fixed overhead related to the remaining five percent (5%) dedicated capacity shall be included in Fully Burdened Cost as reserve capacity. Costs for distribution consist of the labor, materials and reasonably allocated overhead necessary to prepare and package the final product for shipment to AstraZeneca.

**1.68** "*GCP*" means the current standards for clinical trials for pharmaceuticals, as set forth in the U.S. Code of Federal Regulations, ICH guidelines and applicable regulations, laws or rules as promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required in other countries than the U.S. in which a Product is intended to be sold to the extent such standards are not less stringent than U.S. GCP.

**1.69** "*Generic Product*" means, with respect to a Product and a particular country, any pharmaceutical product (a) that is sold in such country by a Third Party that is not a Sublicensee or Distributor selling such product under authorization from AstraZeneca or its Affiliates, (b) that contains the same Collaboration Compound as the relevant Product and that is in the same dosage form as such Product and for the same route of administration as such Product and is approved by the Regulatory Authority for such country for an indication for which such Product obtained Regulatory Approval in such country and (c) that is approved in reliance on the prior approval of such Product as determined by the applicable Regulatory Authority.

**1.70** "*Governmental Authority*" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**1.71** "*Government Official*" means (i) any individual or entity employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (ii) any political party, party official or candidate, (iii) any individual or entity that holds or performs the duties of an appointment, office or position created by custom or convention or (iv) any individual or entity that holds himself, herself or itself out to be the authorized intermediary of any of the foregoing.

1.72 "HICP" means, with respect to a country, the Harmonised Index of Consumer Prices for such country published by Eurostat.

1.73 "HIF Compound" means any compound that stabilizes hypoxia-inducible factor ("HIF") or that modulates HIF prolyl hydroxylase activity.

**1.74** "*Hourly Rate*" means, as of the Effective Date, \$[\*], which is the blended hourly fully burdened rate for FibroGen's employees and agents conducting Development activities. The Hourly Rate will be adjusted annually as of each January 1 (commencing 2014) to reflect the percentage increase or decrease (as the case may be) from the preceding year in the average consumer price, calculated as the average of (i) the annual percentage change of US CPI-U and (ii) the average of the annual percentage changes of HICP for the 5 major EU countries (UK, France, Germany, Italy, and Spain) for such annual period, except as otherwise mutually agreed by the

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Parties. The Hourly Rate includes, without limitation, the following general expense categories: salaries and wages (including bonuses, moving expenses, and payroll taxes), benefits provided (including health benefits, defined contribution, defined benefit plans, vacations, etc.), direct employee costs (including recruitment costs, internal and external training costs, computer charges, automobile leases, subscriptions and reference materials, telephone, fax, cellular phone, and copy machines and related costs), and allocation of other overhead costs (including rent, insurance, and utilities).

**1.75** "*IND*" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.76 "Indirect Taxes" means VAT, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on the invoice.

**1.77** "*Information*" means any data, results and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, compositions of matter of any type or kind, software, algorithms, marketing reports, clinical and non-clinical study reports, regulatory submission documents and summaries, expertise, stability, technology, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, in all cases, patentable or otherwise.

1.78 "Initial Development Plan" has the meaning set forth in Section 3.2(b).

1.79 "Inventions" has the meaning set forth in Section 9.2.

**1.80** "*IP Committee*" has the meaning set forth in Section 9.1.

1.81 "Joint Commercialization Committee" or "JCC" means the committee formed by the Parties as described in Section 2.4.

1.82 "Joint Development Committee" or "JDC" means the committee formed by the Parties as described in Section 2.3.

1.83 "Joint Inventions" has the meaning set forth in Section 9.2.

1.84 "Joint Patents" has the meaning set forth in Section 9.2.

1.85 "Joint Project Team" or "JPT" has the meaning set forth in Section 2.9.

1.86 "Joint Steering Committee" or "JSC" means the committee formed by the Parties as described in Section 2.2.

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**1.87** "*Large Dialysis Organization*" or "*LDO*" means (a) an organization that operates out-patient dialysis centers and that has at least twenty-five percent (25%) of the market share (measured by number of patients as determined by USRDS or any successor) of dialysis centers in the U.S. and (b) Dialysis Clinic Inc. Examples of Large Dialysis Organizations as of the Effective Date in clause (a) are Fresenius Medical Care and DaVita HealthCare Partners Inc.

**1.88** "*Listed Patents*" means the Patents listed on **Exhibit E**. The Parties may update such exhibit from time to time upon mutual written agreement, e.g., to update the status of the listed Patents, to add newly filed FibroGen Patents, or to make other agreed revisions.

**1.89** "*Marketing Authorization Application*" or "*MAA*" means an application for Regulatory Approval in a country, territory or possession other than the U.S.

**1.90** "*Marks*" has the meaning set forth in Section 9.11.

**1.91** "*Material Anti-Corruption Law Violation*" means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement which [ \* ] a material adverse effect on either Party or on the reputation of either Party because of its relationship with the other Party.

**1.92** "*Medical Scientific Liaison*" or "*MSL*" means a field-based professional with scientific, medical and clinical expertise who provides medical and scientific support for marketed products, new indications and compounds in development or registration. An MSL engages in scientific exchange with medical and scientific experts including investigators, key opinion leaders, physicians and other medical professionals and customers.

1.93 "NDA" means a New Drug Application, as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA.

**1.94** "*Net Sales*" means the gross invoiced amount on sales of a Product by AstraZeneca, its Affiliates or its or their Sublicensees to Third Parties (including Distributors but excluding Sublicensees) in the Territory, after deduction of the following amounts:

(a) normal and customary trade, quantity or prompt settlement discounts (including chargebacks and allowances) actually allowed;

(b) amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or bona fide price reductions determined by AstraZeneca, its Affiliates or its or their Sublicensees in good faith;

(c) rebates and similar payments made with respect to sales paid for by managed care organizations, hospitals, other buying groups or any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights under this Agreement, federal or state Medicaid, Medicare or similar state program in the U.S. or equivalent governmental program in any other country;

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(d) any invoiced amounts that are not collected by AstraZeneca, its Affiliates or its or their Sublicensees, including bad debts (provided that such amounts will be added to Net Sales if and when recovered), up to an amount not to exceed [\*]) of Net Sales;

(e) excise taxes, Indirect Taxes, customs duties, customs levies and import fees imposed on the sale, importation, use or distribution of the Products;

(f) [\*]; and

(g) as an allowance for transportation costs, distribution expenses, special packaging and related insurance charges, [\*].

For clarity, any deduction made pursuant to one subsection above, shall not be additionally deducted in the event that such deduction may also apply in a separate subsection (i.e., no double-counting).

In the event that a Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average invoice price in such country of any Product that contains the same Collaboration Compound(s) as such Combination Product as its sole active ingredient(s), if sold separately in such country, and B is the average invoice price in such country of each product that contains active ingredient(s) other than the Collaboration Compound(s) contained in such Combination Product as its sole active ingredient(s), if sold separately in such country for each Product that contains only the Collaboration Compound(s) and each product that contains solely active ingredient(s) other than the Collaboration Compound(s) included in the Combination Product shall be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency or functionality, as applicable. If either such Product that contains the Collaboration Compound(s) is not sold separately in a particular country, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of and all other factors, including patent coverage, reasonably relevant to the relative value of the Collaboration Compound(s) on the one hand and all of the other active ingredient(s), collectively, on the other hand.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with AstraZeneca's, its Affiliates' or its or their Sublicensees' existing allocation method; *provided* that any such allocation shall be done in accordance with applicable law, including any price reporting laws, rules and regulations.

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Net Sales will be calculated using AstraZeneca's internal audited systems consistently applied to report such sales as adjusted for any of the deductions set forth above not taken into account in such systems. Deductions pursuant to item (d) above will be taken in the Calendar Quarter in which such sales are no longer recorded as a receivable.

Any free of charge disposition or use of reasonable quantities of a Product, up to the amount determined by the JCC, for regulatory or marketing purposes (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7) such as compassionate use or indigent patient programs, will not be deemed a sale or disposition for calculating Net Sales. Sales and other transfer of Product between any of AstraZeneca, its Affiliates and Sublicensees will not give rise to Net Sales except if the purchaser is an end user.

**1.95** "*Nonclinical Studies*" means all *in vivo* and *in vitro* non-human studies of Collaboration Compounds and Products, including non-clinical pharmacology, toxicology, tumor and teratogenicity studies.

**1.96** "*Patent*" means (i) all national, regional and international patents and patent applications, including provisional patent applications, (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents and design patents and certificates of invention, (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, (ii) and (iii)), and (v) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

**1.97** "*Personnel Costs*" means, with respect to a reporting period, the total number of hours FibroGen employees and consultants or AstraZeneca employees and consultants, as applicable, actually spent in such reporting period conducting activities under the Development Plan multiplied by the Hourly Rate. Such activities may include, without limitation, clinical development, research activities directly in support of the Development program, management of clinical research organizations and other vendors, regulatory, supply chain, medical monitoring, biostatistics, safety data collection, monitoring and exchange, and clinical and nonclinical finance and contracting.

1.98 "Pharmacovigilance Agreement" has the meaning set forth in Section 4.3.

1.99 "Phase 2 Clinical Trial" means a Clinical Trial of a Product that would satisfy the requirements of 21 CFR 312.21(b) or its foreign equivalents.

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1.100 "Phase 3 Clinical Trial" means a Clinical Trial of a Product that would satisfy the requirements of 21 CFR 312.21(c) or its foreign equivalents.

**1.101** "*Phase 4 Clinical Trial*" means a Clinical Trial of a Product conducted after Regulatory Approval of such Product has been obtained from an appropriate Regulatory Authority, which trial is (a) conducted voluntarily by a Party to enhance marketing or scientific knowledge of the Product, or (b) conducted due to a request or requirement of a Regulatory Authority.

**1.102** "*Product*" means any pharmaceutical product (including all forms, presentations, dosage strengths and formulations) containing as an active ingredient a Collaboration Compound alone or in combination with one or more other therapeutically active ingredients.

1.103 "Product Information" has the meaning set forth in Section 12.1.

1.104 "Product Infringement" has the meaning set forth in Section 9.5(a)(i).

**1.105** "*Promotional Materials*" means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, including, without limitation, journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings and sites and broadcast advertisements intended for use or used by either Party or its Affiliates or sublicensees in connection with any promotion of a Product.

1.106 "Publication" has the meaning set forth in Section 12.5(b).

**1.107** "*Regulatory Approval*" means all approvals necessary for the manufacture, marketing, importation and sale of a Product for one or more indications in the Field and in a country or regulatory jurisdiction, which may include, without limitation, satisfaction of all applicable regulatory and notification requirements, but which shall exclude any pricing and reimbursement approvals.

**1.108** "*Regulatory Authority*" means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, pricing or reimbursement approval of a Product in such country or regulatory jurisdiction.

**1.109** "*Regulatory Materials*" means regulatory applications, submissions, notifications, registrations, Regulatory Approvals and/or other material filings or correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), or other approvals granted by, a Regulatory Authority that are necessary or reasonably desirable in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or regulatory jurisdiction. Regulatory Materials include, without limitation, INDs, MAAs, and NDAs.

1.110 "Representatives" has the meaning set forth in Section 10.3(a).

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**1.111** "*RoW*" means all countries of the Territory other than the U.S. For clarity, except as expressly set forth in Article 2, the territories licensed under the China Agreement are not included in RoW.

1.112 "SEC" means the U.S. Securities and Exchange Commission.

1.113 "Sublicense Agreement" has the meaning set forth in Section 7.3(b).

**1.114** "*Sublicensee*" means any Third Party granted a sublicense by AstraZeneca or any of its Affiliates under the rights licensed to AstraZeneca pursuant to Article 7.

1.115 "Subsequent Agreement" has the meaning set forth in Section 7.4(c).

1.116 "Subsequent Licensee" has the meaning set forth in Section 7.4(c).

1.117 "Supply and Quality Agreement" has the meaning set forth in Section 6.5.

**1.118** "*Tax and Taxation*" means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

**1.119** "*Tax Authority*" or "*Tax Authorities*" means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official anywhere in the world, authorized to levy Tax.

**1.120** "*Technical Product Failure*" means (a) a [\*] of a Collaboration Compound or Product under Development or Commercialization under this Agreement, as determined (including following a review of the Carcinogenicity Studies) (i) by a consensus decision by the JSC or (ii), following referral of the matter to the Executive Officers pursuant to Section 2.6(c), by a consensus decision by the Executive Officers, or (iii), in the event that a consensus decision by the Executive Officers has not been attained within twenty (20) Business Days after the JSC's submission of the matter to them, by expedited resolution in accordance with Section 14.8; or (b) a Regulatory Authority action or decision [\*].

1.121 "Term" has the meaning set forth in Section 13.1.

**1.122** "*Territory*" means all countries of the world other than (a) the countries listed on **Exhibit A** and (b) China (including Hong Kong SAR and Macau SAR, but excluding Taiwan region). The Territory consists of the U.S. and RoW.

1.123 "Third Party" means any entity other than FibroGen or AstraZeneca or an Affiliate of either of them.

1.124 "Transatlantic Clinical Development Plan" or "TCDP" has the meaning set forth in Section 3.2(b).

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1.125 "U.S." means the United States of America (including all possessions and territories thereof).

**1.126** "U.S. Commercialization Budget" has the meaning set forth in Section 5.2.

**1.127** "U.S. Commercialization Plan" has the meaning set forth in Section 5.2.

1.128 "U.S. GAAP" means generally accepted accounting principles in the U.S.

**1.129** "*Valid Claim*" means, with respect to a Product in a particular country, any claim of a FibroGen Patent that specifically or generically claims (i) the Collaboration Compound included in such Product as a composition of matter, (ii) a method of manufacture of such Collaboration Compound, or (iii) a method of treatment or other use of such Collaboration Compound [\*] and either:

(a) with respect to a granted and unexpired Patent in such country, that (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal, and (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or

(b) with respect to a pending Patent application, that was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application. For purposes hereof, a claim in a patent application that has not been granted within [\*]) years from the priority date for such claim (or, with respect to [\*]) shall not be considered to be a Valid Claim, unless and until such claim thereafter issues such that it is included in subsection (a) above.

#### **ARTICLE 2**

#### **COLLABORATION; GOVERNANCE**

**2.1 Collaboration Overview.** The Parties desire and intend to collaborate with respect to the Development and Commercialization of Products in the Field in the Territory, as and to the extent set forth in this Agreement (the "*Collaboration*"). It is intended that the Collaboration utilize AstraZeneca's position as a large, fully-integrated pharmaceutical company, while recognizing FibroGen's current experience and expertise in, and aspirations to further develop its clinical development and commercialization capabilities with respect to, HIF Compounds.

#### 2.2 Joint Steering Committee.

(a) **Purpose; Formation.** The Parties hereby establish a joint steering committee (the "*JSC*") that will monitor and oversee their activities under this Agreement in the Territory and under the China Agreement in China, resolve disputes within subcommittees and facilitate communications between the Parties with respect to the Development and Commercialization of Products in the Territory and in China (under the China Agreement), all in accordance with this Section 2.2.

16.

(b) Composition. Each Party shall initially appoint five (5) representatives of such Party or its applicable Affiliates to the JSC. Each representative appointed to the JSC shall have sufficient seniority within the applicable Party or its Affiliate to make decisions arising within the scope of the JSC's responsibilities. The Parties' initial representatives to the JSC are set forth on **Exhibit G**. The JSC may change its size from time to time by mutual consent of its members, provided that the JSC shall at all times consist of an equal number of representatives of each of FibroGen and AstraZeneca. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of the JSC, provided that such participants shall have no voting authority at the JSC. Each Party shall appoint a secretariat to the JSC who is not a member of the JSC.

(c) Specific Responsibilities. In addition to its overall responsibility for monitoring and providing a forum to discuss and coordinate the Parties' activities under this Agreement, the JSC shall in particular:

(i) oversee the collaborative activities of the Parties under this Agreement and the China Agreement, including overseeing the China Committee;

(ii) oversee and delegate responsibility for the use of any information arising under the Astellas Agreements, to the extent that (A) [\*] such information; and (B) such information [\*] this Agreement;

(iii) review and fully discuss the Development and Commercialization of Products and any other ongoing activities;

(iv) receive and discuss reports from the JDC and JCC and provide guidance thereto, and approve the Development Plan (and associated Development Budget) and U.S. Commercialization Plan and amendments thereto;

(v) receive and discuss reports from the China Committee and provide guidance thereto, and approve the applicable Development and Commercialization plans and budgets;

(vi) receive and discuss reports from the IP Committee, provide guidance thereto and review strategies for obtaining, maintaining, defending and enforcing patent and trademark protection for Products within the Territory;

(vii) attempt to resolve issues presented to it by, and disputes within, the JDC, JCC and China Committee or any other subcommittee;

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(viii) at least annually, discuss and determine indications for Development of Products;

(ix) review and approve the filing of an NDA for a Product in the U.S. prior to submission;

(x) establish such additional joint subcommittees as it deems necessary to achieve the objectives and intent of this Agreement;

(xi) review and approve the JPT Charter and any subsequent amendments thereto, including the composition and responsibilities of the

Core JPT; and

or

(xii) perform such other functions as appropriate to further the purposes of this Agreement as allocated to it in writing by the Parties.

The JSC shall further – until the date when the JDC or the JCC has been formed – assume the responsibilities of the JDC and the JCC, as applicable, and delegate certain responsibilities to the Core JPT as set forth in Schedule G(a) for the JDC and Schedule G(b) for the JCC.

(d) Delegation or Assumption of Responsibilities by the JSC. The JSC may by mutual consent of its members:

(i) delegate any of its responsibilities set out in this Section 2.2 or in Schedule G(a) or G(b) to any of its subcommittees or the Core JPT;

(ii) assume any responsibilities assigned to any of its subcommittees.

(e) Meetings. The JSC shall hold its first meeting within thirty (30) days after the Effective Date. The JSC shall meet at least one (1) time per Calendar Quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) by at least ten (10) Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such Party shall provide the JSC no later than ten (10) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision; provided, however, that where a special meeting is called for on shorter notice with regard to a matter that does not admit delay, such notice and such materials shall be provided as early as possible in advance of such meeting. No later than ten (10) Business Days (or such shorter period as may be necessary in the event of a special meeting called for on shorter notice in accordance with the foregoing) prior to any meeting of the JSC, the secretariats of the JSC shall jointly prepare and circulate an agenda for such meeting. The JSC may meet in person, by videoconference or by teleconference. Notwithstanding the foregoing, at least two (2) meetings per Calendar Year shall be in person unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. In-person JSC meetings will be held at locations alternately selected and hosted by FibroGen and by AstraZeneca. The host Party shall be responsible for the costs and expenses of

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the JSC meeting hosted, provided that each Party will bear the expense of its respective JSC members' and other attendees' participation in JSC meetings, including travel costs. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The JSC secretariat of the host Party will be responsible for keeping reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC secretariat of the host Party shall send draft meeting minutes to the other Party's JSC secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the JSC within ten (10) Business Days after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

(f) Decision-Making. In addition to resolving issues specifically delegated to it, the JSC shall have the authority to resolve any disputes within the Collaboration not resolved by the JDC, JCC, China Committee and any other committees that the Parties may subsequently create to assist in governance of the Collaboration, except where expressly specified elsewhere in this Agreement. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party, and all decision making shall be by consensus. Disputes at the JSC shall be handled in accordance with Section 2.6.

#### 2.3 Joint Development Committee.

(a) Formation; Composition. At a time determined by the JSC, the Parties shall establish a committee to oversee Development of Product(s) in the Territory and in China in accordance with the Development Plan(s) for such Product(s) and to coordinate the Development activities of the Parties (the "*JDC*") and prior thereto, the JSC will be responsible for all JDC responsibilities except for the specific responsibilities it delegates to the Core JPT as set out in Schedule G(a).

Each Party shall appoint three (3) representatives of such Party or its Affiliates to the JDC at its inception. Each representative appointed to the JDC shall have knowledge and expertise in relevant aspects of the development of small molecule pharmaceutical products, including in the area of chronic kidney disease or cardiovascular or metabolic disorders and having sufficient seniority within the applicable Party or Affiliate to make decisions arising within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual consent of its members, provided that the JDC shall consist at all times of an equal number of representatives of each of FibroGen and AstraZeneca. Each Party may replace its JDC representatives at any time upon written notice to the other Party. The JDC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of the JDC, provided that such participants shall have no voting authority at the JDC. The JDC shall have two (2) co-chairmen, one selected by FibroGen and one selected by AstraZeneca. The role of the co-chairmen shall be to convene and preside at meetings of the JDC, but they shall have no additional powers or rights beyond those held by the other JDC representatives. Each Party shall appoint a secretariat to the JDC.

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**(b) Specific Responsibilities of the JDC.** In addition to its general responsibilities, the JDC (or the JSC until the JDC is formed, with certain delegations as set forth in this Section 2.3 and Schedule G(a)) shall in particular:

(i) provide regular reports to the JSC regarding the development of the Product, and discuss, prepare and submit to the JSC for approval annual and interim amendments to the Development Plan (and the Development Budget) for each Product;

(ii) discuss and manage the implementation of the Initial Development Plan;

(iii) oversee the conduct of Development;

(iv) discuss the audited final report from the Carcinogenicity Studies, including whether or not a Technical Product Failure has occurred, and provide input thereon to the JSC;

(v) propose to the JSC particular studies to be conducted;

(vi) create, implement and review the Development Strategy for Development in the Territory and the design of all Clinical Trials and Nonclinical Studies conducted under each Development Plan, including Phase 4 Clinical Trials;

(vii) oversee any CMC related development activities, e.g. stability studies or packaging development, as well as other activities to prepare for supply of drug substance and finished Product for Commercialization, including to oversee the selection process for, and select (pursuant to Section 6.4), a contract manufacturer to be used by FibroGen for commercial supplies;

(viii) decide whether and when to initiate or discontinue any Clinical Trial and any Nonclinical Study under each Development Plan, including Phase 4 Clinical Trials;

(ix) allocate budgeted resources and determine priorities for each Clinical Trial and Nonclinical Study under each Development Plan, including Phase 4 Clinical Trials;

(x) oversee the conduct of all Clinical Trials and Nonclinical Studies under each Development Plan, including Phase 4 Clinical Trials;

(xi) select Third Party contractors to conduct Clinical Trials of Products;

(xii) facilitate the flow of Information between the Parties with respect to the Development of Products, including Development Data [\*] under this Agreement;

(xiii) discuss whether to Develop Products for other indications and propose any such indications to the JSC;

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(xiv) allocate primary responsibility as between the Parties for tasks relating to Development of Products where not already specified in the Development Plan;

(xv) discuss the requirements for Regulatory Approval in the Territory and oversee and coordinate regulatory matters with respect to Products in the Territory, including to review and approve material regulatory filings (other than the filing of an NDA in the U.S., which shall be approved by the JSC) prior to submission thereof;

(xvi) establish a publication strategy for publications and presentations related to Products in the Territory and review and approve all such publications in accordance with Section 12.5;

(xvii) facilitate the flow of Information between the Parties with respect to obtaining Regulatory Approval for Products; and

(xviii) perform such other functions as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

(c) Meetings. Following its inception, the JDC shall meet at least one (1) time per Calendar Quarter (or more frequently when necessary), spaced at regular intervals, unless the Parties mutually agree in writing to a different frequency. Either Party may also call a special meeting of the JDC (by videoconference or teleconference) by at least ten (10) Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such Party shall provide the JDC no later than ten (10) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision; provided, however, that where a special meeting is called for on shorter notice with regard to a matter that does not admit delay, such notice and such materials shall be provided as early as possible in advance of such meeting. No later than ten (10) Business Days (or such shorter period as may be necessary in the event of a special meeting called for on shorter notice in accordance with the foregoing) prior to any meeting of the JDC, the secretariats shall jointly prepare and circulate an agenda for such meeting; provided, however, that either Party shall be free to propose additional topics to be included on such agenda, either prior to or, subject to the consent of the other Party, in the course of such meeting. The JDC may meet in person, or at the request of either Party, by videoconference or teleconference. In-person JDC meetings will be held at locations alternately selected and hosted by FibroGen and by AstraZeneca. Each Party shall report to the JDC on all material issues relating to the Development of Products for and in the Territory at the JDC meeting occurring after such issues arise. The host Party shall be responsible for the costs and expenses of the JDC meeting hosted, provided that each Party will bear the expense of its respective JDC members' and other attendees' participation in JDC meetings, including travel costs. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The secretariat of the host Party shall be responsible for keeping reasonably detailed written minutes of all JDC meetings that reflect all decisions made at such meetings. The secretariat of the host Party shall send meeting minutes to the other Party's secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the JDC within ten (10) Business Days after each JDC meeting. Minutes will be deemed approved unless one or more members of the JDC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

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(d) Decision-Making. The JDC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the JDC cannot reach consensus on an issue that comes before the JDC and over which the JDC has oversight, then the Parties shall refer such matter to the JSC for resolution in accordance with Sections 2.2(e) and 2.6(b).

#### 2.4 Joint Commercialization Committee.

(a) Formation; Composition. At a time determined by the JSC, but no later than the earlier of (i) eighteen (18) months prior to the date of the expected First Commercial Sale of the Product in the U.S. and (ii) six (6) months prior to the projected date of submission of the first NDA for the Product in the U.S., the Parties shall establish a committee to oversee Commercialization of Products in the Territory and in China (the "*JCC*"), and prior thereto, the JSC will be responsible for all JCC responsibilities except for the specific responsibilities it delegates to the Core JPT as set out in Schedule G(b).

Each Party shall appoint three (3) representatives of such Party or its Affiliate to the JCC at its inception. Each representative appointed to the JCC shall have knowledge and expertise in relevant aspects of the commercialization of small molecule pharmaceutical products, including in the area of chronic kidney disease or cardiovascular or metabolic disorders and having sufficient seniority within the applicable Party or its Affiliate to make decisions arising with the scope of the JCC's responsibilities. The JCC may change its size from time to time by mutual consent of its members, provided that the JCC shall consist at all times of an equal number of representatives of each of FibroGen and AstraZeneca. Each Party may replace its JCC representatives at any time upon written notice to the other Party. The JCC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of the JCC, provided that such participants shall have no voting authority at the JCC. The JCC shall have a chairman, who shall be selected by AstraZeneca. The role of the chairman shall be to convene and preside at meetings of the JCC, but the chairman shall have no additional powers or rights beyond those held by the other JCC representatives.

**(b) Specific Responsibilities of the Joint Commercialization Committee.** In addition to its general responsibilities, the Joint Commercialization Committee (or the JSC until the JCC is formed, with certain delegations as set forth in this Section 2.4 and Schedule G(b)) shall in particular:

(i) oversee Commercialization in the Territory and (as set out in more detail in the China Agreement) China;

(ii) regularly report to the JSC regarding the Commercialization of the Products, and discuss, prepare and submit for approval to the JSC the U.S. Commercialization Plan for each Product in the U.S., including any amendments thereto;

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(iii) review and approve each commercialization plan for the RoW prepared by AstraZeneca;

(iv) oversee implementation of each U.S. Commercialization Plan;

launch activities;

(v) coordinate the Commercialization activities of FibroGen and AstraZeneca with respect to Products, including pre-launch and post-

(vi) allocate primary responsibility as between the Parties for tasks relating to Commercialization of Products in the U.S.;

(vii) determine the amount of Product to be distributed free of charge annually for regulatory or marketing purposes or investigatorinitiated trials (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7);

(viii) oversee global harmonization of the Product;

JCC; and

(ix) be responsible for publication matters as described in Section 2.3(b)(xvi) upon transition of such responsibility from the JDC to the

(x) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

(c) Meetings. Following its inception, the JCC shall meet at least one (1) time per Calendar Quarter, spaced at regular intervals unless the Parties mutually agree in writing to a different frequency. Either Party may also call a special meeting of the JCC (by videoconference or teleconference) by at least ten (10) Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such Party shall provide the JCC no later than ten (10) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision; provided, however, that where a special meeting is called for on shorter notice with regard to a matter that does not admit delay, such notice and such materials shall be provided as early as possible in advance of such meeting. No later than ten (10) Business Days (or such shorter period as may be necessary in the event of a special meeting called for on shorter notice in accordance with the foregoing) prior to any meeting of the JCC, the secretariats shall jointly prepare and circulate an agenda for such meeting; provided, however, that either Party shall be free to propose additional topics to be included on such agenda, either prior to or, subject to the consent of the other Party, in the course of such meeting. The JCC may meet in person, by videoconference, or by teleconference. In-person JCC meetings will be held at locations alternately selected and hosted by FibroGen and by AstraZeneca. Meetings of the JCC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. Each Party shall report to the JCC on all material issues relating to the Commercialization of Products promptly after such issues arise. The host Party shall be responsible for the costs and expenses of the JCC meeting hosted, provided that each Party will bear the expense of its respective JCC members' and other attendees' partic

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Party will be responsible for preparing reasonably detailed written minutes of JCC meetings that reflect all decisions made at such meetings. The secretariat of the host Party shall send meeting minutes to the other Party's secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the JCC within ten (10) Business Days after each JCC meeting. Minutes will be deemed approved unless one or more members of the JCC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

(d) Decision-Making. The JCC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the JCC cannot reach consensus on an issue that comes before the JCC and over which the JCC has oversight, then the Parties shall refer such matter to the JSC for resolution in accordance with Sections 2.2(e) and 2.6.

**2.5 Coordination with Astellas.** FibroGen shall designate one of AstraZeneca's JSC representatives (as selected by AstraZeneca) to serve as a member of the steering committee under the Astellas Collaboration, who (except as described in the next sentence) shall be entitled to participate in the decision-making of such committee pursuant to the Astellas EU Agreement. The designated representative will be permitted to attend meetings of such committee; provided that such representative shall not have the right to attend portions of (or participate in decision-making with respect to) any such meeting that are not relevant to the Development or Commercialization of Products in the Territory or in China.

#### 2.6 Resolution of Committee Disputes.

(a) Within Operating Committees. All decisions within any Committee other than the JSC shall be made by consensus, and if a dispute arises which cannot be resolved within such Committee, then the representatives of either Party may cause such matter to be referred to the JSC for resolution as provided in Section 2.2(e).

(b) Within The JSC. All decisions within the JSC (whether originating there, or referred to it by an operating Committee) shall be made by consensus. If a matter is referred by an operating Committee to the JSC, it shall use good faith efforts, in compliance with Section 2.6(d), to resolve promptly such matter. If the JSC is unable to reach consensus on any issue for which it is responsible, within ten (10) Business Days after a Party affirmatively states that a decision needs to be made, either Party may elect to submit such issue to the Parties' Executive Officers in accordance with Section 2.6(c).

(c) Referral to Executive Officers. If a Party makes an election under Section 2.6(b) to refer a matter to the Executive Officers, the JSC shall submit in writing the respective positions of the Parties to their respective Executive Officers. Such Executive Officers shall use good faith efforts, in compliance with Section 2.6(d), to resolve promptly such matter, which good faith efforts shall include at least one meeting (in-person, by telephone, video conference or other appropriate means) between such Executive Officers within twenty (20) Business Days after the JSC's submission of such matter to them. If the Executive Officers are unable to reach consensus on any such matter within such twenty (20) Business Day period, then either Party may invoke the dispute resolution provisions of Article 14; provided, however, that:

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(i) FibroGen's Executive Officer shall have the final say with respect to: [\*]

(1) [\*];

(ii) AstraZeneca's Executive Officer shall have the final say with respect to:

(1) [\*].

(d) Good Faith. In conducting themselves on Committees, and in exercising their rights under this Section 2.6, all representatives of both Parties shall consider diligently, reasonably and in good faith all input received from the other Party, and shall use reasonable efforts to reach consensus on all matters before them. In exercising any decision making authority granted to it under this Article 2, each Party shall act based on its good faith judgment of what is in the best interests of the Products and the Collaboration.

**2.7 Alliance Managers.** Each Party shall, within thirty (30) days following the Effective Date, appoint a single person who shall oversee contact between the Parties for all subject matter related to the Collaboration between meetings of the JSC, JPT, JDC and JCC, and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (such person, the "*Alliance Manager*"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate the Collaboration governance meetings and the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

**2.8 General Committee Authority.** Each Committee shall have solely the powers expressly assigned to it in this Article 2 and elsewhere in this Agreement. No Committee shall have any power to amend, modify, or waive compliance with this Agreement (or any agreement entered into in connection with this Agreement). It is expressly understood and agreed that the control of decision-making authority by FibroGen or AstraZeneca, as applicable, pursuant to Section 2.6, so as to resolve a disagreement or deadlock on a Committee for any matter will not authorize either Party to perform any function not delegated to a Committee, and that neither FibroGen nor AstraZeneca shall have any right to unilaterally modify or amend, or waive its own compliance with, the terms of this Agreement.

**2.9 Joint Project Team**. The Parties hereby establish a joint project team (the "*Joint Project Team*" or "*JPT*") to develop and propose plans to governing committees, manage operational activities and serve as an information resource for the Committees. The members of the JPT representing core functions relevant to the joint development and commercialization of Products (the "*Core Joint Project Team*" or "*Core JPT*") shall provide oversight to the overall JPT. Until such time as when the JDC and the JCC have been formed, the Core JPT shall have the additional responsibilities set out in Schedule G(a) and G(b), respectively. Neither the JPT nor the Core JPT will have any decision-making authority, except as set out in Schedule G(a) or G(b) or

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otherwise explicitly authorized by an appropriate Committee. The Parties agree to establish a JPT Charter on or prior to October 31, 2014, which contains the composition and responsibilities of the JPT and the Core JPT. Subject to the JPT Charter, the Core JPT will consist of project leaders as appointed by FibroGen and by AstraZeneca, and such additional members as the Parties deem appropriate from time to time. Each Party will appoint appropriately qualified and authorized representatives for each applicable operational area or function. The JPT members will serve as the point of contact for operational matters between the Parties. The JPT may form subteams to support the efforts of the JPT as agreed by the Parties. As appropriate, FibroGen may arrange, on its own initiative or at AstraZeneca's reasonable request from time to time, a joint meeting between the JPT and the project team under the Astellas Collaboration.

**2.10 Executive Meetings.** FibroGen's Chief Executive Officer and an appropriate Executive Vice President of AstraZeneca (or other appropriate representative of AstraZeneca of equivalent seniority) will meet in advance of the occurrence of key scheduled Development and Commercialization events or in connection with key decisions, to review and discuss the status and direction of the Collaboration.

**2.11 Discontinuation of Participation on a Committee.** Each Committee shall continue to exist until the first to occur of (a) the Parties mutually agreeing to disband the Committee, or (b) FibroGen providing to AstraZeneca written notice of its intention to disband and no longer participate in such Committee, which FibroGen retains the right to do at any time during the Term, in its sole discretion, provided, however, that doing so shall not relieve FibroGen of any of its obligations under this Agreement or the China Agreement (save from the obligation to participate at the relevant Committee meetings). Once FibroGen has provided written notice as referred to in subsection (b) above, such Committee shall have no further obligations under this Agreement and AstraZeneca shall have the right to solely decide, without consultation, any matters previously before such Committee, subject to the other terms of this Agreement.

#### **ARTICLE 3**

#### DEVELOPMENT

**3.1 Overview.** The Parties agree to undertake a joint development program to further Develop the Collaboration Compounds and Products as provided in this Article 3 under the direction of the JDC (or, the JSC prior to the inception of the JDC), and pursuant to the Development Plan (such program, the "*Development Program*"). Prior to the JDC's inception, all references to the JDC in this Article 3 and elsewhere in this Agreement will be deemed references to the JSC (which may delegate certain responsibilities to the Core JPT in accordance with Schedule G(a)).

#### 3.2 Development Plans.

(a) General. All Development of any given Product pursuant to this Agreement for the U.S. and RoW shall be conducted pursuant to a development plan (the "*Development Plan*") that describes (i) the proposed overall program of Development for the applicable Product and indications in the U.S. and RoW, including Clinical Trials and Nonclinical

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Studies, toxicology, formulation, packaging development, process and analytical development, production of registration and validation batches, regulatory plans and other elements of obtaining Regulatory Approval(s) in each applicable country; (ii) the anticipated start dates and data availability dates of such Clinical Trials, Nonclinical Studies and CMC development activities, and timelines for key Regulatory Authority meetings, filing of applications for Regulatory Approval, and the receipt of Regulatory Approvals and (iii) the respective roles and responsibilities of each Party in connection with such activities. The Development Plan will be associated with a detailed budget for all such activities conducted by the Parties for the U.S. In the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail.

(b) Initial Development Plan. The initial Development Plan, along with the associated Development Budget, describing (among other things) the planned development of the Product for the CKD Indications for the U.S., is attached hereto as **Exhibit H** (the "*Initial Development Plan*"). The Initial Development Plan includes and shall be integrated with those Phase 3 Clinical Trials that are currently being conducted by FibroGen or Astellas under the U.S. and EU plan for conducting Phase 3 Clinical Trials of the Product for the CKD Indications under the Astellas EU Agreement (the "*Transatlantic Clinical Development Plan*" or the "*TCDP*"). FibroGen shall notify AstraZeneca, via the JDC, of all material updates and material changes to the TCDP. The Initial Development Plan shall further outline such additional Phase 3 Clinical Trials as the Parties have agreed to conduct (i.e. in addition to those being conducted under the TCDP). Within thirty (30) days after the Effective Date, the JPT will initiate implementation of the Initial Development Plan.

(c) Development Strategy. Within one (1) year after the Effective Date or at such other time as the Parties may mutually agree, the JDC will prepare for the JSC's review and approval an overall development strategy for the Product in the Field in the Territory, including the CKD Indications for the RoW and any other indications (or other life cycle management) the Parties are considering to develop (or conduct) throughout the Territory, which strategy will include anticipated dates (estimated based on the date of completion of certain development events) for preparing detailed descriptions of applicable events for inclusion in an amended Development Plan (the "*Development Strategy*"). The Development Strategy will include reasonable timeframes for any additional indications (i.e., in addition to the CKD Indications) to be developed hereunder, with the understanding that not all such indications will be developed concurrently.

#### (d) Amendments to the Development Plan.

(i) On an annual basis (no later than October 31<sup>st</sup> of the preceding Calendar Year), or more often as the Parties deem appropriate, the JDC shall prepare amendments to the then-current Development Plan and Development Budget for approval of the JSC. Each such amended Development Plan shall specify, with a reasonable level of detail, the items described in Section 3.2(a). Such amended Development Plan shall cover the next Calendar Year (and additional periods as reasonably determined by the Parties) and shall contain a corresponding budget for U.S. activities. Such updated and amended Development Plan shall reflect any changes, re-prioritization of studies within, reallocation of resources with respect to, or additions

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to the then-current Development Plan. In addition, the JDC may prepare amendments for approval of the JSC to the Development Plan and corresponding Development Budget from time to time during the Calendar Year in order to reflect changes in such plan and budget for such Calendar Year, in each case, in accordance with the foregoing. At the request of either Party, but no more frequently than quarterly, the JDC shall review the Development Budget and propose any necessary amendments to the JSC for approval. Once approved by the JSC, the amended annual Development Plan and Development Budget shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended Development Plan and Development Budget shall supersede the previous Development Plan and Development Budget for the applicable period.

(ii) Each Party shall notify the other Party promptly upon becoming aware that it is likely to exceed, or has exceeded, the budget for a particular activity for U.S. Development of the Product allocated to such Party in the Development Plan. Thereafter, the JDC shall promptly meet and determine whether to amend the Development Plan or Development Budget accordingly, provided that the JDC shall not unreasonably withhold its agreement to any budget amendment proposed by either Party that results from causes outside of such Party's reasonable control or that the Parties agree includes expenses reasonably incurred in the performance of the Development Plan. Any such amendment proposed by the JDC shall not be subject to the JSC's review and will be deemed automatically approved by the JSC, unless such amendment would cause the total Development Costs incurred by a Party in any Calendar Year to exceed [\*] percent [\*]%) of the budgeted Development Costs for such Party in such Calendar Year, in which event JSC approval will be required; provided that the JSC shall not unreasonably withhold its agreement to any budget amendment proposed by either Party that results from causes outside of such Party's reasonable control and that the Parties agree includes expenses reasonably incurred in the performance of the Development Plan.

(e) Development Responsibilities. Unless the Parties agree in writing upon an alternate allocation of responsibility, the Parties shall have the following rights and obligations with respect to operational responsibilities under each Development Plan:

(i) U.S. Operational responsibility for all studies designed to support Regulatory Approvals in the U.S. will be shared between the Parties as allocated in the Development Plan; provided that FibroGen and Astellas (it being agreed that as between the Parties FibroGen will be responsible for all such activities conducted by Astellas; provided however, that [\*] Astellas [\*] Astellas [\*] FibroGen [\*] this Agreement [\*] FibroGen [\*] under the Astellas Agreements with respect to such activities) will be responsible for conducting the first Phase 3 Clinical Trials (that are included also in the TCDP) of the Product in the CKD Indications under the Initial Development Plan. For clarity, the term 'first Phase 3 Clinical Trials', as used in this section, shall be the studies identified as [\*] in the Initial Development Plan.

(ii) RoW. AstraZeneca shall be solely responsible for all aspects of the Development of Collaboration Compounds and Products that are solely applicable to the RoW (which, for clarity, does not include China).

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(iii) Development Sharing Period. During the Development Sharing Period, FibroGen shall conduct all Development in good faith, and using Commercially Reasonable Efforts to achieve the then-current timelines in such Development Plan.

(f) Development Decision-Making. Except as otherwise expressly provided in this Agreement, all matters regarding the Development Plan shall be decided by consensus by the JDC, subject to Section 2.6.

## 3.3 Coordination with Astellas.

(a) AstraZeneca understands and agrees that FibroGen's and AstraZeneca's conduct of certain Development and Commercialization activities for North America (meaning the U.S., Mexico and Canada) hereunder are subject to the terms of the Astellas EU Agreement, and that FibroGen's obligations to Astellas may require additional procedures, consents or adherence to notification obligations. Accordingly, the Parties shall, as applicable, take into consideration such obligations when formulating the plans for, and coordinate, [\*], and FibroGen shall use Commercially Reasonable Efforts to obtain [\*] Development in the Territory under this Agreement. [\*]. Notwithstanding anything else in this Agreement to the contrary, however, FibroGen shall not be required to perform (or refrain from performing) any Development activity that would constitute a violation of its obligations under the Astellas Agreements, as disclosed to AstraZeneca prior to the Effective Date.

(b) If, [\*], FibroGen shall promptly notify AstraZeneca and such matter shall be discussed at a specially convened JSC meeting. In the event that AstraZeneca, pursuant to Section 3.9, both (i) is not obligated to use Commercially Reasonable Efforts to Develop such Product in such indication; and (ii) following notification by FibroGen, determines that it does not wish to participate in such Development in such indication, the following shall apply:

Territory;

(i) FibroGen shall be free to Develop, obtain Regulatory Approval for and Commercialize such Product in such indication throughout the

(ii) As between the Parties, such Development and Commercialization shall be undertaken at FibroGen's sole cost;

(iii) FibroGen shall use Commercially Reasonable Efforts to ensure that such Development and Commercialization shall not materially impact AstraZeneca's rights under this Agreement (it being understood that such Development and Commercialization are not considered per se to materially impact AstraZeneca's rights under this Agreement);

(iv) The Parties shall, as soon as practicable, discuss in good faith an option arrangement whereby AstraZeneca may obtain rights to such Product in such indication at a future decision point. The Parties shall negotiate in good faith the terms under which AstraZeneca would obtain such rights, which terms include [\*] and [\*]; and

(v) The Parties shall discuss in good faith, appropriate amendments to the provisions of this Agreement to reflect such Development and Commercialization of such Product in such indication by FibroGen, including, without limitation, amendments to the pharmacovigilance provisions in Section 4.3. If the Parties fail to agree on such terms within a reasonable time period, either Party may refer the matter to the Executive Officers for discussion.

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(c) The Parties shall ensure that each amended Development Plan allows for the conduct of such Clinical Trials as are included in the then current TCDP. If the JDC agrees that additional studies (i.e. in addition to those included in the TCDP) are required for the Product in the CKD Indications for the U.S., then the Parties shall, where required, [\*]. FibroGen shall use Commercially Reasonable Efforts to [\*], shall use Commercially Reasonable Efforts to [\*].

(d) FibroGen shall use Commercially Reasonable Efforts from time to time during the Term to [\*] or other rights that AstraZeneca or the Parties reasonably believe [\*] in order to allow AstraZeneca to obtain the benefit of its rights and licenses pursuant to this Agreement.

## 3.4 Development Costs.

(a) Allocation. The Parties shall share equally all costs and expenses incurred by or on behalf of either Party to conduct Development of the Product for the U.S. under the Development Plan during the Development Sharing Period, according to the terms of Section 8.2, including for supply of Collaboration Compound or Product in accordance with Article 6, in each case to the extent that such Development Costs are not borne or reimbursed by Astellas under the Astellas EU Agreement, provided that FibroGen will timely inform AstraZeneca of any such costs borne or reimbursed by Astellas. AstraZeneca shall be responsible for all costs and expenses it incurs in the conduct of activities under the Development Plan for the RoW and shall reimburse FibroGen for all costs and expenses FibroGen incurs (including Personnel Costs, the Fully Burdened Cost of Collaboration Compound or Product or comparator drug, concomitant drug, placebo or other materials used in any Clinical Trial or Nonclinical Studies, and all other out-of-pocket costs) for activities conducted by FibroGen (i) for the U.S. after the Development Sharing Period and (ii) for the RoW, in each case (i) and (ii) under the Development Plan within the applicable Development Budget (for the U.S.) or budget (for RoW) (subject to overages described in Section 3.4(b)) and according to the terms of Section 8.2, together with the reimbursement for supply of Collaboration Compound or Product in accordance with Article 6. For clarity, all Clinical Trials set out in the Initial Development Plan shall be deemed to be Development of the Product for the U.S.

(b) Overage. Notwithstanding the foregoing in Section 3.4(a), unless otherwise agreed by the JDC (subject to JSC approval to the extent set forth in Section 3.2(d)(ii)) or by the Parties, either before or after the applicable expense is incurred (which agreement shall not be unreasonably withheld for any budget overage outside the applicable Party's reasonable control and reasonably incurred in the performance of the Development Plan), for any Calendar Quarter, each Party will be solely responsible for Development Costs it incurs in excess of [\*] percent [\*]%) of the total amount allocated to such Party's activities in such Calendar Quarter in the Development Budget, and for any Calendar Year, each Party will be solely responsible for Development Costs it incurs in excess of [\*] percent [\*]%) of the total amount allocated to such Party's activities in such Calendar Year in the Development Budget, provided that Development

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Costs incurred in excess of [\*]% for the Calendar Quarter or [\*]% for the Calendar Year, as applicable, of the amounts so budgeted shall also be reimbursed if the Parties determine in good faith that such Development Costs were reasonably incurred in the performance activities under the Development Plan and that such budget overage was caused by circumstances outside of such Party's reasonable control.

## 3.5 Indications Outside the Field.

(a) Inclusion. If either Party desires to develop a particular Product for an indication outside the Field, it may propose such indication to the other Party in writing by providing the other Party with a high-level proposed development plan for such Product in such indication. Upon the other Party's request within sixty (60) days after receipt of such development plan, the Parties shall meet to discuss such proposed indication and shall work together in good faith to generate and gather the necessary information to support such potential development and to prepare a detailed development plan. If the Parties agree on such plan, AstraZeneca shall have the right to include the proposed indication in the Field, solely with respect to the applicable Product, by written notice to FibroGen. If AstraZeneca exercises such right, such indication will be a "*Designated Indication*", the Field will automatically be expanded to include the Designated Indication (without payment of any additional upfront fees, milestones or other consideration except those payments already provided for under this Agreement), the terms of this Agreement (including payment terms and diligence obligation) will apply to such indication and the JDC shall promptly prepare a development plan for such indication for review and approval by the JSC.

(b) Termination. The Field will automatically be amended to remove any Designated Indication upon the occurrence of any of the following events: (a) the permanent cessation (excluding, for example, suspension, termination or completion pending further review, consideration or development planning) of all Clinical Trials by both Parties with respect to such Product for such Designated Indication prior to Regulatory Approval in any country in the Territory in such Designated Indication, (b) the termination of all Regulatory Approvals for such Designated Indication in the Territory without either Party intending or considering to restore or replace any such Regulatory Approval, or (c) the decision of the JSC to permanently cease all Commercialization of such Product in such Designated Indication.

(c) Restriction. For clarity, Designated Indications are only those indications outside the Field that AstraZeneca agrees to include in this Agreement. Except for Designated Indications pursuant to this Agreement, FibroGen shall not Develop or Commercialize (directly or indirectly, by license, supply of Product or otherwise) any Product for any indication outside the Field in the Territory during the term of this Agreement.

## 3.6 Additional Compounds.

(a) Added by FibroGen. At any time during the Term, FibroGen may upon written notice to AstraZeneca include any HIF Compound in the definition of Collaboration Compound (and Product). Effective upon such written notice, the identified HIF Compound shall be deemed a Collaboration Compound, provided that AstraZeneca shall not have any obligations with respect to such Collaboration Compound (or Product) under this Agreement unless and until AstraZeneca's acceptance thereof through written notice to FibroGen.

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## (b) Added by Agreement.

(i) If AstraZeneca wishes to include additional HIF Compounds as Collaboration Compounds (and Products), it may make such a request to FibroGen. Upon receipt of such request, FibroGen shall make good faith and diligent efforts to present to the JSC for review all reasonably relevant data and other information (excluding chemical structures) Controlled by FibroGen that is related to those HIF Compounds that it reasonably believes offer substantial clinical benefit over then-current Collaboration Compounds from its library of HIF Compounds, including results from any Phase 2 Clinical Trial conducted in the Field. For clarity, the foregoing does not impose any obligation on FibroGen to identify or generate any additional HIF Compounds.

(ii) If AstraZeneca and FibroGen, through the JDC and JSC, agree upon a development program for any such HIF Compounds, then the Parties shall negotiate in good faith to agree on any additional consideration to be payable by AstraZeneca to FibroGen for inclusion of such additional HIF Compounds as Collaboration Compounds, and upon agreement, will amend this Agreement accordingly.

(c) Subject to Section 3.3 and to FibroGen's obligations under the Astellas EU Agreement, FibroGen will use good faith in designating additional HIF Compounds as Collaboration Compounds pursuant to this Section 3.6, and shall not nominate additional HIF Compounds for Development in the [\*] without approval of the JSC.

**3.7 Veterinary Applications**. Following the first approval of an NDA for a Product, the Parties may agree to develop the Product for a veterinary application. No additional consideration shall be payable by AstraZeneca to FibroGen with respect to such development. Upon agreement, the Parties shall enter into a separate agreement governing such applications or amend this Agreement accordingly prior to conducting any activities with respect to veterinary applications.

**3.8 Research Collaboration**. Upon FibroGen's request, the Parties will discuss conducting a research program funded by AstraZeneca and directed toward franchise enhancement and lifecycle management for HIF Compounds or other topics that the Parties determine relevant to the Products and the Field. Upon agreement on the terms of such research program, the Parties will enter into a separate agreement or amend this Agreement accordingly.

### 3.9 Diligence; Standards of Conduct.

(a) Each Party shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for the Products throughout the Territory (i) in the CKD Indications and (ii) in each [\*], other indication in the Field and Designated Indication that [\*] in the Development Plan. If at any time there is only one Collaboration Compound (either because no additional Collaboration Compounds have been developed or because development of all other Collaboration Compounds have been terminated), then the foregoing obligation shall be for one Product only.

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(b) Each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the Development Plan in a timely and effective manner. Each Party shall conduct its activities under the Development Plan in a good scientific manner and in compliance in all material respects with all applicable laws and regulations. Without prejudice to the aforesaid, the Party responsible for the conduct of any Clinical Trials hereunder shall perform such Clinical Trials in a good scientific manner, in compliance with all applicable laws and regulations, GCP, this Agreement and the Development Plan as well as the relevant protocol and investigator's brochure. Such Party shall further require the principal investigators, study sites and any contractors involved in the performance of such Clinical Trials to comply with all safety reporting procedures set forth in the Pharmacovigilance Agreement in connection with their performance of such Clinical Trials.

### 3.10 Development Data.

(a) Ownership and Disclosure. FibroGen shall solely own all data, records and reports generated by or on behalf of either Party in the conduct of Development activities under this Agreement (collectively, the "*Development Data*"), and AstraZeneca hereby assigns, and shall assign, to FibroGen, all of its right, title and interest in and to the Development Data. Each Party shall provide access to and, where practical, copies of the Development Data it (or its Affiliates or Sublicensees, or Third Parties acting on their behalf) generates to the other Party promptly upon receipt or development thereof, including nonclinical and clinical data (including raw data), analysis, reports and protocols. With respect to any data, records and reports, including nonclinical and clinical data (including raw data), analysis, reports and protocols, generated by or on behalf of FibroGen [\*]"), the following shall apply. [\*]. AstraZeneca shall reimburse FibroGen for any translation costs, costs for photocopying or other similar administrative expenses incurred by FibroGen in connection with providing access to the [\*]. Each Party will reasonably respond to the other Party's request for access to and questions about the Development Data and Astellas Data. Such Development Data will be provided in electronic form if requested by the other Party or reasonably convertible to such electronic form.

(b) Use. Each Party shall have the right to use the Development Data, and [\*], for the purpose of Developing and Commercializing Products in the Field in the Territory in accordance with the terms of this Agreement and in China in accordance with the terms of the China Agreement. [\*]. AstraZeneca hereby grants [\*]. AstraZeneca will take all actions reasonably requested by FibroGen to enable [\*], at FibroGen's cost and expense. FibroGen hereby grants AstraZeneca, its Affiliates and Sublicensees a right of access, a right of reference and a right to use and incorporate all Development Data [\*] in any regulatory filings for Products in the Territory. FibroGen will take all actions reasonably requested by AstraZeneca to enable AstraZeneca and its Affiliates and Sublicensees to practice such rights, at AstraZeneca's cost and expense.

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**3.11 Development Records and Reports.** Each Party shall maintain or cause to be maintained complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf under the Development Plan and all Information resulting from such work, including in the case of FibroGen, records of whether Development Costs are borne or reimbursed by Astellas under the Astellas EU Agreement. Such records, including any electronic files where such Information may also be contained, shall fully and properly reflect all work done and results achieved in the performance of the Development Plan in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Such records shall be retained by such Party for at least five (5) years after the term of this Agreement or such longer period as may be required by applicable laws. Each Party shall have the right to review and copy such records maintained by the other Party at reasonable times and to obtain access to originals to the extent needed for patent or regulatory purposes or for other legal proceedings. Each Party shall provide the JDC with regular reports, at least annually, detailing its Development activities under the Development Plan and the results of such activities.

**3.12 Subcontracts**. Each Party may perform any of its Development Program obligations under this Agreement through one or more subcontractors or consultants, provided that (a) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Product Information and Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (c) the subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work under the Development Program to the Party retaining such subcontractor. A Party may also subcontract work on terms other than those set forth in this Section 3.12, with the prior approval of the JDC.

## **ARTICLE 4**

#### **REGULATORY MATTERS**

#### 4.1 Regulatory Filings and Approvals.

(a) In General. The Parties intend that the Development Plan will set forth the regulatory strategy for seeking Regulatory Approvals (including any pricing and reimbursement approvals) throughout the Territory for all Products being Developed. All decisions regarding regulatory issues shall be made in accordance with the decision-making rules that are set forth in Article 2.

#### (b) Rights and Obligations.

(i) Lead Regulatory Party. The lead regulatory Party, on a jurisdiction-by-jurisdiction basis, shall be responsible for preparing and filing all Regulatory Materials, including INDs, shall be the holder of all Regulatory Approvals in such jurisdiction and will have primary operational responsibility for interactions with Regulatory Authorities, including taking the lead role at all meetings with Regulatory Authorities, subject to the right of the other Party to attend such meetings, participate in such activities and provide input, which the lead regulatory Party will consider in good faith. Without limitation, this right of participation covers all regulatory activities, including development of regulatory strategy and review of regulatory submissions, attendance at all meetings with Regulatory Authorities that may potentially impact the Development of or registration package for a particular Product, and review of outcomes of such meetings.

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(ii) U.S. FibroGen shall be the lead regulatory Party in the U.S. with respect to each Product and each indication through approval of the first NDA or supplemental NDA for such Product and indication. The Parties shall cooperate in maintaining each IND and preparing and submitting each NDA and applying for Regulatory Approval in the U.S. Following such approval, FibroGen will assign and transfer each such approved NDA or supplemental NDA to AstraZeneca (but not the ownership of Development Data therein, which shall be retained by FibroGen pursuant to Section 3.10(a)), and AstraZeneca will become the lead regulatory Party for such Product and indication in the U.S.; provided that (A) FibroGen will remain the lead regulatory Party with respect to the CMC section of each NDA for so long as FibroGen is conducting manufacturing activities under this Agreement, and (B) FibroGen will continue to have access to all information in each NDA. FibroGen shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts, including the filing of such assignments, agreements, documents and instruments, as may be reasonably necessary to effectively complete such assignment and transfer of such approved NDA or supplemental NDA to AstraZeneca. Each Party shall provide reasonable cooperation, information and other support to the other Party with respect to such other Party's obligations to comply with regulatory requirements, regardless of whether such other Party is the lead regulatory Party, including following the transfer of an NDA to AstraZeneca following Regulatory Approval.

(iii) RoW. AstraZeneca shall be the lead regulatory Party in the RoW for all Products and indications.

## (c) Reporting and Review.

(i) The JPT or JDC shall develop and implement procedures for drafting and review of material Regulatory Materials for Products in the Territory, which shall provide sufficient time (at least one week) for each Party to provide substantive comments prior to the filing of such Regulatory Materials (with material regulatory filings, or regulatory filings that materially change existing regulatory filings, subject to prior approval by the JPT or, when formed, the JDC or the JSC pursuant to Section 2.2(c)(ix) or Section 2.3(b)(xv), as applicable).

(ii) Each Party shall promptly notify the other Party of all Regulatory Materials that it submits for Products anywhere in the Territory and shall promptly (and in any event within one week) provide the non-responsible Party with a copy (which may be wholly or partly in electronic form) of such Regulatory Materials. The lead regulatory Party will provide the non-responsible Party with reasonable advance notice of any scheduled meeting with any Regulatory Authority and/or any Regulatory Materials with respect to Products throughout the Territory, and the non-responsible Party shall have the right to participate in any such meeting, except to the extent prohibited under applicable law and regulations. Representatives of the Party primarily responsible for such Regulatory Materials will be the primary spokespeople at any such meeting. The Party primarily responsible for such Regulatory Materials also shall promptly furnish the non-responsible Party with copies of all material correspondence to or from, and minutes of material meetings with, any Regulatory Authority relating to Development of such Product.

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**4.2 Notification of Threatened Action**. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may materially affect the Development, Commercialization or regulatory status of a Product, whether in or outside the Territory. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

4.3 Adverse Event Reporting and Safety Data Exchange. At a time determined by the JSC, but in any event prior to the first to occur of (i) the commencement of any Clinical Trial to be conducted by AstraZeneca or (ii) the transfer of the first NDA in the U.S. to AstraZeneca, the Parties shall define and finalize the methods and procedures (based on and consistent where possible with those methods and procedures used by Astellas and FibroGen under the Astellas EU Agreement, unless otherwise mutually agreed) that the Parties shall employ with respect to Products to protect patient safety and promote the appropriate treatment of safety information of Products in a written pharmacovigilance agreement (the "*Pharmacovigilance Agreement*"). For clarity, the Pharmacovigilance Agreement shall include all relevant safety data regarding the Product, irrespective of territory or indication. These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of any Product. Such guidelines and regulations. Furthermore, such agreed procedure shall be consistent with GCP and relevant ICH guidelines, except where such guidelines may conflict with existing local regulatory reporting or safety reporting requirements, in which case the local reporting requirements shall prevail. FibroGen shall maintain a global safety database for the Products, the expenses for which will be included in Development Costs and reimbursed by AstraZeneca, to the extent not borne or reimbursed by Astellas. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and permitted sublicensees to comply with such obligations. If and to the extent necessary, the Pharmacovigilance Agreement shall be amended by the Parties, or shall be superseded, so that an appropriate commercial-

**4.4 Product Withdrawals and Recalls.** If any Regulatory Authority in or outside the Territory (a) threatens, initiates or advises any action to remove any Product from the market or (b) requires or advises FibroGen, AstraZeneca, or any of their respective Affiliates or Sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product, then FibroGen or AstraZeneca, as applicable, shall notify the other Party of such event within three (3) Business Days (or sooner if required by law) after such Party becomes aware of the action, threat, advice or requirement (as applicable). The JSC will discuss and attempt to agree upon whether to recall or withdraw a Product; provided, however, that if the Parties fail to agree within an appropriate time period, the Party who is the then-holder of the NDA for the Product at issue shall decide whether to

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recall or withdraw such Product. AstraZeneca shall be responsible, at its sole expense, for conducting any recalls or taking such other necessary remedial action in the Territory, except that FibroGen will be responsible for such expenses to the extent (i) resulting from the failure of any Product supplied by FibroGen to conform to the applicable specifications; or (ii) such recall results from an event outside the Territory and outside the territory licensed under the China Agreement.

## **ARTICLE 5**

### COMMERCIALIZATION

**5.1 Overview.** The Parties agree to collaborate with respect to the Commercialization of Products in the Field in the U.S. as provided in this Article 5 under the direction of the JCC, and pursuant to the U.S. Commercialization Plan applicable to each Product. AstraZeneca shall have the sole right and responsibility for Commercializing Products in the Field in the RoW under the direction of the JCC, in accordance with this Agreement and as provided in this Article 5. Prior to the JCC's inception, all references to the JCC in this Article 5 and elsewhere in this Agreement will be deemed references to the JSC (which may delegate certain responsibilities to the Core JPT in accordance with Schedule G(b)).

**5.2** U.S. Commercialization Plan. As further described in this Section 5.2, the comprehensive strategy for the Commercialization of each Product in the U.S. shall be described in a comprehensive plan that describes the pre-launch, launch and subsequent Commercialization of such Product in the U.S. (including without limitation the high level strategies regarding messaging, branding, pricing, advertising, planning, marketing, sales force training and allocation, and reimbursement/managed care), key tactics for implementing those activities and the relative responsibilities of the Parties (each such plan, a "U.S. Commercialization Plan"), and the associated budget for such activities that details the anticipated Commercialization Costs (each such budget, a "U.S. Commercialization Budget").

(a) Promptly after the Effective Date, the JCC (or if not formed, the JSC) will determine the initial pre-commercial activities for which AstraZeneca will prepare an initial U.S. Commercialization Plan, which activities will include [\*], but need not include all activities described in the first paragraph of this Section 5.2. Within ninety (90) days thereafter, AstraZeneca will present such plan to the JCC for review and approval. Within two (2) years after the Effective Date but in any event not later than two (2) years prior to the then currently anticipated NDA submission date, AstraZeneca will present to the JCC a U.S. Commercialization Plan covering all activities described in the first paragraph of this Section 5.2, for review and approval by the JCC, which plan will include the key prelaunch and launch activities, marketing and sales deployment required for the initial launch of the Product and associated budgets. The JCC shall review, revise and recommend for approval by the JSC such U.S. Commercialization Plan.

(b) AstraZeneca will prepare a detailed U.S. Commercialization Plan and U.S. Commercialization Budget in preparation for U.S. launch of the Product for review and approval by the JCC no later than the submission of the first NDA for the Product, or at such other time determined by the JSC.

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(c) All U.S. Commercialization Plans and U.S. Commercialization Budgets with respect to Products in the U.S. and subsequent revisions thereto will contain such information as the JCC believes necessary for the successful Commercialization of such Product in the U.S., both pre- and post-launch, and shall generally conform to the level of detail utilized by AstraZeneca in preparation of its own product commercialization plans. On an annual basis (no later than October 31<sup>st</sup> of the preceding Calendar Year), or more often as the Parties deem appropriate, the JCC shall prepare amendments to the then-current U.S. Commercialization Plan(s) and the corresponding U.S. Commercialization Budgets. In the event of any inconsistency between a U.S. Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. Each Party shall conduct its activities under the U.S. Commercialization Plan in compliance in all material respects with all applicable laws and regulations.

**5.3 RoW Commercialization Plans.** AstraZeneca shall prepare Commercialization plans with respect to Products in the RoW on an annual basis, shall submit such plans to the JCC for review and approval, and shall respond in a timely fashion to any reasonable requests of FibroGen or the JCC with respect to such plans and Commercialization activities in the RoW.

**5.4 Commercialization Costs.** AstraZeneca shall be solely responsible for all Commercialization Costs incurred by it or by or on behalf of FibroGen under the Co-Commercialization Agreement and in the Commercialization of Products in the U.S. and RoW. AstraZeneca will reimburse FibroGen for such costs incurred by FibroGen, plus a markup of [\*]) to be applied to FibroGen's [\*] costs only, all pursuant to more detailed provisions to be included in the Co-Commercialization Agreement.

**5.5 Sales and Distribution; Returns; Customer Support.** AstraZeneca shall be solely responsible for handling all returns, recalls, order processing, invoicing and collection, booking of sales, distribution, and inventory and receivables for Products in the Territory. FibroGen shall not accept orders for Products or make sales for its own account or for AstraZeneca's account, and if FibroGen receives any order for Products in the Territory, it shall refer such orders to AstraZeneca for acceptance or rejection. AstraZeneca shall be responsible for handling all returns of any Product. If Products are returned to FibroGen, FibroGen shall promptly ship such Products to AstraZeneca. FibroGen, if requested by AstraZeneca, shall advise the customer who made the return that the Products have been returned to AstraZeneca. AstraZeneca shall be responsible for providing customer support, handling medical queries, and responding to product and medical complaints relating to Products.

**5.6 Commercialization Reports.** Each Party shall keep the JCC fully informed regarding the progress and results of Commercialization activities for Products in the U.S. and RoW, including an annual review of results versus plans (as set forth in the U.S. Commercialization Plan(s)).

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**5.7 Samples.** At a time determined by the JSC, the Parties will discuss in good faith whether, how, and under what circumstances the Parties would allow distribution of samples (i.e., Products provided free of or for a nominal charge) of Product for treatment of anemia in patients with chronic kidney disease not undergoing dialysis, or in other applicable indications outside of the CKD Indications. Neither Party will have the right to distribute Product samples without the prior written consent of the other Party, and, if such consent is granted, each Party will distribute such samples only according to the procedures and in the amounts agreed by the Parties in writing.

### 5.8 Commercialization Standards of Conduct.

(a) Execution of U.S. Commercialization Plan. Each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the U.S. Commercialization Plan and the Co-Commercialization Agreement in a timely and effective manner and in compliance with all applicable laws and regulations.

(b) AstraZeneca Diligence Obligations. AstraZeneca shall use Commercially Reasonable Efforts to Commercialize each Product in each indication and country in the Territory for which Regulatory Approval is obtained, except for indications and countries for which FibroGen has independently obtained Regulatory Approval, without opt-in by AstraZeneca, under Section 3.3(b).

**5.9 Subcontracts.** Each Party may perform any of its obligations under the U.S. Commercialization Plan through one or more subcontractors or consultants, provided that (a) AstraZeneca will not subcontract any such activities without [\*]; (b) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (c) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Product Information and Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (d) the subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work under the U.S. Commercialization Plan to the Party retaining such subcontractor. A Party may also subcontract work on terms other than those set forth in this Section 5.9, with the prior approval of the JCC. AstraZeneca will have [\*] (subject to compliance with clauses (b) – (d) of this Section 5.9), except that AstraZeneca will be required to reasonably [\*] Third Party subcontractors for such activity.

**5.10 Co-Commercialization Agreement.** Following submission of the first NDA for a Product or at such earlier time as AstraZeneca may request, the Parties will negotiate and enter into an agreement (the "*Co-Commercialization Agreement*") governing the Parties' conduct of activities for Commercializing the Product in the U.S. The Co-Commercialization Agreement will be consistent with the terms of this Article 5, Exhibit I, other terms agreed by the Parties, and other customary terms for such an agreement.

## 5.11 Regulatory Compliance.

(a) Each of FibroGen and AstraZeneca shall reasonably cooperate with the other Party in its efforts toward ensuring that all government reporting (including price and gift reporting), sales, marketing and promotional practices in respect of each Product meet the standards required by (A) applicable laws and regulations; (B) applicable guidelines concerning

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the advertising and promotion of prescription drug products, including without limitation the Office of the Inspector General's ("*OIG*") Compliance Guidance Program issued in 2003, the American Medical Association (the "*AMA*") Guidelines on Gifts to Physicians, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, as hereafter amended from time to time (the "*PhRMA Code*"), the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, and the standards set forth by the Accreditation Council for Continuing Medical Education relating to educating the medical community in the United States ("*ACCME Standards*"); (C) the Prescription Drug Marketing Act of 1987, as amended, and the rules, regulations and guidelines promulgated thereunder; (D) federal, state and local agencies and all payor "fraud and abuse", and consumer protection and false claims statutes and regulations, including the Medicare and State Health Programs Anti-Kickback Law (42 U.S.C. §1320a-7b(b)) and the Safe Harbor Regulations which are found at 42 C.F.R. §1001.952 et seq.; and (E) the FCPA. The Parties shall cooperate in good faith to update their obligations under this Section 5.11(a) from time to time to reflect any changes in any of the foregoing (A) – (E) or to resolve any conflicts in any of the foregoing standards as applied to the Parties' activities under this Agreement.

(b) Each Party shall be responsible for tracking and reporting transfers of value initiated and controlled by its employees and/or contractors pursuant to the requirements of Section 6002 (Transparency Reports and Reporting of Physician Ownership and Investment Interest) of the Affordable Care Act, commonly referred to as the "Sunshine Act", and state marketing reporting laws. The value reported to the Centers for Medicare & Medicaid Services shall be the amount expended by the controlling Party, irrespective of the division of or reconciliation of expenses between the Parties.

(c) AstraZeneca shall provide its sales representatives appropriate training on proper marketing and sales techniques. Such training will include, among other topics, FDA requirements and other state and federal regulations and guidelines concerning the advertising of prescription drug products, the OIG Compliance Guidance Program, the AMA Guidelines on Gifts to Physicians, the PhRMA Code, and the ACCME Standards. If requested by FibroGen, AstraZeneca shall provide a written description of the training to FibroGen no less frequently than on an annual basis.

(d) Each of FibroGen and AstraZeneca shall reasonably cooperate with the other Party to provide the other Party access to any and all information, data and reports required by the other in order to comply with the relevant provisions of the Medicare Modernization Act and any other applicable laws and regulations, including without limitation reporting requirements, in a timely and appropriate manner. AstraZeneca shall ensure that its reporting to the Centers for Medicare and Medicaid Services and other federal and state healthcare programs related to the Products is true, complete and correct in all respects; provided however, that AstraZeneca shall not be held responsible for submitting erroneous reports if such deficiencies result from information provided by FibroGen which itself was not true, complete and correct.

(e) AstraZeneca shall, so far as practicable, provide to FibroGen in advance any submission containing any information provided by FibroGen pursuant to this Section 5.11 that AstraZeneca proposes to submit to any governmental entity. AstraZeneca further agrees to seek confidential treatment of any such information related to FibroGen that it submits to any governmental entity to the extent permitted under any applicable laws and regulations.

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(f) FibroGen and AstraZeneca shall confer with each other on a regular basis to discuss and compare their respective procedures and methodologies relating to each Party's compliance to any applicable laws or regulations or fulfillment of any other obligation contained in this Section 5.11. In the event that the parties have different understandings or interpretations of this Section 5.11 or of the applicability of, or standards required by, any applicable laws or regulations, then the Parties shall confer and seek to reach common agreement on such matters.

(g) Each of AstraZeneca and (where applicable) FibroGen agrees that:

(i) it will instruct its sales representatives to use, and will use Commercially Reasonable Efforts to train and monitor its sales representatives to ensure that such sales representatives use, only Promotional Materials and literature approved for use under subsection (h) of **Exhibit I** for the promotion of the Products in the U.S.;

(ii) it will instruct its sales representatives not to misbrand, change, alter or adulterate any Promotional Materials supplied to it in any way prior to or during their distribution or use; and

(iii) it will instruct its sales representatives to do, and will use Commercially Reasonable Efforts to train its sales representatives to do, and will establish appropriate internal systems, policies and procedures for the monitoring of its sales representatives with the goal of ensuring that such personnel do, the following:

(1) limit claims of efficacy and safety for the Products to those that are (A) consistent with approved promotional claims in, and not add, delete or modify claims of efficacy and safety in the promotion of such Products in any respect from those claims of efficacy and safety that are contained in, the then effective U.S. Commercialization Plan, (B) consistent with applicable laws and regulations, and (C) consistent with the Product labeling approved by the FDA;

(2) not make any changes in Promotional Materials, and use Promotional Materials within the U.S. only in a manner that is consistent with (A) the then effective U.S. Commercialization Plan, (B) applicable laws and regulations and (C) the Product labeling approved by the FDA;

(3) promote the Products in compliance with applicable legal and professional standards that are generally accepted by the pharmaceutical industry in the applicable market, including applicable laws and regulations and the applicable guidelines concerning the advertising and promotion of prescription drug products described in this Section 5.11; and

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(4) not to, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any official or employee of any Governmental Authority, or to any political party, or official thereof, or to any candidate for political office (including any party, official, or candidate) for the purpose of promoting the sale or improper use of a Product.

# **ARTICLE 6**

## MANUFACTURE AND SUPPLY

6.1 Purchase and Supply Commitment. AstraZeneca hereby appoints FibroGen as its exclusive supplier of Product (drug substance and drug product) for the Territory for use in accordance with the terms of this Agreement. AstraZeneca agrees to purchase, and FibroGen agrees to supply, all of AstraZeneca's and its Affiliates' and their respective Sublicensees' requirements of Product (as bulk drug product and drug substance) for Development and Commercialization in the Territory under the terms of this Article 6. AstraZeneca shall have the exclusive right to perform (itself or through its Affiliates, Sublicensees or Distributors) and shall be solely responsible for final product labeling and secondary packaging for sale to end users in the Territory. To the extent that such labeling and packaging are relevant to FibroGen's activities to seek and obtain Regulatory Approval for the Product, AstraZeneca will reasonably and timely cooperate with FibroGen, in a manner sufficient to enable FibroGen to receive Regulatory Approval and to provide materials and Information as requested by FibroGen. The right of FibroGen to manufacture on behalf of AstraZeneca contemplates that at a time to be determined by the JSC, and in any event before the point in time when [\*] in any twelve (12) month period, AstraZeneca will have the right to select, or obligate FibroGen to select, a second supplier (which may be AstraZeneca itself), and FibroGen will have the obligation to complete activities to undertake technology transfer in order for such secondary source to establish and secure regulatory approval as a second source for drug substance for Product, which shall in any event not limit FibroGen's right to continue to ensure that a source of Product be maintained in the U.S. in order to satisfy FibroGen's obligations under the Astellas Agreements and the DFCI Agreement. For clarity, FibroGen shall have the right to manufacture Product outside the Territory to fulfill its supply obligations under this Agreement. For clarity, subject to the terms of this Agreement, FibroGen shall have the right to satisfy its obligations under this Article 6 through a Third Party contract manufacturer. In connection with FibroGen's manufacture of Products for use under this Agreement, FibroGen shall have the right to manufacture in the Territory for supply of Products under the Astellas Agreements.

**6.2 Development Supply.** In connection with the supply of any Product for non-commercial use, FibroGen shall supply Product in compliance with applicable law and regulations, including GMP requirements, and in accordance with forecasts set forth in the Development Plan or, if not specified therein, the forecasts developed by the JDC as necessary for the conduct of Clinical Trials set forth in the Development Plan. FibroGen shall use Commercially Reasonable Efforts to meet any applicable timelines for supplying Product, subject to the reasonable lead time requirements of Third Party contract manufacturers. AstraZeneca will pay FibroGen's Fully Burdened Cost for all Product supplied for Development, within forty-five (45) days after receipt of invoice therefor. All Products supplied for a country after Regulatory Approval in such country will be considered to be for commercial use, unless used specifically for Clinical Trials under the Development Plan. The terms of supply by FibroGen to AstraZeneca for use in any Clinical Trial conducted under the sponsorship of AstraZeneca or for other non-commercial use by or on behalf of AstraZeneca, are as set forth on **Exhibit J**.

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**6.3 Commercial Supply Agreement**. At a time specified by AstraZeneca, but in any event in a reasonable period in advance of the anticipated launch date for the Product in the U.S., the Parties will negotiate in good faith and enter into separate supply and quality agreements governing the commercial supply of Product (in bulk and primary packaged forms) from FibroGen to AstraZeneca (together, the "*Supply and Quality Agreement*"). The Supply and Quality Agreement will include the terms and conditions set forth on **Exhibit K** and contain such further customary and commercially reasonable terms governing similar supply arrangements and other terms as the Parties may agree, including appropriate forecasting and firm purchase order lead times, taking into consideration the reasonable notice requirements of FibroGen as well as any other terms set forth in this Article 6. The initial Supply and Quality Agreement shall have a term of [\*]) years for the supply of drug substance, after which AstraZeneca would have the right to extend the term for an additional [\*] years or to assume responsibility for drug substance manufacture upon agreement of terms mutually agreed by the Parties, including [\*] in the form of drug substance. Under the Supply and Quality Agreement, the obligation to supply drug product shall have a term of five (5) years, which will automatically renew for succeeding five (5)-year terms and will include the price applicable pursuant to Section 6.5. In the event of any inconsistency between the Supply and Quality Agreement and Article 6 of this Agreement with regard to matters relating to supply, quality control and quality assurance, the terms of the Supply and Quality Agreement shall prevail.

**6.4 Contract Manufacture Process**. FibroGen is currently utilizing a contract manufacturer to fulfill its manufacturing timelines to complete drug product development in time for the expected commercial launch of the Product in the U.S. and under the Astellas Agreements. Notwithstanding the provisions of Section 6.3, upon AstraZeneca's written request to FibroGen, not to be submitted earlier than six (6) months after the Effective Date, the Parties will discuss in good faith whether to select a separate contract manufacturer mutually acceptable to the Parties to be used for formulation and bulk drug product manufacture (using drug substance supplied by FibroGen) for commercial supply under this Agreement. The Parties shall discuss in good faith the transfer, including timely technology transfer, as soon as practicable following such mutual agreement. Such selection will be conducted in accordance with the following process: As soon as reasonably practicable to the Parties, consent not to be unreasonably withheld, to submit bids to conduct such manufacture. Such bids shall be based on a request for quotation, the contract manufacturer to submit a bid with respect to such manufacture). AstraZeneca and its Affiliates shall provide a proposal on the same basis as the Third Party contract manufacturers. The Parties shall review and assess in good faith the bids submitted by the Third Party manufacturers and by AstraZeneca or its Affiliate and shall recommend to the JDC the bid that, on the whole, offers the most favorable terms for such manufacture based on a reasonable assessment of the relevant factors, including price, capital requirements, quality, capacity,

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capability to maintain continuity of supplies, considerations related to the supply of Product to Astellas and global supply of Product and overall timeline. FibroGen will enter into a supply and quality contract with the Third Party contract manufacturer, on terms consistent with the selected bid and otherwise reasonably acceptable to the Parties, or the responsibility to manufacture shall be transferred to AstraZeneca, as determined by the JDC. In the event FibroGen shall contract with AstraZeneca or its Affiliate in accordance with this Section 6.4, FibroGen shall – as soon as reasonably practicable after the completion of the selection process – provide the necessary technology transfer as well as all necessary assistance to obtain required regulatory approvals, all to enable AstraZeneca or its Affiliate to conduct the formulation and bulk drug product manufacture (using drug substance supplied by FibroGen) for supply of Product under this Agreement, and to Astellas under the Astellas Agreements. If AstraZeneca is not selected as the contract manufacturer, then at any time after the [\*], at AstraZeneca's request, the Parties shall [\*]. For clarity, to the extent that the alternative formulation and drug product manufacture is transferred to such Third Party, FibroGen shall have the right to use such source of supply to satisfy FibroGen's obligations under the Astellas Agreements.

### 6.5 Transfer Price.

(a) FibroGen will supply to AstraZeneca (or its designated Affiliate or Sublicensee) Product for commercial use as drug product at a transfer price equal to [\*] during the Calendar Year in which such Product is delivered. Notwithstanding the foregoing, in the event that the Parties agree that AstraZeneca shall supply drug product and FibroGen shall only supply drug substance, the transfer price for such drug substance shall be [\*] during the Calendar Year in which such Product is delivered.

(i) If FibroGen supplies Product as drug product, then not less than thirty (30) days prior to the beginning of each Calendar Year during which FibroGen will be supplying product (each a "*Delivery Year*"), the Parties will calculate a preliminary transfer price per unit (the "*Preliminary Price Per Unit*"), which shall be equal to [\*] multiplied by the fraction (A)/(B), where (A) shall be the estimated [\*] for such Delivery Year and (B) shall be the estimated [\*] in the Territory during such Delivery Year (all estimations to be made by the Parties in good faith). FibroGen will invoice AstraZeneca upon delivery of each shipment of product at the Preliminary Price Per Unit and AstraZeneca will pay for such product at such price within forty-five (45) days after its receipt of such invoice. Within forty-five (45) days following the end of each Delivery Year, the Parties will calculate the definitive transfer price per unit ("*Definitive Price Per Unit*") for such year, which shall be equal to [\*] multiplied by the fraction (A)/(B), where (A) shall be the actual [\*] made during the Delivery Year and (B) shall be the actual [\*] in the Territory during such Delivery Year (excluding [\*]). If the transfer price for the total volume of product actually delivered by FibroGen during the Delivery Year at the Definitive Price Per Unit (the "*Total Definitive Price*") exceeds the transfer price for such volume based on the Preliminary Price Per Unit (the "*Total Preliminary Price*"), then AstraZeneca shall pay the difference to FibroGen within forty-five (45) days after its receipt of an invoice from FibroGen for such amount. If the Total Preliminary Price exceeds the Total Definitive Price, FibroGen shall issue a credit note to AstraZeneca for the difference. AstraZeneca shall be entitled to set off the amount due under the credit note against any subsequent payments owed by AstraZeneca to FibroGen under this Agreement (or, in the absence of any such subsequent payments, such credit note shall be settled by FibroGen within

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(ii) If FibroGen supplies Product as drug substance, then the Parties shall calculate the price for Product according to a process similar to that described in clause (i) above, except that the multiplier shall be [\*] during the Delivery Year.

(b) Potential Cost Reductions. At either Party's request during the Term, the Parties shall discuss and explore potential means of collaborating to reduce the overall costs of manufacture and supply of Products as drug substance or bulk drug product under this Agreement, with the understanding that the Parties shall share the financial benefits of any such cost reductions achieved in a reasonable manner taking into account to what extent each Party has contributed to such cost reductions.

(c) Adjustment for Generic Entry. If at any time FibroGen's net margin percentage on any Product supplied to AstraZeneca falls below [\*]) after a Generic Product is sold in any country in the Territory, FibroGen shall have the right to renegotiate the manufacturing and supply payment terms under the Supply and Quality Agreement. Upon FibroGen's request, the Parties shall renegotiate reasonable terms in good faith, taking into account also the overall profitability of such Product to AstraZeneca.

## **ARTICLE 7**

### LICENSES AND EXCLUSIVITY

# 7.1 License to AstraZeneca.

(a) License Grant. Subject to the terms and conditions of this Agreement, FibroGen hereby grants AstraZeneca (i) a co-exclusive (with FibroGen), royalty-bearing, sublicensable (solely as permitted in accordance with Section 7.3) license under the FibroGen Technology to Develop (solely in accordance with the Development Plan) Products in the Field in the Territory and (ii) an exclusive, royalty-bearing, sublicensable (solely as permitted in accordance with Section 7.3) license under the FibroGen Technology to Commercialize, to make and have made (solely for use in the Territory under this Agreement), and to use, sell, offer for sale, and import Products in the Field in the Territory (subject, however to a retained right for FibroGen to perform Development and Commercialization (including manufacturing) activities pursuant to this Agreement or the China Agreement or under the Astellas Agreements).

## (b) DFCI Agreement.

(i) The terms and conditions of Sections [\*] of the DFCI Agreement are binding on AstraZeneca in its capacity as a sublicensee of FibroGen under the DFCI Agreement.

(ii) AstraZeneca acknowledges and agrees that its rights to the FibroGen Technology that is licensed to FibroGen under the DFCI Agreement are at all times subject to the applicable terms of the DFCI Agreement. [\*].

(iii) FibroGen shall use best efforts to maintain the DFCI Agreement in effect. [\*].

(iv) The license granted in Section 7.1(a) is subject to certain reserved rights as set forth in Section [\*] of the DFCI Agreement.

**7.2 License to FibroGen.** Subject to the terms and conditions of this Agreement, AstraZeneca hereby grants FibroGen a non-exclusive, worldwide, sublicensable, royalty-free, fully-paid license, under the AstraZeneca Technology during the Term, to conduct any and all activities assigned to FibroGen under the Development Plans and U.S. Commercialization Plans, and to Develop and Commercialize Products outside the Territory.

## 7.3 Sublicensing.

(a) Scope of Permissible Sublicensing. The license granted by FibroGen to AstraZeneca in Section 7.1 may be sublicensed by AstraZeneca: (i) to an Affiliate of AstraZeneca without any requirement of consent, provided that such sublicense to an Affiliate of AstraZeneca shall immediately terminate if and when such party ceases to be an Affiliate of AstraZeneca, or (ii) where such sublicense is made to enable a Third Party to provide contract research or development services or contract manufacturing services for AstraZeneca, its Affiliates or Sublicensees, without such Third Party being granted the right to distribute, market or sell a Product, to such Third Party without any requirement of consent, but upon written notice to FibroGen and subject to Sections 3.12 and 5.9, and no sooner than twelve (12) days after such notice, or (iii) otherwise (i.e. other than pursuant to (i) or (ii) above) only with the prior written consent of FibroGen, not to be unreasonably withheld, and no sooner than twelve (12) days after such consent is obtained. It will not be unreasonable for FibroGen to withhold its consent to a sublicense pursuant to subsection (iii) above to (1) any entity that [\*] or (2) any company engaged in the sales of tobacco or tobacco-related products. AstraZeneca shall be liable to FibroGen for the acts or omissions of its Sublicensees, and any breach of an applicable provision of this Agreement by a Sublicensee shall be deemed to be a breach by AstraZeneca.

(b) Sublicense Agreements. AstraZeneca shall, in each agreement under which it grants a sublicense under a license set forth in Section 7.1 (each, a "Sublicense Agreement"), require the Sublicensee to (A) comply with the obligations in Section 7.8 (as applied to such Sublicensee and its Affiliates) and (B) provide the following to FibroGen if this Agreement terminates and to AstraZeneca if only such Sublicense Agreement terminates: (i) the assignment and transfer of ownership and possession of all Regulatory Materials and Regulatory Approvals held or possessed by such Sublicensee (which assignment could also be directly to AstraZeneca prior to any such termination), and (ii) the assignment of, or a freely sublicensable exclusive license to, all intellectual property Controlled by such Sublicensee that covers or embodies a Product or Collaboration Compound or its respective use, manufacture, sale, or importation and was created by or on behalf of such Sublicensee during the exercise of its rights or fulfillment of its

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obligations pursuant to such Sublicense Agreement. Each Sublicense Agreement shall be subject to the applicable terms and conditions of this Agreement, the DFCI Agreement and any Third Party licenses sublicensed to the Sublicensee. AstraZeneca shall include a copy of the DFCI Agreement in all Sublicense Agreements. AstraZeneca shall forward a copy of each Sublicense Agreement (which may be redacted but shall contain all provisions relevant to this Agreement unredacted) to FibroGen within twenty (20) days after execution thereof, and FibroGen shall have the right to provide such copy to DFCI; provided that with respect to any Sublicense Agreement with an Affiliate of AstraZeneca, AstraZeneca shall only be required to provide such copy upon FibroGen's request. Annually, AstraZeneca shall forward to FibroGen a copy of the reports received by AstraZeneca from its Sublicensee during the preceding twelve (12) month period under each Sublicense Agreement, in each case solely to the extent relevant to FibroGen's rights under this Agreement or (to the extent different, as notified by FibroGen to AstraZeneca) DFCI's rights under the DFCI Agreement. FibroGen shall have the right to provide each such report to DFCI. FibroGen shall require DFCI to comply with confidentiality and non-use obligations in respect of information disclosed to DFCI in accordance with this Section 7.3(b), which obligations shall be substantially the same as those undertaken by the Parties pursuant to Article 12.

(c) Distributorships. AstraZeneca shall have the right, in its sole discretion, to appoint its Affiliates, and AstraZeneca, its Affiliates and its Sublicensees shall have the right, in their sole discretion, to appoint any other person or entity, in the Territory, to distribute, market and sell the Products, with or without packaging rights. In circumstances where such appointed person or entity purchases its requirements of Products from AstraZeneca, its Affiliates or its Sublicensees, but does not otherwise make any royalty or other payment to AstraZeneca, its Affiliates or its Sublicensees with respect to intellectual property rights, and where such person is not an Affiliate of AstraZeneca, then that person or entity shall be a "*Distributor*" for purposes of this Agreement. The term "packaging rights" in this Section 7.3(c) shall mean the right for the Distributor to package Products supplied in unpackaged bulk form into individual ready-for-sale packs.

(d) Co-Promotion. Subject to Section 5.9, AstraZeneca and its Affiliates shall have the right, in their sole discretion, to co-promote the Products with any other person or entity, or to appoint one or more Third Parties to promote the Products without AstraZeneca in all or any part of the Territory, provided however that the foregoing shall not adversely impact FibroGen's right to co-promote the Product as described under this Agreement.

#### 7.4 FibroGen's Activities.

(a) Covenant by FibroGen. Except pursuant to this Agreement or the China Agreement, FibroGen and its Affiliates shall not, and shall not license or authorize any Third Party to, directly or indirectly,

(i) at any time during the Term Develop or Commercialize any Product in the Territory within or outside of the Field;

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(ii) at any time during the period starting on the Effective Date and continuing until the earlier to occur of (A) the [\*] this Agreement and (B) the [\*] this Agreement ("*Covenant Period 1*") Develop any HIF Compound in any ESA Indication in the Territory or any indication for which AstraZeneca is Developing or Commercializing a Collaboration Compound or Product under this Agreement; and

(iii) at any time during the period starting on the Effective Date and continuing until the earlier to occur of (A) the [\*] of this Agreement and (B) the [\*] in the Territory ("*Covenant Period 2"*) Commercialize any HIF Compound in any ESA Indication in the Territory or any indication for which AstraZeneca is Developing or Commercializing a Collaboration Compound or Product under this Agreement.

## (b) Astellas Agreements. [\*].

(c) Termination of Astellas Agreements. Effective upon the termination of either of the Astellas Agreements with respect to a particular country or countries (the "Astellas Terminated Territory"), FibroGen hereby grants AstraZeneca a right of first negotiation to obtain a license to develop and commercialize Products in the Astellas Terminated Territory, as detailed in this Section 7.4(c). Accordingly, prior to entering into any agreement with a Third Party for such purpose, FibroGen shall provide to AstraZeneca a written notice of FibroGen's interest in entering into an agreement with respect to the development and/or commercialization of Products in the Astellas Terminated Territory. [\*]. If the Parties do not reach an agreement with respect to the grant of such rights with respect to Products in the Astellas Terminated Territory [\*] FibroGen shall have no further obligation with respect to the Astellas Terminated Territory [\*] FibroGen enters into an agreement with a Third Party (a "Subsequent Licensee") with respect to the Products and the Astellas Terminated Territory (a "Subsequent Agreement"), FibroGen shall ensure that Such Subsequent Agreement [\*], and in any event shall ensure that AstraZeneca's rights with respect to the Subsequent Licensee [\*].

(d) Remedy. FibroGen hereby acknowledges and agrees that in the event of any actual or threatened breach of this Section 7.4, AstraZeneca will suffer an irreparable injury, such that no remedy at law shall afford it adequate protection against, or appropriate compensation for, such injury. Accordingly, FibroGen hereby agrees that AstraZeneca shall be entitled to specific performance of FibroGen's obligations under this Section 7.4, as well as such further timely injunctive relief as may be granted by a court of competent jurisdiction.

# 7.5 Cross-Territorial Restriction.

(a) AstraZeneca hereby covenants and agrees that it shall not, and will ensure that its Affiliates and Sublicensees will not, either directly or indirectly, actively promote, market, distribute, import, sell or have sold Product into countries outside the Territory. As to such countries outside the Territory: (i) AstraZeneca shall not, and will ensure that its Affiliates and Sublicensees will not, engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in such countries;

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and (ii) AstraZeneca shall not, and will ensure that its Affiliates and Sublicensees will not, solicit orders for Products from any prospective purchaser located in such countries. If AstraZeneca receives any order for Products from a prospective purchaser located in a country outside the Territory from which reimports into the Territory are unlikely, AstraZeneca shall immediately refer that order to FibroGen. AstraZeneca shall not accept any such orders. AstraZeneca may not deliver or tender (or cause to be delivered or tendered) any Product into a country outside of the Territory from which reimports into the Territory are unlikely. AstraZeneca shall not, and will ensure that its Affiliates and Sublicensees will not, restrict or impede in any manner FibroGen's exercise of its retained rights outside the Territory, provided that any such exercise of rights by FibroGen shall comply with the terms of this Agreement.

(b) FibroGen hereby covenants and agrees that it shall not and will ensure that its Affiliates and any Subsequent Licensee shall not, either directly or indirectly, actively promote, market, distribute, import, sell or have sold Product into countries within the Territory. As to such countries within the Territory: (i) FibroGen shall not, and will ensure that its Affiliates and Subsequent Licensees will not, engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in such countries; and (ii) FibroGen shall not, and will ensure that its Affiliates and Subsequent Licensees will not, solicit orders for Products from any prospective purchaser located in such countries. If FibroGen receives any order for Products from a prospective purchaser located in a country within the Territory from which re-imports out from the Territory are unlikely, FibroGen shall immediately refer that order to AstraZeneca. FibroGen shall not accept any such orders. FibroGen may not deliver or tender (or cause to be delivered or tendered) any Product into a country within the Territory from which re-imports out of the Territory, provided that any such exercise of rights by AstraZeneca shall comply with the terms of this Agreement. In addition to the foregoing, FibroGen shall use Commercially Reasonable Efforts to invoke and enforce the provisions of the Astellas Agreements with respect to restrictions on supply and commercialization in the Territory.

**7.6 Negative Covenant.** Each Party covenants that it will not knowingly use or practice any of the other Party's intellectual property rights licensed to it under this Article 7 except for the purposes expressly permitted in the applicable license grant.

**7.7 No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license, express or implied, under its intellectual property rights. This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents owned in whole or in part by DFCI other than the particular patents and patent applications licensed under the DFCI Agreement.

## 7.8 Exclusivity.

(a) Restrictive Covenant by AstraZeneca. Except pursuant to this Agreement or the China Agreement, AstraZeneca and its Affiliates shall not, and shall not license or authorize any Third Party to, directly or indirectly,

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(i) at any time during Covenant Period 1, or such longer period as may follow from Section 13.6(i), research or Develop any HIF Compound in the Field; or

(ii) at any time during Covenant Period 2 and three (3) years thereafter, Commercialize any HIF Compound in the Field and in the Territory.

(b) Acquisition. Notwithstanding the foregoing in Section 7.8(a), neither AstraZeneca's nor any of its Affiliates' direct or indirect acquisition of or merger with, in whole or in part, a person or entity (or group of companies) or the business of a person or entity (or group of companies) having any activity contravening the covenants set forth in Section 7.8(a) shall constitute a breach of such covenants by AstraZeneca if AstraZeneca or its Affiliate, as the case may be, notifies FibroGen within forty-five (45) days following the closing of such acquisition or merger of its intent to divest itself of such assets and complies with the following:

(i) AstraZeneca shall ensure that no Development Data, Information related to Commercialization in connection with this Agreement, FibroGen Technology or Confidential Information of FibroGen is used in or for the purpose of the activities contravening such covenants.

(ii) AstraZeneca shall (or, as the case may be, cause its relevant Affiliate to) [\*] the sale or transfer to a Third Party of the relevant part of the business contravening such covenants, and in any case, shall enter into (or, as the case may be, cause its relevant Affiliate to enter into) a binding definitive agreement with a Third Party for such sale or transfer no later than [\*] after the closing of the acquisition or merger transaction under which the relevant business was acquired.

(iii) Neither AstraZeneca nor its Affiliates shall, during such [\*] period, Commercialize a product being the subject of research or Development activities forming part of the relevant business which is to be divested, unless such product was already Commercialized prior to the closing of the acquisition or merger transaction.

(iv) AstraZeneca shall, notwithstanding anything to the contrary in this Section 7.8(b), at all times continue to be obligated to use Commercially Reasonable Efforts to Develop or Commercialize a Product in accordance with its obligations under and subject to Sections 3.9 and 5.8.

(c) Remedy. AstraZeneca hereby acknowledges and agrees that in the event of any actual or threatened breach of this Section 7.8, FibroGen will suffer an irreparable injury, such that no remedy at law shall afford it adequate protection against, or appropriate compensation for, such injury. Accordingly, AstraZeneca hereby agrees that FibroGen shall be entitled to specific performance of AstraZeneca's obligations under this Section 7.8, as well as such further timely injunctive relief as may be granted by a court of competent jurisdiction.

(d) [\*]. In the event AstraZeneca or its Affiliates conducts any activities prohibited under this Section 7.8, any [\*] shall be subject to the following [\*]. AstraZeneca [\*]. Such [\*] shall be in addition to all other remedies available to FibroGen.

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## 7.9 Additional Provisions Regarding Restrictive Covenants and Exclusivity.

(a) The Parties agree that the restrictions contained in Sections 7.4, 7.5, 7.8 and 13.6(i) are reasonable and necessary for the protection of the Parties' and their Affiliates' respective confidential information and business, that such restrictions are reasonable in all the circumstances and that the Parties would not have entered into this Agreement without the protections afforded to them under Sections 7.4, 7.5, 7.8 and 13.6(i).

(b) The words "Develop" and "Commercialize" and all variations thereof included in Sections 7.4 and 7.8 with reference to HIF Compounds shall include the activities described in the definitions of such words in Article 1, but with such activities being with respect to HIF Compounds rather than with respect to a Product as set forth in the relevant definition.

# **ARTICLE 8**

## FINANCIALS

**8.1 License Fees**. AstraZeneca shall pay to FibroGen each of the following non-refundable, non-creditable license fees on or before the applicable date set forth below; provided that with respect to payment 1, FibroGen shall provide an invoice on or before the Effective Date, and with respect to payments 2, 3 and 4, FibroGen shall provide an invoice at least forty-five (45) days before each applicable due date:

Number	Due Date	Payment
1	15 <sup>th</sup> Business Day after	
	the Effective Date	\$ 70 million
2	June 30, 2014	\$ 110 million
3	June 30, 2015	\$120 million
4	June 30, 2016	\$ 62 million

If this Agreement is terminated prior to the due date of payment 2 or 3, then each such payment shall remain due and payable despite such termination. If this Agreement is terminated prior to the due date of payment 4, then payment 4 will remain due and payable despite such termination; [\*].

### 8.2 Development and Commercialization Cost Reimbursement.

(a) Prior to First NDA Approval during Development Sharing Period. The following procedure in this subsection (a) will apply prior to the first NDA approval for a Product and during the Development Sharing Period.

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(i) On or before the Effective Date, FibroGen will submit an invoice to AstraZeneca for an amount of [\*] in respect of certain Development Costs incurred by FibroGen under the Development Plan prior to the Effective Date. AstraZeneca shall pay such invoice within fifteen (15) Business Days of receipt of invoice.

(ii) Within twenty (20) days if reasonably possible for AstraZeneca using reasonable endeavors to meet such timeline and in no event later than twenty five (25) days after the end of each Calendar Quarter during the Development Sharing Period, and within fifteen (15) days if reasonably possible for FibroGen using reasonable endeavors to meet such timeline and in no event later than twenty (20) days after the end of each Calendar Quarter, the Party shall provide the other Party with a statement setting forth (A) the actual Development Costs incurred by such Party in such Calendar Quarter, (B) the Development Costs budgeted for activities conducted by such Party in such Calendar Quarter under the Development Plan, (C) the amount (if any) by which the actual costs differed from the budgeted costs, subject to the provisions on budget overages in Section 3.4(b), (the "Excess Spend"), (D) the amount carried over from the previous Calendar Quarters for which the Development Costs incurred by AstraZeneca were greater than the Development Costs incurred by FibroGen. As soon as practicable, and not later than within thirty two (32) days of the end of the Calendar Quarter, the Parties shall discuss and resolve any issues with respect to such statements and shall use best efforts to agree the amount owed from one Party to the other for Development Costs in such Calendar Quarter, so that each Party bears fifty percent (50%) of the Development Costs incurred (subject to Section 3.4(b)), provided, however that each Party shall generate any questions and respond to any inquiries regarding the invoices as promptly as reasonably possible following receipt, including within forty-eight (48) hours for response to ordinary inquiries. Following the reconciliation process for the applicable Calendar Quarter, and not later than thirty two (32) days of the end of the Calendar Quarter, each of FibroGen and AstraZeneca shall provide an invoice to the other Party reflecting fifty percent (50%) of their respective Development Costs incurred. Within forty five (45) days after its receipt of such invoice from FibroGen, if the amount invoiced by FibroGen to AstraZeneca is greater than the amount invoiced by AstraZeneca to FibroGen, then AstraZeneca shall pay FibroGen an amount equal the difference between the invoices, subject to the offset of outstanding Development Costs as detailed below in this Section 8.2(a)(ii). If during the Development Sharing Period and following the quarterly process set out above, FibroGen owes a payment to AstraZeneca, then no payment will be made by FibroGen, to AstraZeneca. Instead such amount, in aggregate with any other such amounts, will be carried forward by AstraZeneca and set off against any subsequent Development Cost payments owed by AstraZeneca to FibroGen under this Section 8.2. For clarity, Development Costs advanced or paid under this Section 8.2(a)(ii) do not include amounts incurred prior to August 1, 2013.

**(b) Prior to First NDA Approval after the Development Sharing Period.** The following procedure in this subsection (b) will apply prior to the first NDA approval for a Product and after the Development Sharing Period.

(i) No earlier than forty-five (45) days prior to the beginning of each Calendar Quarter after the Development Sharing Period, FibroGen shall submit to AstraZeneca an invoice for the Development Costs budgeted to be incurred by FibroGen to conduct its activities under the Development Plan in such Calendar Quarter, as adjusted for the Cost Difference as set forth in 8.2(b)(ii) below. AstraZeneca shall pay each such invoice within forty-five (45) days after the invoice date, subject to the offset of Development Cost provisions in Section 8.2(a).

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(ii) No later than twenty (20)) days after the end of each Calendar Quarter after the Development Sharing Period, FibroGen shall send to AstraZeneca a statement setting forth (i) the actual Development Costs incurred by FibroGen in such Calendar Quarter, (ii) the Development Costs budgeted for activities conducted by FibroGen in such Calendar Quarter in the Development Plan, (iii) the amount (if any) by which the actual costs differed from the budgeted costs and (iv) the difference between the amount advanced by AstraZeneca under this Section 8.2(b) and the Development Costs actually incurred, to the extent below [\*] percent [\*]%) of the budgeted amount (the "Cost Difference"). FibroGen shall adjust the invoice to be submitted to AstraZeneca under 8.2(b)(i) for the subsequent Calendar Quarter to account for the Cost Difference. Not later than within thirty two (32) days of the end of the Calendar Quarter, the Parties shall discuss and resolve any issues with respect to such statement and shall use best effort to agree the amount payable thereunder. If any items not material to FibroGen's financial statements remain outstanding at the end of the reconciliation and resolution process, the parties shall continue to work toward resolution by the end of following calendar quarter. Notwithstanding anything else set forth herein, if all amounts invoiced by FibroGen and settled under Section 8.2(a) exceed fifty per cent (50%) of the difference between the Development Costs incurred by AstraZeneca during the Development Sharing Period (subject to the provisions on budget overages in Section 3.4(b)), then any such excess may be credited by AstraZeneca against any subsequent Development Costs payments owed by AstraZeneca to FibroGen under this Section 8.2(c) and Section 8.2(c), or, in the event that the Development Costs incurred by FibroGen are no longer being incurred under this Agreement, antil fully used.

(c) Adjustment in Payment Schedule. At any time after January 1, 2015 and prior to the time at which ninety percent (90%) of the targeted enrollment in any CKD Indication Clinical Trials (conducted by FibroGen and for which FibroGen will be incurring Development Costs) has been achieved (the "Increased Advance Period"), upon request of FibroGen, the Parties shall discuss in good faith the upcoming spending plans for the Development Budget in which FibroGen reasonably anticipates that significant cost variances, such as those associated with patient enrollment rates or other reasonably unforeseen causes, may occur with respect to such CKD Indication Clinical Trials during the next Development Budget year and thereafter. The Parties shall agree upon the timing of the implementation of a further advance in any Calendar Quarter in an upcoming period during the Increased Advance Period: If FibroGen reasonably determines that anticipated spending in respect of such CKD Indication Clinical Trials such as enrollment rate is proceeding in a manner that the Development Costs for which advances have been received in a Calendar Quarter under Section 8.2(a) or (b) will likely be exceeded, then FibroGen shall notify the JSC of the basis for such anticipated overage and if such overage is anticipated to exceed by [\*] percent [\*]%) or more such budgeted amount, then FibroGen may invoice AstraZeneca prior to the end of the Calendar Quarter an amount it reasonably believes is necessary to cover such overage. AstraZeneca shall pay such amount within forty-five (45) days of invoice and any such amounts advanced under such invoice under this Section 8.2(c) shall be deducted from the subsequent payment under Section 8.2(a), (b) or (d).

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(d) Following First NDA Approval. The following procedure in this subsection (d) will apply after the first NDA approval for a Product, unless otherwise agreed by the JDC. Within thirty (30) days after the end of each Calendar Quarter in which FibroGen conducts activities under the Development Plan, FibroGen shall send to AstraZeneca an invoice for all Development Costs incurred by FibroGen in such Calendar Quarter, up to an amount equal to [\*] percent ([\*]%) of the budgeted amount for the applicable activities. AstraZeneca shall pay each such invoice within forty-five (45) days after receipt thereof.

(e) Annual Reconciliation. Within thirty (30) days after the end of each Calendar Year in which either Party conducts activities under the Development Plan, such Party shall send to the other Party a statement setting forth the Development Costs actually incurred by such Party and the budgeted amounts for all activities conducted by such Party under the Development Plan during such Calendar Year; provided that if no part of such Calendar Year was during the Development Sharing Period, or if only FibroGen is conducting Development activities, only FibroGen shall be required to provide such statement. FibroGen's statement will also include the Development Costs incurred by FibroGen and actually reimbursed by Astellas for such Calendar Year. If during the Development Sharing Period, such actual amount exceeds the budgeted amount (or amount otherwise approved by the JSC) by more than [\*] percent [\*]%) of the budgeted amount, then fifty percent (50%) of the excess (i.e., above [\*] percent [\*]%)) will be credited against or added to (depending on which Party incurred the excess) the subsequent payment from AstraZeneca to FibroGen under this Section 8.2. After the Development Sharing Period, if such actual amount (or amount otherwise approved by the JSC) by more than [\*] percent [\*]%) of the budgeted amount, the excess (i.e., above [\*] percent ([\*]%)) will be credited against the subsequent payment from AstraZeneca to FibroGen under this Section 8.2.

(f) RoW Activities. Within thirty (30) days after the end of each Calendar Quarter in which FibroGen conducts activities under the Development Plan for the RoW, FibroGen shall send to AstraZeneca an invoice for all costs incurred by FibroGen in such Calendar Quarter for such activities, including Personnel Costs, the Fully Burdened Cost of Collaboration Compound or Product or comparator drug, concomitant drug, placebo or other materials used in any Clinical Trial or Nonclinical Studies, and all other out-of-pocket costs. AstraZeneca shall pay each such invoice within forty-five (45) days after receipt thereof.

(g) Commercialization Cost. Within thirty (30) days after the end of each Calendar Quarter in which FibroGen conducts activities under the U.S. Commercialization Plan, FibroGen shall send to AstraZeneca an invoice for all Commercialization Costs incurred by FibroGen in such Calendar Quarter. AstraZeneca shall pay each such invoice within forty-five (45) days after receipt thereof.

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## 8.3 Development Milestone Payments.

(a) **Payments**. AstraZeneca shall make milestone payments to FibroGen based on achievement by AstraZeneca, its Affiliate or a Sublicensee (or, if applicable, by FibroGen) of the development and regulatory milestone events set forth in this Section 8.3(a) with respect to any indication other than an indication independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in.

Number	Milestone Event	Payment
1	This milestone event will be deemed achieved on the [*] after AstraZeneca's	
	receipt from FibroGen of the audited final report from the Carcinogenicity Studies,	
	[*].	\$ 15 million
2	[*]	<pre>\$[ * ] million</pre>
3	[*]	<pre>\$[ * ] million</pre>
4	[*]	<pre>\$[ * ] million</pre>
5	[*]	<pre>\$[ * ] million</pre>
6	[*]	<pre>\$[ * ] million</pre>
7	[*]	<pre>\$[ * ] million</pre>

# (b) Clarifications.

(i) With respect to the first milestone event in Section 8.3(a), if AstraZeneca [\*] within such thirty (30) day period, then (A) this milestone event will be [\*] and (B) this milestone event will be [\*].

(ii) Each milestone payment in Section 8.3(a) shall be paid only once, without regard to whether two or more Products ultimately achieve any such milestone event. For the purposes of milestone events no. 5, 6 and 7 in Section 8.3(a), the Parties agree that the [\*] shall be regarded as one and the same indication and thus not constitute [\*].

55.

(iii) The foregoing milestone events do not include events achieved by the Product for indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in.

(c) Notice; Payment. The applicable Party shall notify the other Party upon achievement of each milestone in Section 8.3(a). AstraZeneca shall pay to FibroGen the amounts set forth in Section 8.3(a) within forty-five (45) days after receipt by AstraZeneca of an invoice from FibroGen for the relevant amount, following the achievement of the applicable milestone event by AstraZeneca, its Affiliate or a Sublicensee (or, if applicable, by FibroGen). Each such payment shall be made by wire transfer of immediately available funds into an account designated by FibroGen. Each such payment is nonrefundable and non-creditable against any other payments due hereunder.

## 8.4 [ \* ] Milestone.

payment.

(a) Milestone. AstraZeneca shall pay a milestone to FibroGen in the amount of the discounted value of [\*])], discounted using ten percent (10%) annual compounding, applied from the Trigger Date to the Discount Date (each as defined below) (such value, the [\*] *Milestone*") following the first [\*] (meaning that – notwithstanding anything else set forth herein – AstraZeneca shall never be obligated to pay the Deferred Approval Milestone prior to the [\*]) as of the payment date determined in accordance with Section 8.4(b); provided that and notwithstanding anything else set forth below in this Section 8.4, if any of [\*]") on or before [\*]") then the [\*] Milestone will not be payable. The [\*] Milestone is nonrefundable and non-creditable against any payments due hereunder.

(b) Payment Date. If payable pursuant to Section 8.4(a), the [\*] Milestone will be due as follows:

(i) If all [\*], the "*Discount Date*" will be the date of first [\*], and the [\*] Milestone will be payable within forty-five (45) days thereafter, provided that there is then no [\*].

(ii) If [\*], the "*Discount Date*" will be January 1 of the Calendar Year following the Calendar Year in which [\*], and the [\*] Milestone will be payable on the Discount Date, provided that there is then no [\*].

(iii) If [\*], but if there is no [\*], then the [\*] Milestone (the full undiscounted amount of [\*] will be payable on the Trigger Date.

(iv) If any [\*], the Discount Date will be the later to occur of (a) the date of [\*] and (b) the first [\*], and the [\*] Milestone will be payable within forty-five (45) days after the Discount Date.

(v) At any time prior to the Trigger Date, AstraZeneca may elect to pay the [\*] Milestone, and the Discount Date will be the date of

## 56.

(c) Trigger Date. The "*Trigger Date*" means [\*], the date on which such [\*]. For example, if no [\*], the Trigger Date is [\*]. If a [\*], then the Trigger Date is [\*].

### 8.5 Sales Milestone Payments.

(a) U.S. Events. AstraZeneca shall make each of the sales milestone payments indicated below to FibroGen when aggregate Annual Net Sales of all Products across all indications in the U.S. (other than sales by FibroGen in indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in) first reach the Dollar values indicated below.

Aggregate Annual Net Sales in the U.S.	Payment
\$[ * ]	\$[ * ] million
\$[*]	\$[ * ] million
\$[*]	\$[ * ] million

Each milestone in this Section 8.5(a) shall be paid only once.

(b) Additional U.S. Milestones. AstraZeneca shall make each of the sales milestone payments indicated below to FibroGen when aggregate Annual Net Sales of Products in LDOs in the U.S. (other than sales by FibroGen in indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in) first reach the Dollar values indicated below in any Calendar Year from 2018-2022 (inclusive).

Aggregate Annual Net Sales to LDOs in the U.S.	Payment
\$[ * ]	\$[ * ] million
\$[*]	\$[ * ] million
\$[*]	\$[ * ] million

(c) RoW Events. AstraZeneca shall make each of the sales milestone payments indicated below to FibroGen when aggregate Annual Net Sales of all Products across all indications in the RoW (other than sales by FibroGen in indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in) first reach the Dollar values indicated below.

Aggregate Annual Net Sales in RoW	Payment
\$[ * ]	\$[ * ] million
\$[*]	\$[*] million

Each milestone in this Section 8.5(c) shall be paid only once.

57.

(d) Notice; Payment. AstraZeneca shall notify FibroGen of achievement of each of the milestone events in this Section 8.5 within forty-five (45) days after the end of the Calendar Quarter in which achieved. AstraZeneca will pay to FibroGen the amounts set forth in Sections 8.5(a), 8.5(b) and 8.5(c) within forty-five (45) days after AstraZeneca's receipt of an invoice from FibroGen following the end of the Calendar Quarter during which the applicable milestone event has been achieved. If more than one such milestone is achieved in any Calendar Quarter, then all applicable payments will be due. Each such payment shall be made by wire transfer of immediately available funds into an account designated by FibroGen. Each such payment is nonrefundable and non-creditable against any other payments due hereunder.

## 8.6 Royalties

(a) Royalty Rates. AstraZeneca shall pay to FibroGen non-refundable, non-creditable royalties on the amount of aggregate Annual Net Sales of each Product in the Territory as calculated by multiplying the applicable royalty rates set forth below by the corresponding amount of incremental aggregate Annual Net Sales in the Territory of such Product in such Calendar Year. For clarity, royalties are not due on sales of Products by FibroGen solely in indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in.

Aggregate Annual Net Sales (Per Product)	Royalty Rate
Portion less than \$[ * ]	[*]%
Portion greater than or equal to \$[ * ]	[*]%

By way of example, if the aggregate Annual Net Sales of a Product in the Territory in a particular Calendar Year is two billion five hundred million Dollars (\$2,500,000,000), the amount of royalties payable hereunder shall be as follows:

\$[*]	
\$[*]	
[*]	

58.

(b) Sales Subject to Royalties. Sales between AstraZeneca, its Affiliates and Sublicensees shall not be subject to royalties hereunder unless the purchaser is an end user. Royalties shall be calculated on AstraZeneca's, its Affiliates' and Sublicensees' sales of the Products to a Third Party, including Distributors (but excluding for the avoidance of doubt Sublicensees). Royalties shall be payable only once for any individual S.K.U. of a Product. For the purpose of determining Net Sales, the Product shall be deemed to be sold when invoiced and a "sale" shall not include, and no royalties shall be payable on, transfers by AstraZeneca, its Affiliates or Sublicensees of reasonable quantities of clinical trial materials, or other transfers or dispositions of reasonable quantities of Products for charitable, promotional, nonclinical, clinical, manufacturing, testing or qualification, regulatory or governmental purposes in compliance with this Agreement (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7).

(c) Generic Competition. If, in any country in the Territory, the Net Sales of any Product in any rolling four Calendar Quarter period following the first sale of a Generic Product to such Product in such country is less than [\*] of the Net Sales for such Product in such country in the immediately preceding four Calendar Quarter period, then the royalty rate for such Product in such country shall be reduced to [\*] that would otherwise have been applicable under Section 8.6(a) for Net Sales of such Product in such country. For clarity, if the Generic Product is barred or withdrawn from sale in such country and the Net Sales in such country in any rolling four Calendar Quarter period is greater than [\*] of the value for the rolling four quarter period prior to the first sale of a Generic Product, then the foregoing reduction shall no longer apply effective as of the Calendar Quarter in which the Generic Product is barred or withdrawn from sale. The calculation of the royalty reduction under this Section 8.6(c) shall be conducted separately for each Product in each country. By way of example, if during the first Calendar Quarter of a particular Calendar Year in which the foregoing reduction applies are one billion five hundred million Dollars (\$1,500,000,000), and the Net Sales in such Calendar Quarter in a country in which the foregoing royalty reduction does not apply are one billion Dollars (\$1,000,000,000), the following shall apply with respect to the royalty payment owed for such Calendar Quarter: The royalty payment without regard to the reduced rate would be [\*].

(d) Compulsory Licenses. If a court or a governmental agency of competent jurisdiction requires AstraZeneca or its Affiliate or Sublicensee to grant a compulsory license to a Third Party and if as a result of the compulsory license the Net Sales of such Product in any rolling four Calendar Quarter period following the first grant of such compulsory license in such country is less than [\*] of the Net Sales for such Product in such country in the immediately preceding four Calendar Quarter period, then the royalty rate for such Product in such country. For clarity, to the extent that the compulsory licenses in the relevant country are duly terminated or expire in such country and the Net Sales in such country in any rolling four Calendar Quarter period is greater than [\*] of the value for the rolling four quarter period prior to the first grant of the compulsory license in such country, then the foregoing reduction shall no longer apply effective as of the Calendar Quarter in which the compulsory license is terminated or expires. The calculation of the royalty reduction under this Section 8.6(e) shall be conducted separately for each Product in each country.

59.

(e) Order of Royalty Reduction and Royalty Floor. Any reductions set forth in Sections 8.6(c), 8.6(d) and 8.8(c) shall be applied in the order in which the event triggering such reduction occurs, provided that in no event shall, due to the cumulative reductions set out in Sections 8.6(c) and 8.6(d), the royalty that would otherwise have been payable to FibroGen under this Section 8.6 in a particular Calendar Quarter be reduced below [\*]) of the royalty set forth in Section 8.6(a).

(f) Royalty Term. AstraZeneca's obligation to pay royalties due under this Section 8.6 with respect to a particular Product in each country in the Territory will commence upon the First Commercial Sale of such Product in such country and will be payable for so long as such Product is sold in such country by AstraZeneca or its Affiliate or Sublicensee.

(g) Royalty Payments and Reports. All amounts payable to FibroGen pursuant to this Section 8.6 shall be paid in Dollars within forty-five (45) days after the end of each Calendar Quarter with respect to Net Sales in such Calendar Quarter. Each payment of royalties due to FibroGen shall be accompanied by a statement, on a country-by-country basis, of the amount of gross sales of Products in the Territory during the applicable Calendar Quarter, a calculation of Net Sales in the Territory showing the aggregate deductions from gross sales provided for in the definition of Net Sales during such Calendar Quarter, and a calculation of the amount of royalty payment due on such sales for such Calendar Quarter. For the avoidance of doubt, FibroGen acknowledges and agrees that each statement provided by AstraZeneca under this Section 8.6(g) shall constitute Confidential Information of AstraZeneca and FibroGen shall comply with its confidentiality and non-use obligations in respect of such statements as set forth in Article 12.

(h) Clarification. AstraZeneca acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to AstraZeneca of certain elements of, the FibroGen Technology pursuant to this Agreement, as well as from AstraZeneca's own development of inventions derived from the practice of such license and AstraZeneca's use of such FibroGen Technology, even after the expiration of all FibroGen Patents claiming the Product in a particular country in which Products are sold. In addition, AstraZeneca acknowledges that the application of a uniform royalty structure during the sale of Products is more convenient to the Parties, facilitates payments, and reduces accounting burdens on the Parties, as compared with a payment structure dependent on the expiration of FibroGen Patents.

**8.7 FibroGen IPO.** AstraZeneca shall make a one-time, non-refundable, non-creditable payment of [\*] to FibroGen upon a FibroGen IPO; provided that (a) if such IPO has not occurred prior to December 1, 2015, AstraZeneca will make such payment on December 15, 2015, and (b) if the Parties agree upon terms (and FibroGen undertakes, upon AstraZeneca's request, to negotiate such terms in good faith), including a lock-up and standstill agreement (subject to maximum ownership of [\*]%), then in lieu of such payment, AstraZeneca will make a [\*] equity investment in FibroGen at the initial public offering price simultaneous with the closing of a FibroGen IPO.

60.

## 8.8 Third Party Intellectual Property.

(a) DFCI Agreement. FibroGen shall be solely responsible for all payments to DFCI under the DFCI Agreement.

(b) Right to Obtain License. If either Party desires to obtain a license under any Third Party's intellectual property in connection with the Development and Commercialization of Products, such Party will notify the other Party. FibroGen will have the first right (but not the obligation) to obtain such license. If FibroGen elects not to obtain such license, or is unsuccessful in doing so, then AstraZeneca will have the right (but not the obligation) to negotiate and obtain such license at its sole discretion and expense (but subject to Section 8.8(c)). The negotiating Party will obtain such license, with the right to sublicense, in order to permit AstraZeneca to exercise its rights and to perform its obligations under this Agreement. Subject to the foregoing, the terms and conditions involved in obtaining such license shall be determined at such negotiating Party's sole discretion.

(c) AstraZeneca Obtains License. In the event AstraZeneca obtains a license under any Third Party patents that claim the composition of matter, formulation (to the extent AstraZeneca is performing any formulation activities, which activities it may perform only with FibroGen's prior written consent), method of treatment or other use of a Collaboration Compound or Product, AstraZeneca shall provide to FibroGen a copy thereof and shall have the right to offset, against royalties payable to FibroGen under Section 8.6 for the applicable Product, [\*] actually paid by AstraZeneca to such Third Party under such license for the sale of the applicable Product in the applicable country and Calendar Quarter; provided that the royalties payable to FibroGen for any Product in any Calendar Quarter under Section 8.6 may not be reduced by more than [\*] of those otherwise due to FibroGen under Section 8.6(a) in any Calendar Quarter for such Product as a result of such offset and other reductions under Section 8.6. Except as provided above in this subsection (c), AstraZeneca will be solely responsible for all amounts owed by AstraZeneca or its Affiliates to Third Parties under a license to intellectual property on account of AstraZeneca's or its Affiliates' manufacture, use, sale, offer for sale, or import of Products.

(d) FibroGen Obtains License. Except as provided in subsection (a) above, the FibroGen Technology licensed to AstraZeneca in this Agreement will include patents, patent applications and Information licensed to FibroGen by a Third Party if (i) AstraZeneca assumes [\*] of all payment obligations under such license agreement to the extent arising out of the use, Development or manufacture of any Product or Commercialization of any Product by or on behalf of AstraZeneca in the Territory, as well as all other obligations of such license agreement that are applicable to AstraZeneca, and (ii) AstraZeneca acknowledges in writing that its sublicense under such license agreement is subject to the terms and conditions of such license agreement. If any such payments are not allocated among countries, the Parties shall reasonably allocate such payments to within and outside the Territory in good faith.

61.

### 8.9 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement.

(b) Withholding Tax. The Party making payments under this Agreement (the "*Payor*") to the other Party (the "*Payee*") shall deduct or withhold from the payments any Taxes that it is required by applicable law to deduct or withhold. The Payee shall provide the Payor any tax forms or appropriate governmental authorization that may be reasonably necessary in order for Payor to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. The Payee shall use reasonable efforts to provide any such tax forms to the Payor at least thirty (30) days prior to the due date for any payment for which the Payee desires that Payor apply a reduced withholding rate and in any event at least fifteen (15) days prior to the time the applicable payment is due. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable laws and regulations, of withholding taxes, Indirect Taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or Indirect Taxes.

(c) Payment of Tax. To the extent the Payor is required by applicable law or regulations to deduct and withhold taxes on any payment to the Payee, the Payor shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the Payee an official tax certificate or other evidence of such withholding sufficient to enable the Payee to claim such payment of taxes.

(d) Indirect Tax. All payments to be made by one Party to another Party, pursuant to the terms of this Agreement, are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of such payments, the Party making shall payment shall pay such Indirect Taxes at the applicable rate following the receipt where applicable of an Indirect Taxes invoice in the appropriate form issued. Each Party shall issue valid invoices for all amounts payable under this Agreement consistent with all applicable laws and irrespective of whether such amounts may be netted for settlement purposes. The Parties shall cooperate in accordance with applicable law to minimize Indirect Taxes.

(e) Imports. For the avoidance of doubt, the Parties acknowledge and agree that none of the upfront payments, milestone payments or royalties payable under this Agreement are related to the license (or right) to import or any import of Products. The Parties shall cooperate to ensure that the Party responsible for shipping values Product in accordance with applicable laws and maximizes the full benefits of available duty free or savings programs and minimizes where permissible any such duties and any related import taxes that are not reclaimable from the relevant authorities. The receiving Party shall be responsible for any import clearance, including payment of any import duties and similar charges, in connection with any Products transferred to such Party under this Agreement.

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**8.10 Blocked Currency.** In each country where the local currency is blocked and cannot be removed from the country, royalties accrued on Net Sales in that country shall be paid to FibroGen in the equivalent amount in Dollars.

**8.11 Foreign Exchange.** Conversion of sales or expenses recorded in local currencies to Dollars will be performed in a manner consistent with each Party's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates.

**8.12 Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to the U.S. Prime Rate for the date payment was due as reported by the *Wall Street Journal*.

#### 8.13 Financial Records; Audits.

(a) Records. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the amount to be reimbursed, pursuant to Section 8.2, with respect to Development Costs or Commercialization Costs or other amounts to be reimbursed or shared hereunder incurred or generated (as applicable) by such Party, achievement of sales milestones, royalty payments and other compensation payable under this Agreement. Each Party shall keep or cause its Affiliates to keep such records for a period of the later of (a) six (6) years after the end of the period to which such books, records and accounts pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by applicable law. Each Party shall maintain such records at its principal place of business or the principal place of business of the appropriate division of such Party to which this Agreement relates.

(b) Procedure. Upon reasonable prior notice, such records shall be open during regular business hours for a period of three (3) years from the creation of individual records, in each case, for examination at the auditing Party's expense, and not more often than once each Calendar Year, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party (or in the case of audits of AstraZeneca, by DFCI under the terms of Section 4.2.2 of the DFCI Agreement) for the sole purpose of verifying for the auditing Party the accuracy of the financial reports or sales milestone notices furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party to the other pursuant to this Agreement. Any such auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party under this Agreement. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, shall be paid or refunded (as the case may be) within thirty (30) days after the accountant's report, plus interest (as set forth in Section 8.12) from the original due date (unless challenged in good faith by the audited Party in which case any dispute with respect thereto shall be resolved in accordance with Article 14). The auditing Party shall bear the full cost of such audit unless such audit reveals an overcharge or underpayment by the audited Party that resulted from a discrepancy in a report that the audited Party provided to the other Party during the applicable audit period, which underpayment or overcharge was more than five percent (5%) of the amount set forth in such report, in which case the audited Party shall bear the full cost of such audit.

63.

(c) Audit Dispute. In the event of a dispute with respect to any audit under Section 8.13(b), FibroGen and AstraZeneca shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to an independent certified public accounting firm jointly selected by each Party's certified public accountants or to such other entity or individual as the Parties shall mutually agree (the "Auditor"). The decision of the Auditor shall be final and the costs of such resolution as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than ten (10) days after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.12 or the auditing Party shall reimburse the excess payments, as applicable.

**8.14 Manner and Place of Payment.** All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by FibroGen or AstraZeneca (as applicable), unless otherwise specified in writing by such Party. All payments hereunder shall be invoiced by the Payee to the Payor. Each invoice to AstraZeneca shall fulfill the requirements set forth on **Exhibit L**.

**8.15 Estimated Sales and Accruals**. To the extent Net Sales are based on quarterly estimates or accruals for anticipated sales of Products in the Territory, AstraZeneca shall notify FibroGen of any such estimates or accruals or adjustments or changes based on a revision in estimates and accruals within thirty (30) days of each Calendar Quarter in order to allow FibroGen to timely meet any then applicable public reporting requirements of FibroGen with respect to sales and royalties to FibroGen for Products.

## **ARTICLE 9**

#### INTELLECTUAL PROPERTY

**9.1 Intellectual Property Committee.** The Parties shall, promptly after the Effective Date, establish an intellectual property committee (the "*IP Committee*") comprised of at least one senior patent attorney from each Party, together with other representatives of the Parties as the Parties may determine to be appropriate from time to time, to review and discuss, in each case with respect to FibroGen Patents and Joint Patents, the patent prosecution strategy (including whether and where to file patent applications), Orange Book Listings, applications for patent term extension and notices of infringement, as well as the selection, registration, maintenance and defense of Marks and interest in Third Party intellectual property. The IP Committee will serve solely an advisory purpose and shall not have authority to approve or disapprove any actions with respect to patent filing, prosecution and maintenance under this Agreement.

64.

**9.2 Ownership of Inventions.** Ownership of Information and inventions, whether or not patentable, made during the Term in the course of conducting activities under this Agreement, including all intellectual property rights therein (collectively, "*Inventions*") shall be as follows: (a) FibroGen shall own all Inventions [\*], whether made solely by employees, agents or independent contractors of either Party or its respective Affiliates, or jointly by employees, agents or independent contractors of both Parties or their respective Affiliates (collectively, "*Collaboration Inventions*"), (b) AstraZeneca shall own all Inventions that are made solely by employees, agents or independent contractors of AstraZeneca or its Affiliates that are not Collaboration Inventions, (c) FibroGen shall own all Inventions that are made solely by employees, agents or independent contractors of FibroGen or its Affiliates that are not Collaboration Inventions, and (d) the Parties shall jointly own all Inventions that are made jointly by employees, agents, or independent contractors of each Party or its Affiliates that are not Collaboration Inventions ("*Joint Inventions*"). Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, grant licenses to, assign and exploit the Joint Inventions and Patents claiming Joint Inventions ("*Joint Patents*") without the duty of accounting or seeking consent from the other Party. AstraZeneca hereby assigns to FibroGen to evidence such assignment, except where such Collaboration Inventions have been made by an independent contractor retained by AstraZeneca without such contractor having agreed to assign such Collaboration Inventions to AstraZeneca, as approved by the JDC.

**9.3 Disclosure of Inventions.** Each Party shall promptly disclose to the other all Inventions promptly after becoming aware of them, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', employees, agents or independent contractors describing such Inventions. Such Party shall also respond promptly to reasonable requests from the other Party for more Information relating to such Inventions.

## 9.4 Prosecution of Patents.

(a) FibroGen Patents. Except as otherwise provided in this Section 9.4(a), as between the Parties, FibroGen shall have the sole right and authority to manage all FibroGen Patent prosecution activities under this Agreement, at its sole expense. This includes the right and authority to prepare, file, prosecute and maintain all FibroGen Patents in any jurisdiction in the world, including defending such FibroGen Patents in any patent office proceedings, preor post-grant or issuance, including reissue, reexamination, limitation or invalidation proceedings, or any opposition- or interference-type proceeding or challenge. FibroGen shall provide AstraZeneca reasonable opportunity to review and comment on filing and prosecution efforts regarding the FibroGen Patents in the Territory. FibroGen shall, if requested by AstraZeneca, provide AstraZeneca with copies of material communications from any patent authority in the Territory regarding any FibroGen Patents, and shall if requested provide drafts of any material filings or material responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses so that AstraZeneca may have the opportunity to review and comment thereon. FibroGen shall further take into account and may include, at FibroGen's sole discretion, any reasonable comments provided by AstraZeneca prior to submission of any such filings or responses.

65.

(b) Requested Filings. If AstraZeneca desires FibroGen to file, in a particular jurisdiction in the Territory, a FibroGen Patent that claims priority to (or is based on the subject matter of) another FibroGen Patent, or that claims a Collaboration Invention, AstraZeneca shall provide written notice to FibroGen requesting that FibroGen file such patent application in such jurisdiction. If AstraZeneca provides such written notice to FibroGen shall file and prosecute such patent application and maintain any patent issuing thereon in such jurisdiction; provided that FibroGen shall not be obligated to conduct any such activities (including filing a patent application) that FibroGen reasonably believes may have an adverse effect on the FibroGen Patents anywhere in the Territory.

(c) Joint Patents. With respect to any potentially patentable Joint Invention, AstraZeneca shall have the first right, but not the obligation, to prepare patent applications based on such Joint Invention, to file and prosecute (including defense of any oppositions, interferences, reissue proceedings and reexaminations) such patent applications, and to maintain any Joint Patents issuing therefrom, in any jurisdictions throughout the Territory. FibroGen shall have the corresponding first right, but not the obligation, in any jurisdictions outside of the Territory other than China, in respect of which the China Agreement shall govern. If AstraZeneca determines in its sole discretion to abandon, cease prosecution or otherwise not file or maintain any Joint Patent anywhere in the Territory, then AstraZeneca shall provide FibroGen written notice of such determination at least thirty (30) days before any deadline for taking action to avoid abandonment (or other loss of rights) and shall provide FibroGen with the opportunity to prepare, file, prosecute and maintain such Joint Patent. The Party that is responsible for preparing, filing, prosecuting, and maintaining a particular Joint Patent (the "Prosecuting Party") shall provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding such Joint Patent, and such other Party shall provide the Prosecuting Party reasonable assistance in such efforts. The Prosecuting Party shall provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, each Party agrees to provide the other Party with all information necessary or desirable to enable the other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case: (i) the disclaiming Party shall, if requested in writing by the other Party, assign its ownership interest in such Joint Patent in such country or jurisdiction to the other Party for no additional consideration; and (ii) if such assignment is effected, any such Joint Patent would thereafter be deemed a FibroGen Patent in the case of assignment to FibroGen, or a AstraZeneca Patent in the case of assignment to AstraZeneca; provided, however, that the disclaiming party would have an immunity from suit under such FibroGen Patent or AstraZeneca Patent, as the case may be, in the applicable country or jurisdiction. In addition, any Joint Patent that becomes a FibroGen Patent pursuant to the preceding sentence shall be excluded from the license granted to AstraZeneca in Section 7.1. Each Party shall bear its own internal costs in respect of the prosecution of Joint Patents. Out-of-pocket costs incurred in respect of the prosecution and maintenance of Joint Patents in the Territory shall be borne equally by AstraZeneca and FibroGen. In the event a Party elects to disclaim its interest in a Joint Patent, the costs incurred with respect to such Patent after the date of such disclaimer shall thereafter be borne exclusively by the other Party, without reimbursement or credit.

66.

(d) Cooperation in Prosecution. Each Party shall, through the IP Committee, provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 9.4, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

### 9.5 Infringement of FibroGen Patents by Third Parties.

## (a) Notification.

(i) Within five (5) Business Days from (A) a Party's or its Affiliate's receipt of any notice of any certification filed under the U.S. "Drug Price Competition and Patent Term Restoration Act" of 1984 as amended or supplemented or any successor law or (B) a Party's or its Affiliate's receipt of any notice of any certification filed under Section 505(j) of the FD&C Act or an application under Section 505(b)(2) of the FD&C Act naming a Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV) or 505(b)(2)(A)(iv), respectively or (C) any equivalent proceeding in any country in RoW (each of (A), (B) and (C), a "*Product Infringement*") such Party shall notify the other Party thereof in writing.

(ii) If there is any infringement, threatened infringement, imminent infringement or alleged infringement of any FibroGen Patent on account of a Third Party's manufacture, use, offer for sale, or sale of a Collaboration Compound or Product in the Territory not within Section 9.5(a)(i) ("*Other Infringement*") then each Party shall promptly notify the other Party in writing of any such Other Infringement of which it becomes aware, and shall provide evidence in such Party's possession demonstrating such Other Infringement.

### (b) Enforcement Rights.

(i) RoW Litigation. AstraZeneca shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity allegedly engaged in any Product Infringement or Other Infringement of the FibroGen Patents in the RoW (and to defend any related counterclaim), at AstraZeneca's expense. AstraZeneca shall have a period of one hundred eighty (180) days after its receipt or delivery of notice and evidence pursuant to Section 9.5(a)(i), to elect to so enforce such FibroGen Patent in the RoW (or to settle in accordance with Section 9.5(c) or otherwise secure the abatement of such Product Infringement or Other Infringement). In the event AstraZeneca does not so elect (or settle or otherwise secure the abatement of such Product Infringement or Other Infringement), it shall so notify FibroGen in writing as soon as practicable following the decision and in any event within such one hundred eighty (180)-day period, and FibroGen shall have the right to commence a suit or take action to enforce the applicable FibroGen Patents with respect to such Product Infringement or Other Infringement in the RoW (and to defend any related counterclaim) at FibroGen's expense. The IP Committee shall take the necessary actions to ensure that AstraZeneca has proper standing to bring suit under this Section 9.5(b)(i).

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(ii) U.S. Litigation. AstraZeneca shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity allegedly engaged in any Product Infringement or Other Infringement of the FibroGen Patents in the U.S. (and to defend any related counterclaim), at AstraZeneca's expense. AstraZeneca shall have a period of thirty (30) days, with respect to a Product Infringement, and one hundred eighty (180) days with respect to an Other Infringement, after its receipt or delivery of notice and evidence pursuant to Section 9.5(a)(i), to elect to so enforce such FibroGen Patent in the U.S. (or to settle in accordance with Section 9.5(c) or otherwise secure the abatement of such Product Infringement or Other Infringement). The Parties shall meet periodically to discuss in good faith and determine an enforcement strategy, and AstraZeneca shall act consistently with any such agreed strategy. In the event AstraZeneca does not so elect (or settle or otherwise secure the abatement of such Product Infringement or Other Infringement), it shall so notify FibroGen in writing as soon as practicable following the decision and in any event within such thirty (30)- or one hundred eighty (180)-day period, as applicable, and FibroGen shall have the right to commence a suit or take action to enforce the applicable FibroGen Patents with respect to such Product Infringement or Other Infringement in the U.S. (and to defend any related counterclaim), at FibroGen's expense. The IP Committee shall take the necessary actions to ensure that AstraZeneca has proper standing to bring suit under this Section 9.5(b)(ii).

(iii) Cooperation. In any action, suit or proceeding instituted under this Section 9.5(b), the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join such action, suit or proceeding and shall be represented using counsel of its own choice, at the requesting Party's expense. If a Party with the right to initiate legal proceedings under this Section 9.5(b) lacks standing to do so and the other Party has standing to initiate such legal proceedings, then the Party with standing shall initiate such legal proceedings at the request and expense of the other Party (including reasonable internal personnel costs at the Hourly Rate).

(c) Settlement. Without the prior written consent of the other Party, neither Party shall settle any claim, suit or action that it brought under Section 9.5(b) involving FibroGen Patents in any manner that would negatively impact such intellectual property or that would limit or restrict the ability of either Party to sell Products anywhere in or outside the Territory.

(d) Recoveries. If either Party recovers monetary damages from a Third Party in a suit or action in respect of a Product Infringement or Other Infringement, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation and any remaining amount shall be deemed Net Sales and retained by (or paid to) AstraZeneca, subject to royalty payments on such deemed Net Sales pursuant to Section 8.6.

(e) Designated Products. Notwithstanding anything to the contrary in this Agreement:

(i) FibroGen shall have the sole right to enforce the FibroGen Patents against any of the Designated Products ("*Designated Product Infringement*"), and AstraZeneca shall be solely responsible for all expenses reasonably incurred in connection therewith and subject further to (ii) below. FibroGen will invoice AstraZeneca for its share of such expenses on a Calendar Quarter basis (including its internal personnel costs at the Hourly Rate), and AstraZeneca will pay each such invoice within forty-five (45) days after receipt thereof.

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(ii) Notwithstanding (i) above, (A) in no event shall [\*]; provided that in Calendar Years 2018, 2019 and 2020, AstraZeneca shall not be obligated to [\*], except that if AstraZeneca reimburses [\*] (the "*Deficit*"), the [\*] (see example below); (B) in enforcing the FibroGen Patents against any of the Designated Products, the Parties shall unanimously select outside counsel to represent FibroGen in such enforcement proceedings (failing such unanimous agreement AstraZeneca shall be [\*] (C) FibroGen shall, at all times, keep AstraZeneca reasonably informed regarding such enforcement proceedings and shall take into account any good faith comments made by AstraZeneca relating to such enforcement proceedings; and (D) FibroGen shall provide AstraZeneca with reasonably sufficient information regarding such enforcement proceedings to demonstrate that any such proceedings have a good faith basis and are brought and maintained in good faith. By way of example of clause (A), [\*].

(f) Non-Product-Related Infringements. As between the Parties, FibroGen shall have the sole right to enforce the FibroGen Patents in the Territory against any infringement, imminent infringement, threatened infringement or alleged infringement that is not a Product Infringement, a Designated Product Infringement or an Other Infringement, at its expense, and to retain all associated recoveries; provided that in no event will FibroGen place an Orange Book-listed FibroGen Patent (or a FibroGen Patent listed on a Form 3542 submitted in accordance with Section 9.12 upon or after approval of the NDA as a timely filed patent) into litigation without AstraZeneca's prior written approval, which approval will not be unreasonably withheld.

(g) Joint Patents. Each Party shall promptly notify the other Party upon becoming aware of any infringement, imminent infringement, threatened infringement or alleged infringement of any Joint Patent (*"Joint Patent Infringement"*). The Parties will promptly thereafter meet to discuss in good faith how and whether to proceed to enforce the applicable Joint Patent against such Joint Patent Infringement. If the Parties fail to agree within sixty (60) days, then either Party shall have the right to take any action permitted under applicable law.

(h) Patents Licensed from Third Parties. Each Party's rights under this Section 9.5 with respect to any FibroGen Patent licensed from a Third Party shall be subject to the rights of such Third Party to enforce such FibroGen Patent and/or defend against any claims that such FibroGen Patent is invalid or unenforceable.

**9.6 Defense of FibroGen Patents**. To the extent any Party receives notice by counterclaim, or otherwise, alleging the invalidity or unenforceability of any FibroGen Patent in the Territory, it shall bring such fact to the attention of the other Party, including all relevant information related to such claim. The Parties, through the JSC, shall discuss such claim. Where such allegation is made within the context of a patent office proceeding, the provisions of Section 9.4 shall apply. Where such allegation is made in a counterclaim to or in connection with a suit or other action brought under Section 9.5, the provisions of Section 9.5 shall apply. In all other cases, (a) where such action relates to a FibroGen Patent in the U.S., FibroGen shall have the first right to defend such action, at FibroGen's expense, and AstraZeneca will cooperate with FibroGen, at FibroGen's expense, in such defense, and (b) where such action relates to a FibroGen Patent within

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the RoW, AstraZeneca shall have the first right but not the obligation to defend such action, at AstraZeneca's expense, and FibroGen will cooperate with AstraZeneca, at AstraZeneca's expense, in such defense. In the event a Party does not so elect to exercise its first right to defend an action under this Section 9.6, it shall so notify the other Party in writing, and such other Party shall have the right to so defend such action at its expense. Each Party shall provide to the Party defending any such rights under this Section 9.6 all reasonable assistance in such enforcement, at such defending Party's request and expense. The defending Party shall keep the other Party regularly informed of the status and progress of such efforts, and shall reasonably consider the other Party's comments on any such efforts.

**9.7 Third Party Patents**. FibroGen shall have the sole right and authority to initiate and/or pursue at its sole expense any patent office proceeding, preor post-grant or issuance, including reissue, reexamination, limitation, or invalidation proceedings, or any opposition- or interference-type proceeding or challenge against any Third Party Patent that relates or that may potentially relate to the manufacture, use, or sale of a HIF Compound, a Product, or a Designated Product.

**9.8 Defense of Infringement Actions.** During the Term, each Party shall bring to the attention of the other Party all information regarding potential infringement or any claim of infringement of Third Party intellectual property rights in connection with the development, manufacture, production, use, importation, offer for sale, or sale of Products in the Territory. Subject to Article 11, each Party shall be solely responsible at its sole expense for defending any action, suit, or other proceeding brought against it alleging infringement of Third Party intellectual property rights in connection with its activities under this Agreement. This Section 9.8 shall not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.

**9.9 Patent Marking**. AstraZeneca shall, and shall require its Affiliates and Sublicensees to, mark Products sold by it hereunder (in a reasonable manner consistent with industry custom and practice) with appropriate patent numbers or indicia to the extent permitted by applicable law and regulations, in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements of patents. The Parties agree that listing the appropriate Patent(s) in the Orange Book shall be deemed a marking in a reasonable manner consistent with industry custom and practice under this Section 9.9, and FibroGen agrees to use good faith efforts to obtain, as soon as reasonably practicable after the Effective Date, a written confirmation from DFCI that DFCI so agrees.

**9.10 Personnel Obligations.** Prior to beginning work under this Agreement relating to any research, Development or Commercialization of a Collaboration Compound or a Product, to HIF or in the Field, each employee, agent or independent contractor of AstraZeneca or FibroGen or of either Party's respective Affiliates shall be bound by non-disclosure and invention assignment obligations which are consistent with the obligations of AstraZeneca or FibroGen, as appropriate, in this Article 9, including without limitation: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to AstraZeneca or FibroGen, as appropriate, all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property right, such that AstraZeneca or FibroGen, as appropriate, can then

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comply with its obligations under this Agreement with respect to such invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any patent and patent application; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) abiding by the obligations of confidentiality and non-use set forth in Article 12. It is understood and agreed that such non-disclosure and invention assignment agreement need not reference or be specific to this Agreement.

**9.11 Trademarks.** The Parties shall use Commercially Reasonable Efforts to develop a worldwide trademark, and if not possible, trademark for the Territory consistent with the trademarks for Products selected under the Astellas Collaboration. AstraZeneca, following discussion with FibroGen, shall be responsible for the selection, registration, ownership, maintenance and defense of all trademarks for use in connection with the sale or marketing of Products in the Field in the Territory (the "*Marks*"), as well as all expenses associated therewith. All uses of the Marks shall be reviewed by the JCC and shall comply with all applicable laws and regulations (including those laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries). Neither Party shall, without the other Party's prior written consent, use any trademarks or house marks of the other Party (including the other Party's corporate name), or marks confusingly similar thereto, in connection with such Party's marketing or promotion of Products under this Agreement, except as may be expressly authorized in connection with activities under Article 5 and except to the extent required to comply with applicable laws and regulations. During the Term, AstraZeneca grants to FibroGen the non-exclusive right, free of charge, to use the AstraZeneca name and logo in the U.S. solely for the purpose of Commercializing the Products in accordance with the terms of this Agreement, the U.S. Commercialization Plan and the Co-Commercialization Agreement, and FibroGen grants to AstraZeneca the non-exclusive right, free of charge, to use the FibroGen name and logo in the U.S. solely for the purpose of Commercializing the Products in accordance with the terms of this Agreement, provided that such rights shall be exercised, and all Products bearing such names and/or logos shall be manufactured, in accordance with the quality standards for such logos and trademarks established by the JSC. AstraZeneca shall remain the owne

**9.12 Listing.** Prior to the submission of the first NDA of a Product in the U.S., the Parties shall discuss in good faith in the IP Committee the Orange Book listings. FibroGen shall be responsible for the submission of documents associated with Orange Book listings in accordance with the plan set forth by the IP Committee. Upon FibroGen's receipt of a notice of allowance (or equivalent) of an applicable FibroGen Patent, FibroGen shall promptly provide AstraZeneca notification of such allowance and the Parties shall discuss in good faith in the IP Committee whether to list such FibroGen Patent in the Orange Book maintained by the FDA or similar or equivalent patent listing source, if any, in other countries in the Territory. FibroGen shall cooperate with AstraZeneca's reasonable requests in connection therewith, including meeting any submission deadlines.

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**9.13 Patent Term Extension.** AstraZeneca shall be responsible for and control, but shall confer with FibroGen in, the selection of the appropriate FibroGen Patents as listed in the patent information section of the NDA or MAA for Products for filing to obtain a Patent Term Extension pursuant to all applicable laws, including without limitation any other extensions that are now or become available in the future wherever applicable to such patents that are applicable to the Products; provided, however, that AstraZeneca shall not have the right to make any such filing with respect to any FibroGen Patent that is not set forth on **Exhibit M** without the prior written consent of FibroGen.

## **ARTICLE 10**

#### **REPRESENTATIONS AND WARRANTIES**

**10.1 Mutual Representations and Warranties.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) No Conflict. It is not a party to and will not enter into any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.

(d) No Debarment. In the course of the Development of Products, such Party has not used prior to the Effective Date and shall not use, during the Term, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

10.2 Representations and Warranties by FibroGen. FibroGen hereby represents and warrants to AstraZeneca, as of the Effective Date, as follows:

(a) Title; Encumbrances. Except for the Patents licensed to FibroGen under the DFCI Agreement and the Information licensed to FibroGen under the Astellas Agreements, FibroGen is the sole and exclusive owner of the entire right, title and interest in (a) the Listed

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Patents and (b) the FibroGen Know-How existing as of the Effective Date. FibroGen has all rights necessary to grant the licenses under the FibroGen Technology that it grants to AstraZeneca under this Agreement. Neither the Listed Patents nor the FibroGen Know-How is subject to any mortgage, pledge, lien, security interest, conditional and installment sale agreements, encumbrance or charges or claims of any kind.

(b) No Other Patents than those Listed. The Listed Patents represent all Patents that, as of the Effective Date, are Controlled by FibroGen and which, to FibroGen's knowledge, cover or claim any invention necessary or useful for the Development or Commercialization of Collaboration Compounds or Products in the Field in the Territory as contemplated as of the Effective Date.

(c) Prosecution of Patents etc. To FibroGen's knowledge, the Listed Patents are being diligently prosecuted before the respective patent authorities in accordance with applicable law. All applicable fees due to patent authorities with respect to the filing and prosecution of the Listed Patents existing as of the Effective Date have been paid on or before the due date for payment (as such due date may be extended in accordance with applicable laws or patent authority rules and regulations). FibroGen has not received any written notice alleging that the Listed Patents existing as of the Effective Date, if issued, would be invalid or unenforceable or that the Patent applications included in such Listed Patents will not proceed to grant. To FibroGen's knowledge, in respect of any pending U.S. patent applications included in the Listed Patents, FibroGen has submitted all material prior art of which it is aware in accordance with the requirements of the United States Patent and Trademark Office. To its knowledge, FibroGen has properly identified each and every inventor of the claims of the Listed Patents existing as of the Effective Date.

(d) No Infringement or Misappropriation. FibroGen has not received any written notice from any Third Party asserting or alleging that any research or development of Collaboration Compounds or Products by FibroGen or by Astellas prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party and FibroGen has no reason to suspect that any such infringement or misappropriation has occurred. To FibroGen's knowledge, the conception, development and reduction to practice of the Listed Patents and FibroGen Know-How existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other proprietary rights of any person or entity.

(e) Non-infringement of Third Party Rights. To FibroGen's knowledge, the research, development, manufacture, use and sale after the Effective Date of FG-4592 in the CKD Indications can be carried out in the manner reasonably contemplated as of the Effective Date without infringing any published patent applications or patents owned or controlled by a Third Party.

(f) No Proceedings. There are no pending actions, suits or proceedings against FibroGen or any of its Affiliates involving the FibroGen Technology, Collaboration Compounds or Products.

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(g) Third Party Activities. To FibroGen's knowledge, except as disclosed in a writing of even date herewith by FibroGen to AstraZeneca, there are no activities by Third Parties that would constitute infringement or misappropriation of the FibroGen Technology (in the case of pending claims, evaluating them as if issued).

(h) DFCI Agreement. The DFCI Agreement is in full force and effect. FibroGen has no cause to believe that the DFCI Agreement is likely to be terminated prior to its expiry. To FibroGen's knowledge, neither DFCI nor FibroGen is in breach of any of its obligations under the DFCI Agreement. [\*].

(i) Astellas Agreements. Nothing in the Astellas Agreements prevents FibroGen from granting the rights to AstraZeneca granted under this Agreement or prevents either FibroGen or AstraZeneca from exercising their rights or performing their obligations under this Agreement.

(j) Documentation Made Available to AstraZeneca. FibroGen has made available to AstraZeneca all material Regulatory Material, FibroGen Know-How and other Information in its possession or Control regarding or related to any Collaboration Compound and Product. All Regulatory Material, FibroGen Know-How and other Information in FibroGen's possession and Control provided to AstraZeneca regarding or related to any Collaboration Compound or Product are, to FibroGen's knowledge, true, complete and correct in all material respects. As of the Effective Date, FibroGen has prepared, maintained and retained in all material respects all material Regulatory Material that FibroGen is required to maintain or report pursuant to and in accordance with GLP, GCP, regulations and other applicable law.

(k) Patent Litigation. Neither FibroGen nor its Affiliates will initiate or maintain any patent enforcement proceeding or litigation with respect to any Designated Product unless it has a good faith basis for doing so.

## 10.3 Anti-Bribery and Anti-Corruption Compliance.

(a) Each Party agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement (together with such Party, the "*Representatives*") that for the performance of its obligations hereunder:

(i) The Representatives shall not directly or indirectly pay, offer or promise to pay, authorize the payment of any money or give, offer or promise to give, or authorize the giving of anything else of value, to: (a) any Government Official in order to influence official action; (b) any individual or entity (whether or not a Government Official) (1) to influence such individual or entity to act in breach of a duty of good faith, impartiality or trust ("acting improperly"), (2) to reward such individual or entity for acting improperly or (3) where such individual or entity would be acting improperly by receiving the money or other thing of value; (c) any individual or entity (whether or not a Government Official) while knowing or having reason to know that all or any portion of the money or other thing of value will be paid, offered, promised or given to, or will otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement; or (d) any individual or entity (whether or not a Government Official) to reward that individual or entity for acting improperly or to induce that individual or entity to act improperly.

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(ii) The Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(b) The Representatives shall comply with the Anti-Corruption Laws plus the AstraZeneca Anti-Corruption Rules and Policies and shall not take any action that will, or would reasonably be expected to, cause either Party or its Affiliates to be in violation of any such laws or policies.

(c) Each Party, on behalf of itself and its other Representatives, represents and warrants to the other Party that to the best of such Party's and its Affiliates' knowledge, no Representative that will participate or support its performance of its obligations hereunder has, directly or indirectly, (i) paid, offered or promised to pay or authorized the payment of any money, (ii) given, offered or promised to give or authorized the giving of anything else of value or (iii) solicited, received or agreed to accept any payment of money or anything else of value, in each case ((i), (ii) and (iii)), in violation of the Anti-Corruption Laws during the three (3) years preceding the date of this Agreement.

(d) Each Party shall promptly provide the other Party with written notice of the following events: (i) upon becoming aware of any breach or violation by such Party or its Representative of any representation, warranty or undertaking set forth in Sections 10.3(a)-(c); or (ii) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of the Representatives connected with this Agreement that any of them is the target of a formal investigation by a governmental authority for a Material Anti-Corruption Law Violation.

(e) Without prejudice to any auditing or inspection rights set forth elsewhere in this Agreement, each Party shall for the term of this Agreement and six (6) years thereafter, for the purpose of allowing the other Party to audit and monitor the performance of its compliance with this Agreement and particularly this Section 10.3 permit the other Party, its Affiliates, any auditors of any of them and any governmental authority to have reasonable access to any premises of such Party or other Representatives used in connection with this Agreement, together with a right to reasonably access personnel and records that relate to this Agreement ("*Compliance Audit*"). The results of any such audit shall constitute Confidential Information of the audited Party, in respect of which the other Party shall comply with the provisions contained in Article 12 (subject to the terms and exceptions set forth therein or in this Section 10.3).

(i) To the extent that any Compliance Audit by a Party requires access and review of any commercially or strategically sensitive information of the other Party or any of its other Representatives relating to the business of such Party or any other Representatives (including information about prices and pricing policies, cost structures and business strategies),

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such activity shall be carried out by a Third Party professional advisor appointed by the other Party and such professional advisors shall only report back to the other Party such information as is directly relevant to informing the other Party on such Party's compliance with the particular provisions of the Agreement being Compliance Audited.

(ii) Each Party shall, and shall cause its Representatives to, provide all cooperation and assistance during normal working hours as reasonably requested by the other Party for the purposes of a Compliance Audit. Such other Party shall ensure that any Third Party auditor enters into a confidentiality agreement consistent with applicable requirements of Article 12 hereof in all material respects. Such other Party shall instruct any Third Party auditor or other Person given access in respect of a Compliance Audit to cause the minimum amount of disruption to the business of the audited Party and its Affiliates and to comply with relevant building and security regulations.

(iii) The costs and fees of any Compliance Audit shall be paid by the auditing Party, except that if an inspection or Compliance Audit reveals any breach or violation by the audited Party (including through its other Representatives) of any representation, warranty or undertaking set forth in Sections 10.3(a)-(c), the costs of such inspection or Compliance Audit shall be paid by the audited Party. The audited Party shall bear its own costs of rendering assistance to the Compliance Audit.

(f) On the occurrence of any of the following events: (A) A Party becomes aware of, whether or not through a Compliance Audit, that the other Party (or any other Representative) is in breach or violation of any representation, warranty or undertaking in Sections 10.3(a)-(c) or of the Anti-Corruption Laws; or (B) notification is received under Section 10.3(d) relating to any suspected or actual Material Anti-Corruption Law Violation by a Party or its Representative, in either case ((A) or (B)), the other Party shall have the right, in addition to any other rights or remedies under this Agreement or to which such other Party may be entitled in law or equity, to (x) take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by such other Party or any of its Affiliates of the Anti-Corruption Laws, including by requiring that the Party agrees to such additional measures, representations, warranties, undertakings and other provisions as such other Party believes in good faith are reasonably necessary ("*Provisions*") and (y) terminate any or all of the activities conducted by the Party pursuant to this Agreement or this Agreement in its entirety, immediately in the event that:

(i) A Party refuses to agree to all of the Provisions required by the other Party pursuant to this clause; *provided* that such other Party has (a) provided the Party an explanation in reasonable detail as to why such other Party considers such provisions necessary, (b) given the Party a reasonable opportunity to review and comment on the proposed Provisions and to provide its view as to the necessity or usefulness of these to address the event concerned and (c) considered such comments in good faith, or

(ii) A Party reasonably concludes that there is no Provision available that would enable such Party or its Affiliates to avoid a potential violation or continuing violation of applicable Anti-Corruption Laws.

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(g) Any termination of this Agreement pursuant to Section 10.3(f) shall be treated as a termination for breach and the consequences of termination set forth in Sections 13.6 and 13.7, as applicable, shall apply and additionally: (i) subject to the accrued rights of the Parties prior to termination, the terminating Party shall have no liability to the other Party for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination; and (ii) any amounts that would otherwise be payable with respect to such terminated activities or pursuant to this Agreement in its entirety, as applicable, including any then outstanding and unpaid claims for payment shall be null and void to the extent permissible under applicable laws.

(h) Each Party shall be responsible for any breach of any representation, warranty or undertaking in this Section 10.3 or of the Anti-Corruption Laws by any of its Representatives.

(i) Each Party may disclose the terms of this Agreement or any action taken under this Section 10.3 to prevent a potential violation or continuing violation of applicable Anti-Corruption Laws, including the identity of the other Party and the payment terms, to any Governmental Authority if such Party determines, upon advice of counsel, that such disclosure is necessary.

(j) Each Party represents and warrants that (i) it has reviewed its internal programs in relation to the Anti-Corruption Laws and the ability of the Representatives to adhere to the AstraZeneca Anti-Corruption Rules and Policies in performance of its obligations hereunder in advance of the signing of this Agreement, (ii) it and the other Representatives can and will continue to comply with such Anti-Corruption Laws and the AstraZeneca Anti-Corruption Rules and Policies in performance of its obligations hereunder. Should either Party identify in writing to the other Party any measures that should be reasonably taken to improve the Representatives' compliance with such Anti-Corruption Laws and the AstraZeneca Anti-Corruption Rules and Policies for the performance of its obligations hereunder (the "*Improvement Plan*"), the other Party shall implement such Improvement Plan within an agreed reasonable timeframe (which shall in any event not be in excess of three (3) calendar months) from the date the Improvement Plan is delivered to the receiving Party or otherwise the requesting Party shall be entitled to (x) terminate this Agreement, upon written notice to the other Party with immediate effect, (y) be relieved of any obligations hereunder and (z) seek compensation from the other Party.

**10.4 Disclaimer.** Each Party understands that the Collaboration Compounds and Products are the subject of ongoing clinical research and development and that the other Party cannot assure the safety or usefulness of the Collaboration Compounds or Products. In addition, FibroGen makes no warranties except as set forth in this Article 10 concerning the FibroGen Technology, and AstraZeneca makes no warranties except as set forth in this Article 10 concerning the AstraZeneca Technology.

**10.5** No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN SECTION 5.11 AND THIS ARTICLE 10, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR

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PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## **ARTICLE 11**

### INDEMNIFICATION

**11.1 Indemnification by FibroGen.** FibroGen shall defend, indemnify, and hold AstraZeneca, its Affiliates, and their respective officers, directors, employees, and agents (the "*AstraZeneca Indemnitees*") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such AstraZeneca Indemnitees (collectively, "*AstraZeneca Damages*"), all to the extent resulting from claims, suits, proceedings or causes of action brought by such Third Party ("*AstraZeneca Claims*") against such AstraZeneca Indemnitee that arise from or are based on: (a) a breach of any of FibroGen's representations, warranties, and obligations under this Agreement; (b) the willful misconduct or grossly negligent acts or omissions of FibroGen, its Affiliates, or the officers, directors, employees, or agents of FibroGen or its Affiliates in the performance of activities under this Agreement; (c) the research or Development of Collaboration Compounds or Products by FibroGen before the Effective Date; or (d) the Development, testing, manufacture, storage, handling, use, sale, offer for sale, distribution and importation of Products by FibroGen or its Affiliates or licensees (excluding, for clarity, AstraZeneca). The foregoing indemnity obligation shall not apply if the AstraZeneca Indemnitees materially fail to comply with the indemnification procedures set forth in Section 11.3, or to the extent that such AstraZeneca Claim is based on or alleges: (i) a breach of any of AstraZeneca's representations, warranties, and obligations under this Agreement; or (ii) the willful misconduct or grossly negligent acts or omissions of AstraZeneca or its Affiliates, or the officers, directors, employees, or agents of AstraZeneca or its Affiliates in the performance of activities under this Agreement.

**11.2 Indemnification by AstraZeneca.** AstraZeneca shall defend, indemnify, and hold FibroGen, its Affiliates, and each of their respective officers, directors, employees, and agents, (the "*FibroGen Indemnitees*") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such FibroGen Indemnitees (collectively, "*FibroGen Damages*"), all to the extent resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "*FibroGen Claims*") against such FibroGen Indemnitee that arise from or are based on: (a) the Development, testing, manufacture, storage, handling, use, sale, offer for sale, distribution and importation of Products by AstraZeneca or its Affiliates, Sublicensees, or distributors; (b) a breach of any of AstraZeneca's representations, warranties, and obligations under the Agreement; or (c) the willful misconduct or grossly negligent acts or omissions of AstraZeneca or its Affiliates, directors, employees, or agents of AstraZeneca or its Affiliates in the performance of activities under this Agreement. The foregoing indemnity obligation shall not apply if the FibroGen Indemnitees materially fail to comply with the

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indemnification procedures set forth in Section 11.3, or to the extent that any FibroGen Claim is based on or alleges: (i) a breach of any of FibroGen's representations, warranties, and obligations under this Agreement; or (ii) the willful misconduct or grossly negligent acts or omissions of FibroGen, its Affiliates, or their officers, directors, employees, or agents in the performance of activities under this Agreement.

**11.3 Indemnification Procedures.** The Party claiming indemnity under this Article 11 (the "*Indemnified Party*") shall give written notice to the Party from whom indemnity is being sought (the "*Indemnifying Party*") promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought ("*Claim*"). The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense of the Claim with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle any such Claim without the prior written consent of the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 11.

**11.4 Insurance.** Each Party shall self-insure or procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold until the expiration or termination of this Agreement or four (4) years after termination of any such clinical testing or commercial distribution, whichever is later. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other with written evidence of such insurance upon request. Each Party shall provide the other with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

## 11.5 DFCI Agreement. [\*]

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## **ARTICLE 12**

### CONFIDENTIALITY

12.1 Product Information. FibroGen recognizes that by reason of, among other things, AstraZeneca's status as licensee pursuant to the grants under Section 7.1, AstraZeneca has an interest in FibroGen's retention in confidence of information relating to the Collaboration Compounds or Products, and the Development and Commercialization thereof. Accordingly, during the Term, FibroGen shall, and shall cause its Affiliates and their respective officers, directors, employees and agents to, keep confidential, and not publish or otherwise disclose, other than under written confidentiality and non-use terms, and not use directly or indirectly for any purpose other than to perform FibroGen's obligations under this Agreement and the China Agreement, to conduct research, Development and Commercialization of Products outside the Territory pursuant to the Astellas Agreements or any Subsequent Agreement entered into pursuant to Section 7.4(c), in connection with FibroGen's research, development and commercialization of other products, and as otherwise authorized under this Agreement (including pursuant to Section 3.10), any (a) Regulatory Material (including any Regulatory Approvals) with respect to any Collaboration Compound or Product and (b) Information that is either Controlled by FibroGen or provided to FibroGen pursuant to this Agreement relating to the Development or Commercialization of Collaboration Compounds or Products, including development, sales or marketing plans therefor (collectively, (a) and (b), "Product Information"), except, in each case, to the extent (i) the Product Information was generally available to the public or otherwise part of the public domain, prior to the Effective Date, or thereafter became generally available to the public or otherwise part of the public domain through no fault of FibroGen, its Affiliates or any of their respective officers, directors, employees or agents or (ii) the disclosure or use of such Product Information would be expressly permitted under Section 12.3 or is otherwise expressly authorized under this Agreement. For clarification, the disclosure or transfer by FibroGen to AstraZeneca or by AstraZeneca to FibroGen of any Product Information shall not cause such information to cease to be subject to the provisions of this Section 12.1. In the event this Agreement is terminated in its entirety or in a given country for any reason, this Section 12.1 shall as from the effective date of such termination have no continuing force or effect (provided that if such termination is with respect to one or several specific country(ies) only, then this Section 12.1 will have no continuing force or effect as to such specific country(ies)) and all Product Information shall be deemed to be Confidential Information of FibroGen for purposes of the surviving provisions of this Agreement. For clarity, the foregoing shall not affect the Parties' respective ownership of Product Information.

**12.2 Confidentiality General.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term and for ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement or the China Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

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(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or

(e) is independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of the disclosing Party's Confidential Information.

For the avoidance of doubt, Confidential Information that is also Product Information is governed both by the terms of Section 12.1 and by the terms of this Section 12.2.

**12.3 Authorized Disclosure.** FibroGen may disclose Product Information and each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting FibroGen Patents in accordance with Article 9;

(b) regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), including filings with the SEC or FDA, with respect to a Product;

(c) prosecuting or defending litigation;

(d) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;

(e) disclosure to its Affiliates, employees, agents, and independent contractors, and any licensees or Sublicensees, in each case only on a need-toknow basis and solely in connection with the performance of this Agreement or the China Agreement (and in the case of FibroGen, the Astellas Collaboration or any Subsequent Agreement entered into pursuant to Section 7.4(c)), provided, however, that each disclose must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 12 prior to any such disclosure and provided, further, that the disclosing Party shall cause such disclose to comply with confidentiality and non-use obligations at least as restrictive as those set forth in this Article 12;

(f) disclosure of the material terms of this Agreement to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner, and in the case of FibroGen, to any licensee or sublicensee of Products (including Astellas and its sublicensees); provided that in connection with such disclosure, the disclosing Party shall inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential; and

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(g) disclosure of any Inventions or status reports (including data from any Clinical Trials) to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner, and in the case of FibroGen, to any licensee of Products (including Astellas and its sublicensees); provided that each disclosee must be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article 12 prior to any such disclosure.

Notwithstanding the foregoing, in the event FibroGen is required to make a disclosure of Product Information or either Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 12.3(a), 12.3(b), 12.3(c) or 12.3(d), it will, except where impracticable, use Commercially Reasonable Efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

#### 12.4 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 12.3 and this Section 12.4. The Parties have agreed to make a joint public announcement of the execution of this Agreement substantially in the form of the press release attached as **Exhibit N** on or promptly after the Effective Date.

(b) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement or any activities under this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld, except that in the case of a press release or governmental filing required by law, the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. A Party commenting on such a proposed press release shall provide its comments, if any, within five (5) Business Days after receiving the press release for review. FibroGen shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals as they occur, subject only to the review procedure set forth in the preceding sentence. In relation to AstraZeneca's review of such an announcement, AstraZeneca may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone or Regulatory Approval has been achieved and triggered a payment hereunder. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 12.4.

(c) The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the SEC or other Government Authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each

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Party will provide the other Party with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.

## 12.5 Publications.

(a) Subject to the International Committee of Medical Journal Editors ("ICMJE") Uniform Requirements for Manuscripts Submitted to Biomedical Journals and applicable legal requirements, the JDC (with approval of the JSC) will determine the overall strategy for publishing and presenting results of studies pertaining to the Products and the JDC shall approve all publications in the Territory prior to publication.

(b) Neither Party shall publicly present or publish results of studies carried out under this Agreement (each such presentation or publication a "*Publication*") without the opportunity for prior review by the other Party, except to the extent otherwise required by applicable laws or regulations, in which case Section 12.4(c) shall apply with respect to disclosures required by applicable securities laws and Section 12.3(b) shall apply with respect to disclosures required for regulatory filings. The submitting Party shall provide the other Party the opportunity to review any proposed Publication at least thirty (30) days prior to the earlier of its presentation or intended submission for publication. The submitting Party agrees, upon request by the other Party, not to submit or present any Publication until the other Party has had thirty (30) days to comment on any material in such Publication. The submitting Party shall consider the comments of the other Party in good faith, and no Publication shall be submitted for publication without the approval of the JDC or JCC. The submitting Party shall provide the other Party a copy of the Publication at the time of the submission or presentation. Notwithstanding the foregoing, AstraZeneca shall not have the right to publish or present FibroGen's Confidential Information without FibroGen's prior written consent, and FibroGen shall not have the right to publish or present Sconfidential Information without AstraZeneca's prior written consent. Each Party agrees to acknowledge the contributions of the other Party, and the employees of the other Party, in all publications as scientifically appropriate.

#### **ARTICLE 13**

#### TERM AND TERMINATION

**13.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect until the date that AstraZeneca is no longer Developing or selling Products in the Territory (the "*Term*").

**13.2 Termination by AstraZeneca at Will.** AstraZeneca shall have the right to terminate this Agreement at any time upon one hundred eighty (180) days prior written notice to FibroGen, either (a) in its entirety or (b) with respect to one or more of the following (each a "region"): (i) the U.S., (ii) Asia, (iii) Africa or (iv) one or more of Mexico, Brazil, Canada, India or Australia and New Zealand (each considered a separate region). During such one hundred eighty (180) day period, AstraZeneca shall continue to perform all of its obligations under this Agreement and shall continue to be responsible for all costs incurred under the Agreement to be borne by AstraZeneca according to the Agreement during such one hundred eighty (180) day period.

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**13.3 Termination by AstraZeneca for Technical Product Failure**. AstraZeneca may terminate this Agreement in its entirety at any time after the Effective Date effective upon written notice to FibroGen in the event of Technical Product Failure, such notice to describe the basis for such Technical Product Failure in reasonable detail; provided, however, that AstraZeneca shall *not* be entitled to terminate this Agreement pursuant to this Section 13.3 if such Technical Product Failure pertains only to one or several specific Collaboration Compound(s) or Product(s) but does not affect (a) FG-4592 (if FG-4592 is then still being Developed or Commercialized under this Agreement) or (b) any other Collaboration Compound or Product then in a Phase 2 Clinical Trial or later stage of Development or Commercialization under this Agreement. Disputes related to whether or not a Technical Product Failure has occurred will be resolved in accordance with Section 14.8.

### 13.4 Termination by Either Party for Breach.

(a) Breach. Subject to Section 13.4(b), FibroGen shall have the right to terminate this Agreement upon written notice to AstraZeneca if AstraZeneca materially breaches its obligations under this Agreement and, after receiving written notice from FibroGen identifying such material breach by AstraZeneca in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice (or within thirty (30) days from the date of such notice in the event such material breach is solely based upon AstraZeneca's failure to pay any material amounts due to FibroGen materially breaches its obligations under this Agreement and, after receiving written notice from AstraZeneca identifying such material breach by FibroGen materially breaches its obligations under this Agreement and, after receiving written notice from AstraZeneca identifying such material breach by FibroGen in reasonable detail, fails to cure such material breach of such notice (or within thirty (30) days from the date of such notice in the event such material breach is solely based upon AstraZeneca identifying such material breach by FibroGen in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice (or within thirty (30) days from the date of such notice in the event such material breach is solely based upon FibroGen's failure to pay any material amounts due to AstraZeneca hereunder).

(b) Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 13.4(a), and such alleged breaching Party provides the other Party notice of such dispute within such ninety (90) day (or thirty (30) day, as the case may be) period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 13.4(a) unless and until the arbitral tribunal, in accordance with Article 14, has determined that the alleged breaching Party has materially breached the Agreement and such Party fails to cure such breach within ninety (90) days following such arbitral tribunal's decision (except to the extent such breach is solely based on the failure to make a payment when due, which breach must be cured within thirty (30) days following such arbitral tribunal's decision); provided that with respect to a failure to pay amounts due, arbitration shall be conducted in accordance with Article 14, except that it shall be conducted by only one arbitrator and shall be resolved within ninety (90) days. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

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## (c) DFCI Agreement. [\*]

**13.5 Termination for Patent Challenge**. FibroGen may terminate this Agreement in its entirety immediately upon written notice to AstraZeneca if AstraZeneca or its Affiliates or Sublicensees (directly or indirectly, individually or in association with any other person or entity) challenges the validity, enforceability or scope of any FibroGen Patent in the Territory and such challenge is not permanently withdrawn within ninety (90) days.

**13.6 Effects of Termination.** Upon any termination of this Agreement other than pursuant to Section 13.3 for Technical Product Failure, the following shall apply (in addition to any other rights and obligations under Section 13.8 or otherwise under this Agreement with respect to such termination) and, in the case of termination with respect to a particular region only, shall apply only to the terminated region (it being understood that any reference below to the "terminated region" will apply to the Territory as a whole if this Agreement is terminated in its entirety):

(a) Rights and Licenses to the FibroGen Technology. As from the effective date of the termination, all licenses and rights to the FibroGen Technology granted to AstraZeneca under Article 7 shall terminate with respect to the terminated region, except to the extent and for so long as is necessary to permit AstraZeneca to comply with its obligations under this Section 13.6, to dispose of any remaining inventory of Products pursuant to Section 13.6(g) and to perform any activity that cannot be terminated as of such date under applicable law, including GCP, it being agreed that all such activities and responsibilities shall be discontinued and ceased (unless otherwise agreed) by transitioning such activities and responsibilities to FibroGen as soon as practicable and subject to applicable law, including GCP.

(b) AstraZeneca Technology. AstraZeneca hereby grants to FibroGen, effective only upon the effective date of such termination, a nonexclusive, fully-paid, perpetual, irrevocable, royalty-free license, with the right to grant multiple tiers of sublicenses, under the AstraZeneca Technology, to research, develop, make, have made, use, import, export, offer for sale, and sell Products in the Field in the terminated region; provided that FibroGen shall indemnify, defend and hold harmless AstraZeneca and each of the AstraZeneca Indemnitees as set forth in Section 11.1 from and against any AstraZeneca Damages arising out of or resulting from AstraZeneca Claims that arise or result from FibroGen's, its Affiliates' or licensees' activities performed under the foregoing license.

(c) Marks. AstraZeneca shall assign to FibroGen all right, title and interest in and to the Marks for the terminated regions (excluding any such Marks that include, in whole or part, any corporate name or logo of AstraZeneca or its Affiliate or Sublicensee or that relate to any other products of AstraZeneca or its Affiliates).

(d) Regulatory Materials. AstraZeneca shall transfer and assign to FibroGen all Regulatory Materials and Regulatory Approvals for Products in the terminated regions, if any, that are Controlled by AstraZeneca or its Affiliates or Sublicensees.

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(e) Transition Assistance. AstraZeneca shall, at no cost to FibroGen, provide reasonable consultation and assistance for a period of no more than one hundred eighty (180) days following the effective date of termination for the purpose of transferring or transitioning to FibroGen, all AstraZeneca Know-How solely related to a Product not already in FibroGen's possession, and, at FibroGen's request, all then-existing commercial arrangements relating specifically to the terminated region and the Products to the extent reasonably necessary or useful for FibroGen to commence or continue developing, manufacturing, or commercializing Products in the terminated region, and further to the extent AstraZeneca is contractually able to do so. The foregoing consultation and assistance shall include, without limitation, assigning, upon request of FibroGen, any agreements with Third Party suppliers or vendors that specifically cover the supply or sale of Products in the Territory, to the extent such agreements are assignable by AstraZeneca. If any such contract between AstraZeneca and a Third Party is not assignable to FibroGen (whether by such contract's terms or because such contract does not relate specifically to Products) but is otherwise reasonably necessary or useful for FibroGen to commence or continue developing, manufacturing, or commercializing Products, then AstraZeneca shall reasonably cooperate with FibroGen to negotiate for the continuation of such license and/or supply from such entity. In any event, if AstraZeneca is manufacturing bulk or finished Product under an agreement entered into pursuant to Section 6.4, then AstraZeneca shall supply such bulk or finished Product, as applicable, to FibroGen and Astellas, for a reasonable transitional period (not to exceed twelve (12) months from the effective date of the termination, subject to reasonable extension by FibroGen if AstraZeneca is unable to timely effect the technology transfer required to have a Third Party manufacturer designated by FibroGen undertake the manufacturing responsibilities) under the terms of such agreement until FibroGen either enters into a separate agreement with such Third Party supplier or vendor or establishes an alternate, validated source of supply for the Products. In consideration of such supplies, FibroGen shall pay to AstraZeneca a price equal to AstraZeneca's actual cost to manufacture or acquire such supplies, provided that where termination is by AstraZeneca pursuant to Section 13.4(a), FibroGen shall pay to AstraZeneca a price equal to AstraZeneca's actual cost to manufacture or acquire such supplies plus a mark-up [\*] of such actual cost.

(f) Ongoing Clinical Trials. As soon as practicable and subject to applicable law, including GCP, AstraZeneca shall transfer to FibroGen the management and continued performance of all Clinical Trials for Products for the terminated regions ongoing as of the effective date of such termination, that are being conducted by AstraZeneca at such time.

(g) Remaining Inventories. If this Agreement is terminated in its entirety, FibroGen shall have the right to purchase from AstraZeneca any or all of the inventory of Products held by AstraZeneca as of the effective date of the termination (that are not committed to be supplied to any Third Party in the ordinary course of business as of the date of termination) at a price equal to AstraZeneca's actual cost to acquire such inventory. FibroGen shall notify AstraZeneca within sixty (60) days after the effective date of the termination whether FibroGen elects to exercise such right. In the event FibroGen does not elect to exercise such right AstraZeneca shall be entitled to dispose of such inventory as it sees fit in compliance with applicable law, subject to all applicable payments to FibroGen under Article 8.

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(h) Funding of Development Costs. If AstraZeneca terminates this Agreement under Section 13.2 (but not in the event of any other termination), then AstraZeneca shall remain responsible for all (or, if during the Development Sharing Period, fifty percent (50%) of) Development Costs and all Commercialization Costs incurred by FibroGen under the respective Development Plans and Commercialization Plans [\*], under the process in Section 8.2. If AstraZeneca terminates this Agreement under Section 13.2 (but not in the event of any other termination), AstraZeneca shall [\*].

(i) Post-Termination Restriction. If this Agreement is terminated by AstraZeneca at will under Section 13.2 or by FibroGen under Section 13.4 for AstraZeneca's material breach or by FibroGen under Section 13.5 for patent challenge, AstraZeneca shall continue to comply with the restrictive covenant set out in Section 7.8(a) for three (3) years after the effective date of the termination.

(j) No Other Rights. For the avoidance of doubt, the rights granted to FibroGen under this Section 13.6 are restricted to Collaboration Compounds and Products and AstraZeneca does not grant any rights whatsoever to any other compounds or products or to any Patents or other intellectual property rights other than as set forth in this Section 13.6. Moreover, AstraZeneca shall not be obligated to provide FibroGen with any other intellectual property rights or other rights or services than that which are explicitly provided for under this Section 13.6.

(k) Certain Additional Provisions for Termination for FibroGen's Breach. If this Agreement is terminated under Section 13.4 for FibroGen's material breach, FibroGen shall – in addition to any other remedies available to AstraZeneca under this Agreement or applicable law as a consequence of such breach – compensate AstraZeneca for any costs or expenses incurred by AstraZeneca or its Affiliates in connection with performing any of the activities contemplated by the applicable provisions in this Section 13.6.

**13.7 Effect of Termination for Technical Product Failure**. Upon termination of this Agreement pursuant to Section 13.3 for a Technical Product Failure, all licenses and rights to the FibroGen Technology granted to AstraZeneca under Article 7 shall terminate and, to the extent appropriate given the nature of the Technical Product Failure and subject to applicable law, including GCP, the other termination consequences set out in Sections 13.6(a) through 13.6(g) as well as Section 13.6(j) shall apply.

**13.8 Other Remedies.** Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to the effective date of such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

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### 13.9 Bankruptcy.

(a) A Party shall have the right to terminate this Agreement in its entirety before the end of the Term upon the bankruptcy or insolvency of, or the filing of an action to commence insolvency proceedings against the other Party, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such Party's property, in each case that is not discharged within sixty (60) days of the applicable filing, action or initiation of proceedings.

(b) All rights and licenses granted under or pursuant to this Agreement by FibroGen and AstraZeneca are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the "*Bankrupt Party*") under the U.S. Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i), following the rejection of this Agreement by the Bankrupt Party upon written request therefor by the other Party.

**13.10 Survival.** Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive and apply after expiration or termination of this Agreement: Sections 3.10(b), 3.11, 4.4 (last sentence only), 7.8(a)-(c) (only as and to the extent set forth in Section 13.6(i)), 7.8(d), 7.9, 8.1, 8.9-8.15, 9.2, 10.5, 12.1 (provided that all Product Information will be FibroGen's Confidential Information upon termination (but not expiration) of this Agreement), 12.2, 12.3, 12.4, 13.6, 13.7, 13.8 and 13.10 and Articles 11, 14 and 15. In addition, the other applicable provisions of Article 8 shall survive to the extent required to make final reimbursements, reconciliations or other payments with respect to Net Sales and costs and expenses incurred or accrued prior to the date of termination or expiration. For any surviving provisions requiring action or decision by a Committee or an Executive Officer, each Party will appoint representatives to act as its Committee members or Executive Officer, as applicable. All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect.

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### **ARTICLE 14**

#### DISPUTE RESOLUTION AND GOVERNING LAW

**14.1 Disputes.** It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (including disputes arising from the JSC that are not resolved pursuant to Section 2.6), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (each, a "*Dispute*"), then upon the request of either Party by written notice, the dispute will be referred to the Executive Officers of each Party, who shall meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 14.2.

**14.2 Arbitration.** Any dispute, controversy, difference or claim which may arise between the Parties, out of or in relation to or in connection with this Agreement (including, without limitation, arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement) that is not resolved pursuant to Section 14.1, except for a dispute, claim or controversy under Section 14.7 or 14.8, shall be settled by binding arbitration administered by the American Arbitration Association (the "AAA") in accordance with its Commercial Arbitration Rules (or the AAA International Arbitration Rules, if recommended under the AAA guidelines), as such rules may be modified by this Section 14.2 or otherwise by subsequent written agreement of the Parties. The arbitration shall be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "*Federal Arbitration Act*"), to the exclusion of any inconsistent state laws. The arbitration will be conducted in New York, New York. The number of arbitrators shall be three (3), of whom the Parties shall select one (1) each. The two arbitrators so selected will select the third and final arbitrator. If the arbitrator selected by the Parties are unable or fail to agree upon the third arbitrator, the AAA shall select the third arbitrator. The language to be used in the arbitrator proceedings will be English. The Parties shall have the right to be represented by counsel. The arbitration proceedings shall be confidential. Except as required by applicable law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by applicable law. Any judgment or award rendered by the arbitrators shall be final and binding on the Parties. The Parties agree that such judgment or award may be enforced in any court of competent ju

**14.3 Governing Law**. Resolution of all Disputes and any remedies relating thereto shall be governed by and construed under the substantive laws of the State of California, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

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**14.4 Decision**. The arbitrators shall issue a reasoned opinion following a full comprehensive hearing, no later than twelve (12) months following the selection of the arbitrators.

**14.5** Award. Any award shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. If as to any issue the arbitrators should determine under the applicable law that the position taken by a Party is frivolous or otherwise irresponsible or that any wrongdoing it finds is in callous disregard of law and equity or the rights of the other Party, the arbitrators shall also be entitled to award an appropriate allocation of the adversary's reasonable attorney fees, costs and expenses to be paid by the offending Party, the precise sums to be determined after a bill of attorney fees, expenses and costs consistent with such award has been presented following the award on the merits. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 14. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrators. With respect to money damages, nothing contained herein shall be construed to permit the arbitrators or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages recoverable under this Agreement are compensatory damages.

**14.6 Injunctive Relief**. Provided a Party has made a sufficient showing under the rules and standards set forth in the U.S. Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Nothing in this Article 14 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

**14.7 Patent and Trademark Disputes**. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patents or trademarks covering the manufacture, use, importation, offer for sale or sale of the Product shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

**14.8 Expedited Arbitration for Disputes Related to Technical Product Failure**. Disputes with respect to a Technical Product Failure that are not resolved at the JSC or by the Executive Officers within twenty (20) Business Days after referral thereto, in the case of a Technical Product Failure as defined in Section 1.120(a), or resolved by the Parties, in the case of a Technical Product Failure as defined in Section 1.120(b), shall be finally determined as set forth in this Section 14.8. Within five (5) Business Days after the end of such twenty (20)-Business Day period, each Party shall propose a list of three (3) individuals, each of whom has at least ten (10) years of significant relevant technical experience in the pharmaceutical industry, and none of whom is or has been affiliated with either Party or with either Party's Affiliates, licensees, sublicensees or business partners, or otherwise has any interest in the resolution of the issue to be

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submitted by the Parties for resolution (the foregoing requirements, the "*Requirements*"). Within five (5) Business Days after the Parties exchange such lists, the Parties shall either agree upon one of such proposed individuals to resolve the disputed matter, or if the Parties do not so select one such individual within such period of time, each Party shall select one (1) such individual from the list proposed by the other Party, and the two (2) selected individuals shall select a third individual who otherwise meets the Requirements to resolve the disputed matter (the selected individual, the "*Industry Expert*"). Each Party shall submit written materials to the other Party and to the Industry Expert relating to the matters in issue within five (5) Business Days after the Industry Expert is selected. Each Party shall then have five (5) Business Days to submit a written rebuttal to the other Party's submission to the other Party and to the Industry Expert. The Industry Expert shall have the discretion to interview the Parties' officers and employees to obtain further information relating to the matters in issue and to hear oral argument. Each Party shall cooperate with the Industry Expert. The Industry Expert's determination shall be binding as to whether a Technical Product Failure has occurred, and such determination shall be given retroactive effect. Until such determination is delivered to the Parties, the Parties shall continue to perform their obligations under this Agreement in good faith and make any applicable payments accordingly. If the Industry Expert decides in FibroGen's favor, then AstraZeneca shall bear all expenses incurred pursuant to this Section 14.8, including reasonable reimbursement of FibroGen's expenses for internal personnel and external advisors.

### **ARTICLE 15**

#### MISCELLANEOUS

**15.1 Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including, without limitation, the Existing Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations pursuant to the Existing Confidentiality Agreement. In the event of any inconsistency between any plan hereunder (including the Development Plan and/or U.S. Commercialization Plan) and this Agreement or between the terms of this Agreement and the China Agreement (but solely with respect to the U.S. and RoW), the terms of this Agreement shall prevail. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

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**15.2 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented or delayed by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). The non-performing Party shall within thirty (30) days after a force majeure provide the other Party a good faith estimate of the anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

**15.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable international expedited delivery service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested.

If to FibroGen:	FibroGen, Inc. 409 Illinois St. San Francisco, CA 94158 USA Attention: Chief Executive Officer
With a copy to:	FibroGen, Inc. 409 Illinois St. San Francisco, CA 94158 USA Attn: Michael Lowenstein, Vice President, Legal

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If to AstraZeneca:	AstraZeneca AB Pepparedsleden 1, 431 83 Mölndal Gothenburg Sweden Attention: Chief Financial Officer
With a copy to:	AstraZeneca UK Limited Alderley Park Macclesfield Cheshire SK10 4TF Attention: Liam McIlveen, Deputy General Counsel

**15.4 No Strict Construction; Headings.** Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in the event an ambiguity or a question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**15.5** Assignment. Neither Party may assign or transfer this Agreement (either in whole or part) or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations (and in any event, any Party assigning this Agreement to an Affiliate shall remain bound by the terms and conditions hereof). In the event that a Party is acquired by a Third Party (such Third Party, hereinafter referred to as an "*Acquiror*"), then the intellectual property of such Acquiror held or developed by such Acquiror (whether prior to or after such acquisition) shall be excluded from the FibroGen Technology (in the case when the acquired Party is FibroGen) and AstraZeneca Technology (in the case when the acquired Party is AstraZeneca), and such Acquiror (and Affiliates of such Acquiror which are not controlled by the acquired Party itself) shall be excluded from "Affiliate" solely for purposes of the applicable components of the foregoing intellectual property of the acquired Party and all research and development assets and operations of the acquired Party with respect to the Product remain with the acquired Party and are not transferred to the Acquiror or another Affiliate of the Acquiror; (c) the scientific and development activities with respect to Product of the acquired Party and the Acquiror (if any) are maintained separate and distinct, and (d) there is no exchange of confidential Information relating to this Collaboration between the

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acquired Party and the Acquiror. For clarity, in the event that a Party is acquired by an Acquiror and any of the criteria described in subsections (a) through (d) is not satisfied, then the intellectual property of such Acquiror shall be included within FibroGen Technology (in the case when the acquired Party is FibroGen) and AstraZeneca Technology (in the case when the acquired Party is AstraZeneca). Any permitted assignment of the rights and obligations of a Party under this Agreement shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

**15.6 Performance by Affiliates.** Subject to the limitations of Section 7.3, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

**15.7 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.8 Compliance with Applicable Law.** Each Party shall comply with all applicable laws and regulations in the course of performing its obligations or exercising its rights pursuant to this Agreement.

**15.9 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY TORT CLAIMS ARISING HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 15.9 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1, 11.2 OR 11.3, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12.

**15.10 Severability.** To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken (within the time period prescribed for appeal), the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one that achieves, as nearly as possible, the objectives contemplated by the Parties when entering this Agreement.

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**15.11 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**15.12 Independent Contractors.** It is expressly agreed that FibroGen, on the one hand, and AstraZeneca, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither FibroGen, on the one hand, nor AstraZeneca, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

**15.13 English Language.** This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

**15.14 Counterparts**. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Execution Date.

# FIBROGEN, INC.

By: /s/ Thomas B. Neff

Name: Thomas B. Neff Title: CEO

# ASTRAZENECA AB

By:/s/ Elisabeth BjorkName:Elisabeth BjorkTitle:VP, GMed Head, CVMD

SIGNATURE PAGE TO AMENDED AND RESTATED

## LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

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## EXHIBITS

Exhibit A – Territory – Excluded Countries

Exhibit B – DFCI Agreement

Exhibit C – Chemical Structure of FG-4592

Exhibit D – Field Indications

Exhibit E – Listed Patents

Exhibit F – AstraZeneca's Anti-Corruption Rules and Policies

Exhibit G – Initial Members of the JSC

Exhibit G(a) – JDC Responsibilities Delegated by the JSC to the Core JPT

Exhibit G(b) – JCC Responsibilities Delegated by the JSC to the Core JPT

Exhibit H – Initial Development Plan

Exhibit I – U.S. Co-Commercialization Terms

Exhibit J – Development Supply Terms

Exhibit K – Commercial Supply Terms

Exhibit L – Invoicing Requirements

 $\label{eq:exhibit M-Patents that May be Extended} Exhibit M-Patents that May be Extended$ 

Exhibit N – Joint Press Release

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# Exhibit A

## **Excluded Countries**

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- Albania
- Andorra
- Armenia
- Austria
- Azerbaijan
- Belarus
- Belgium
- Bosnia & Herzegovina
- Bulgaria
- Croatia
- Cyprus
- Czech Republic •
- Denmark •
- Estonia •
- Finland •
- France
- Georgia
- Germany
- Greece
- Hungary
- Iceland
- Ireland •
- Italy •
- Japan
- •
- Kazakhstan •
- Kyrgyzstan
- Latvia • Liechtenstein
- •
- Lithuania
- Luxembourg
- Macedonia
- Malta
- Moldova
- Monaco
- Netherlands
- Norway •
- Poland

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- Portugal Romania
- Russia • •
- San Marino
- Serbia and Montenegro (Yugoslavia)
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland Tajikistan
- Turkev
- Turkmenistan •
- Ukraine .
- United Kingdom •
- Uzbekistan
- Vatican City
- Bahrain
- Egypt
- Iran
- Iraq
- Israel
- Jordan
- Kuwait
- Lebanon
- Oman
- Qatar
- Saudi Arabia
- Syria
- United Arab Emirates
- Yemen
- South Africa •

## **DFCI Agreement**

{This Exhibit B is filed as Exhibit 10.24 to the Registration Statement on Form S-1 (Commission File No. 333-199069)}

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# **Chemical Structure of FG-4592**

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#### Exhibit F

AstraZeneca's Anti-Corruption Rules and Policies

#### ASTRAZENECA GLOBAL POLICY

#### ETHICAL INTERACTIONS

#### **ANTI-BRIBERY & ANTI-CORRUPTION**

#### EXTERNAL INTERACTIONS

This Global Policy describes what is required to meet our commitment to operate ethically and with integrity in our business and personal interactions and activities.

This Policy applies to all Employees.

The Company is committed to acting responsibly and in compliance with the requirements of the UK Bribery Act, Foreign Corrupt Practices Act and other relevant laws, regulations and adopted industry codes

#### CONTENTS

- 1. SCOPE, APPLICATION & INTERPRETATION.
- 2. ANTI-BRIBERY & ANTI-CORRUPTION
- 3. ITEMS OF VALUE & HOSPITALITY
- 4. PRICING, DISCOUNTS & REBATES
- 5. CONTRIBUTIONS (DONATIONS, SPONSORSHIPS & PARTNERSHIPS)
- 6. POLITICAL SUPPORT & POLITICAL ACTIVITIES
- 7. PAYMENTS TO PUBLIC OFFICIALS & PUBLIC SECTOR ORGANISATIONS
- 8. AVOIDING CONFLICTS OF INTEREST
- 9. MEETINGS
- 10. ENGAGING THIRD PARTIES & ENSURING COMPLIANCE
- 11. PROMOTIONAL & NON-PROMOTIONAL ACTIVITIES & MATERIALS
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- GLOSSARY REFERENCES

#### 1. SCOPE, APPLICATION & INTERPRETATION

#### 1.1 This Policy applies to all Employees and represents the minimum requirements that the Company has set for Interactions.

An alphabetised Glossary containing definitions for all capitalised terms used in this Policy is included at the end of this Policy.

For certain Interactions, You must refer to more than one Section of this Policy. The relevant Sections are cross-referenced as appropriate.

Other Global Policies may also apply to Interactions. For example, the *Global Data Privacy Policy* applies to Interactions where there is a need to protect the confidentiality of Patient information.

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Global Standards may also apply to Interactions. The Global Standards give additional information about what is required to ensure compliance for particular Interactions. The requirements of this Policy and of the supporting Global Standards must be considered as a whole to evaluate and support compliant Interactions. Global Standards are cross-referenced in each relevant section of this Policy.

### 1.2 This Policy expands on the Company's *Code of Conduct*, and aligns with (and in some cases exceeds) the requirements of applicable law and adopted industry codes.

You must follow the spirit of this Policy and not just its letter. The absence of a specific requirement

relating to a particular Interaction does not mean that the Interaction is necessarily permitted; You must avoid any Interaction that breaches the Company's *Code of Conduct* or supporting Global Policies, Global Standards or Relevant Procedures.

### 1.3 Employees must not attempt to avoid the requirements of this Policy by requesting, allowing or enabling Third Parties (including relatives, friends or other associates) to be involved in the Interactions prohibited by this Policy on the Employee's (or the Company's) behalf.

In some cases, local law, adopted industry codes particular to a jurisdiction, or rules particular to a Business Unit (e.g., Senior Executive Team ("SET") function), may apply to Interactions, and may be more restrictive than this Policy. Where that is the case, You must follow the more restrictive rules set out in Relevant Procedures. For example, local marketing organisations must establish Relevant Procedures with respect to Interactions with Public Officials, where local law is more restrictive than this Policy.

To the extent appropriate, Business Units must establish Relevant Procedures to assure compliance with the requirements of this Policy and supporting Global Standards, including requirements for sufficient monitoring and/or audit. Employees must use reasonable judgement to create business records sufficient to demonstrate compliance with the requirements of this Policy, supporting Global Standards and these Relevant Procedures (e.g., business records of required approvals and required rationales for approvals).

For purposes of this Policy, required approvals must be obtained in advance of any Interaction.

Where the scope or interpretation of a particular provision of this Policy, supporting Global Standards or Relevant Procedures is unclear, You should seek guidance from Your line manager or Your relevant Legal and/or Compliance partner.

#### 2. ANTI-BRIBERY & ANTI-CORRUPTION

#### 2.1 AstraZeneca has zero tolerance for Bribery or corruption (i.e., improper influence).

The Company will support Employees and Third Parties who refuse requests to Give or Receive Bribes on the Company's behalf. Employees and Third Parties will not be subject to retaliation or other adverse consequences for such refusal, even if the Company loses business as a result.

See Section 7 for prohibitions and other requirements regarding Facilitation Payments, including payments Given under duress.

### 2.2 You may Give or Receive something of value in compliance with the requirements and limits of this Policy, supporting Global Standards and Relevant Procedures.

For purposes of this Policy, supporting Global Standards and Relevant Procedures, "something of value" means any financial or non-financial benefit of any kind, including, but not limited to:

a) the Giving and Receiving of Items of Value and Hospitality (See Section 3 and the Global Standard on Items of Value and Hospitality);

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b) prices, discounts and rebates for Company Products Given to Third Parties (See Section 4);

c) Contributions Given to Third Parties (See Section 5 and the Global Standard on Contributions);

d) Political Support Given to Public Officials or Political Organisations and participation in Political Activities (See Section 6);

e) payments Given to Public Officials and Public Sector Organisations (See Section 7);

f) appointments, paid and volunteer work outside of the Company or other interests associated with actual, apparent or potential Conflicts of Interest (See Section 8);

g) the venue, conduct or other arrangements made for Meetings, as well as the selection and/or support of External Stakeholders to attend Meetings or independent congresses, including professional education credits and capability-building sessions (See Section 9 and the *Global Standard on Meetings*);

h) the engagement of Third Parties to provide Services, including compensation and expense reimbursement (See Section 10 and the *Global Standard on Engaging Third Parties*); and

i) support for External Stakeholders for Non-Interventional Studies and Investigator Sponsored Studies (See Sections 13 and 14).

#### 2.3 You must not Give or Receive something of value that is intended or could be seen as improper influence.

If you are in doubt about any Interaction, you must consult with your line manager or your relevant Legal and/or Compliance partner for appropriate guidance.

2.4 All monetary payments by the Company to Third Parties that are permitted by this Policy must be made via an approved Company financial payment system by bank transfer, cheque or company credit card, must not take the form of cash or cash equivalent (e.g., debit cards, gift cards, gift cards, gift cards), and must be accurately and appropriately recorded in the Company's books and records.

All such payments may also be made via a specifically authorised Third Party (unless otherwise noted in this Policy or supporting Global Standards), when genuine business needs require, and Relevant Procedures (with adequate controls) support such an arrangement. In such cases, the Third Party must be contractually obligated to accurately document, track and report to the Company the amounts paid on its behalf, as required by the Relevant Procedures.

This Section 2.4 prohibits cash and cash equivalent payments by Employees (or Third Parties acting on the Company's behalf), except as specifically permitted by Relevant Procedures established or approved by the Global Finance function. Also, see paragraph 1.18 of the *Global Standard on Items of Value and Hospitality* for requirements regarding exceptional Cultural Courtesy Gifts in the form of cash or cash equivalent.

#### 2.5 You must not Give a Bribe.

Give means to directly or indirectly offer, promise or give, or to authorise such actions.

You must not Give something of value to any Third Party or any fellow Employee that is intended or could be seen to:

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a) influence or reward an official action or decision (e.g., by a Public Official);

b) enable or induce a Third Party or fellow Employee to perform their function improperly, or make any decision or take any action favourable to the interests of the Company (or You) on an improper basis, or reward them for doing so;

c) provide incentive or reward to a Third Party for past, present or future willingness to prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve, supply or use any Company Product or service; or

d) obtain or retain improper business, or secure any improper professional or personal advantage.

#### 2.6 You must not Receive a Bribe.

Receive means to directly or indirectly solicit, agree to receive or accept, or to authorise such actions. You must not Receive something of value from any Third Party or any fellow Employee that is intended or could be seen to:

a) compromise Your independence or judgement;

b) enable or induce You to perform Your function improperly, or make any decision or take any action favourable to the interests of the Third Party (or fellow Employee) on an improper basis, or reward You for doing so; or

c) obtain or retain improper business, or secure any improper professional or personal advantage.

#### **3. ITEMS OF VALUE & HOSPITALITY**

#### 3.1 You must not Give or Receive Items of Value or Hospitality that are intended or could be seen as improper influence.

To the extent appropriate, Business Units must establish Relevant Procedures on actual or perceived value and frequency when Giving and Receiving Items of Value and Hospitality. These Relevant Procedures must include specific limits on value (modest) and frequency (occasional) and definitions for "modest" and "occasional," to guide Employees on appropriate value and frequency levels that would not create actual or perceived improper influence, taking into account local custom and practice (See paragraph 2.1 of the *Global Standard on Meetings*).

To the extent appropriate, Business Units must establish Relevant Procedures to enable the Company to satisfy transparency obligations, with respect to the Giving of Items of Value and Hospitality to External Stakeholders.

Items of Value and Hospitality that exceed Company limits, either separately or in total, to or from the same individual or organisation, are prohibited.

Any Giving or Receiving of Items of Value or Hospitality that is based upon a genuine personal relationship independent of the Company and that is personally funded by the individuals involved (without Company reimbursement) is permissible and is not restricted by this Policy, if it is not intended and could not be seen as improper influence.

## 3.2 See Section 2 of this Policy and the *Global Standard on Items of Value and Hospitality* for further requirements on Items of Value and Hospitality.

#### 4. PRICING, DISCOUNTS & REBATES

4.1 To the extent appropriate, Business Units must have an approved pricing model in place, based on objective criteria, to govern the pricing, rebates and discounts (and other commercial advantages or favourable terms) that can be Given to Third Parties.

The pricing model must be reviewed on a regular basis by the head of the relevant Business Unit or designee to ensure appropriateness and transparency.

These Business Units must document the purpose of any prices, rebates or discounts (or other commercial advantages or favourable terms) Given to Third Parties that fall outside the approved pricing model, and this documented purpose must be approved by the head of the relevant Business Unit or designee to ensure appropriateness and transparency.

#### 4.2 See Section 2 of this Policy for further requirements on prices, discounts and rebates.

#### 5. CONTRIBUTIONS (DONATIONS, SPONSORSHIPS & PARTNERSHIPS)

### 5.1 The Company is committed to making a positive impact on Our local communities and supporting the work of others in the healthcare and scientific arenas.

Contributions may be classified as Donations, Sponsorships or Partnerships, and may take the form of financial or non-financial support (e.g., funds or inkind assistance, such as resources, facilities or employee time).

Contributions may generally only be Given for legitimate scientific, educational and/or charitable purposes to support the following: health or healthcare, medical or scientific education, advances in medical or scientific research and disaster relief. Contributions may also be Given for other purposes on an exceptional basis, only with senior management approval, as set out in Relevant Procedures.

For the avoidance of doubt, this Section does not prohibit individual Employees from supporting charities and other organisations in a purely personal capacity and without any involvement of the Company, if the support meets the requirements of Section 8 of this Policy. This Section 5 also does not prohibit Employees from organising charitable efforts on the Company premises (such as a local food drive or book drive), with line manager approval, where Employees use only their personal funds and resources to participate, if the support meets the requirements of Section 8 of this Policy.

Generally, Contributions to support a Meeting or other event must only be Given where the venue and location of the supported event are appropriate and conducive to the intended purpose, and where any Meals or other Hospitality provided by the Company or by the recipient of the Contribution are modest and incidental to the purpose of the event. See the *Global Standard on Contributions*, the *Global Standard on Items of Value and Hospitality* and the *Global Standard on Meetings* for specific requirements and exceptions.

Certain charitable Donations, Sponsorships and Partnerships that meet the relevant criteria described in the *Global Standard on Contributions* and the *Global Procedure and Guidance Community Investment* specifically qualify as Community Investment Contributions.

### 5.2 Contributions may only be given to reputable, recognised and independent institutions or other legitimate, established organisations, and only for legitimate purposes.

The relevant Business Unit managing the Contribution must conduct appropriate due diligence on the proposed recipient of any Contribution to establish that the proposed recipient satisfies the requirements of this Section 5.2 and to establish that Contribution will be well used. In addition, the relevant Business Unit may agree upfront with the recipient organisation to conduct appropriate post-funding review (e.g., review of a summary of the completed projects or other results of the

In addition to the requirements of Section 2, a Contribution must not be Given for any other improper purpose or use, including, but not limited to, the following:

a) to help offset an External Stakeholder's cost of purchasing or reimbursing Company Products or to influence any other decisions about listing, purchasing or reimbursing of Company Products;

b) to organisations or activities that are known to discriminate on any unlawful basis;

c) to support programming or editorial content containing gratuitous violence or sexually explicit material or any activity that does not reflect the values and/or mission of the Company, or could cause embarrassment to the Company; or d) to support any activities prohibited by Relevant Procedures.

Contributions that might be considered as excessive or inappropriate in scale and/or affiliation are not permitted.

Contributions must not be Given to avoid the restrictions on Giving Items of Value and Hospitality to Third Parties (See Section 3 and the *Global Standard on Items of Value and Hospitality*).

5.3 Contributions must not be Given to any organisation for the personal benefit of any individual or Healthcare Professional ("HCP") practice (i.e., a group of HCPs sharing premises or other resources) selected by the Company, or to disguise or conceal any such personal benefit (except as permitted in paragraph 4.5 of the *Global Standard on Contributions* regarding Fellowships and Preceptorships for scientists to support research activities).

Contributions must not be Given by the Company directly to an individual or HCP practice.

For the avoidance of doubt, direct Company support for individual External Stakeholders to attend Meetings or independent congresses is not considered to be a Contribution for purposes of this Policy and is permissible only in limited circumstances (See section 3 of the *Global Standard on Meetings*).

For the avoidance of doubt, awards to individuals are not considered Contributions. See the *Global Standard on Items of Value and Hospitality* for requirements regarding awards and awards ceremonies.

An individual who formally represents an organisation may request a Contribution from the Company on behalf of the organisation, and such request must be considered and processed as required by Relevant Procedures. Contributions must not be Given to an organisation at the request of any other individual (e.g., to a Public Official's preferred charity), except for Sympathy Gifts Given to a designated non-profit organisation as a memorial in the event of a death, or Contributions Given at the request of an Employee as part of a Company matching fund programme.

Contributions must not be Given to financially benefit HCPs or HCP practices by replacing any assets or funding any activities that they would be expected or required to provide themselves to fulfil obligations they have under local law, contract or customary business practice. For example, Contributions must not be Given to improve business efficiencies or administrative processes of an HCP or HCP practice, such as support for billing or taxes. For the avoidance of doubt, Contributions to support HCP education are permissible, in the interest of improving Patient care and/or Patient health.

#### 5.4 See Section 2 of this Policy and the Global Standard on Contributions for further requirements on Contributions.

Contributions must not be Given by Third Parties on behalf of the Company, except for Company Product Donations (See the *Global Procedure and Guidance Community Investment* and the *Global Guidance for Product Donations*).

For the avoidance of doubt, Contributions do not include Political Support or participation in Political

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#### 6. POLITICAL SUPPORT & POLITICAL ACTIVITIES

6.1 Employees must not Give Political Support on behalf of the Company unless specifically authorised to do so by the Government Affairs function or the Reviewer.

Third Parties must not Give Political Support on behalf of the Company under any circumstance. The Company will not reimburse in any way or form any Third Party or non-authorised Employee for Giving Political Support.

Political Support may only be Given where it is expressly permitted by local law and where acceptable as part of local custom and practice.

All Political Support must be Given directly to the recipient organisation or individual. The name of the organisation or individual, purpose, nature and value of the Political Support and the date of the Political Support must be properly documented and recorded in the Company's books and records, to enable public disclosure.

The Government Affairs function will establish or approve Applicable Internal Review Procedures for the Giving of Political Support.

### 6.2 Employees and Third Parties must not participate in Political Activities on behalf of the Company unless specifically authorised to do so by the Government Affairs function or the Reviewer.

The Government Affairs function will establish or approve Applicable Internal Review Procedures for participation in Political Activities.

### 6.3 The Company recognises the rights of Employees to use their own funds, time and other personal resources to Give Political Support or to participate in Political Activities.

You must ensure that you do not act or appear to act as a representative of the Company when participating in Political Activities or Giving Political Support in a personal capacity. You must make it clear that your views and actions are Your own, and that any Political Support You provide is Given on a personal basis, using Your own funds, time or other personal resources.

6.4 See Section 2 of this Policy for further requirements on Political Support and Political Activities.

#### 7. PAYMENTS TO PUBLIC OFFICIALS & PUBLIC SECTOR ORGANISATIONS

7.1 The Company does not permit Employees or Third Parties providing Services to Give Facilitation Payments, either directly or indirectly, to Public Officials (including HCPs and other individuals employed by Public Sector Organisations), regardless of whether such payments are nominal in amount.

Employees and Third Parties must not attempt to conceal or disguise Facilitation Payments to avoid the requirements of this Section.

The nature of the Company's business involves legitimate Interactions with a range of Public Officials. Examples include Public Officials responsible for issuing Company Product licences, making Company Product listing decisions, determining Company Product pricing and payment, providing permits and regulatory Authorisations and conducting facility inspections.

You may Give payments to individual Public Officials where they are engaged to provide legitimate Services (See Section 10). You must not Give any other payments to individual Public Officials unless such payments are required or otherwise expressly permitted by local law and not otherwise prohibited by this Policy.

You may Give legitimate and lawful payments to Public Sector Organisations with respect to taxes, permits, licences, inspections and other fees required or otherwise expressly permitted by local law and not otherwise prohibited by this Policy. Official government receipts must be obtained to support all such payments.

# 7.2 The Company recognises that, in exceptional circumstances, payments may be demanded under duress from Employees or Third Parties providing Services. It is permissible for Employees and Third Parties to Give payments demanded under duress, where there is reasonable fear for personal safety.

Duress describes situations of actual or threatened violence or imprisonment to force a person to act against their will. The Company is committed to ensuring the safety of its Employees and Third Parties and does not expect them to compromise their safety in such situations.

Employees and Third Parties must promptly report in writing to their line manager all incidents where:

a) Facilitation Payments are requested but not paid; or

b) payments are demanded under duress, whether paid or not.

The line manager must then promptly inform the relevant Legal partner of such incidents in writing and ensure that any payments actually made are properly documented and recorded in the Company's books and records. The line manager must also consult with the relevant Legal partner regarding the reporting of such incidents to the relevant authorities and the steps to be taken to prevent recurrence.

#### 7.3 See Section 2 of this Policy for further requirements on payments to Public Officials and Public Sector Organisations.

#### 8. AVOIDING CONFLICTS OF INTEREST

# 8.1 You must ensure that Your interests, activities and associations outside of the Company do not result in actual, apparent or potential Conflicts of Interest with Your professional duties and decisions as an Employee, by directly or indirectly compromising Your independence or professional judgement, or creating an appearance of doing so.

You must not allow, or appear to allow, a personal relationship to influence Your decision-making or judgement. You must ensure that the Company's interests are paramount when business opportunities are assessed and commercial decisions are taken.

You may make personal financial investments, pursue other business interests and maintain social relationships with people You meet through Your Employment, if all of the relevant requirements of this Section of the Policy are met. You must ensure that these Interactions do not result in actual, apparent or potential Conflicts of Interest with the Company's business activities.

You must not use Company resources or your position as an Employee for Your own personal benefit or for the benefit of Your relatives, friends or other associates.

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#### 8.2 You must inform Your line manager in writing of any actual, apparent or potential Conflicts of Interest at the time they become known. Engagement Owners must also inform their line managers in writing of any actual, apparent or potential Conflicts of Interest of a Third Party providing Services, at the time they become known.

Line managers must provide written direction on how to resolve or avoid the Conflict of Interest after obtaining any necessary advice from the relevant Legal and/or Compliance partner.

If You, a relative or close friend has a financial or management interest in a Third Party (other than a nominal shareholding interest through a publiclyavailable investment), You must disclose the situation as a potential Conflict of Interest to Your line manager. You must not participate in any purchasing or other Company decisions related to that Third Party.

# 8.3 You must not do any volunteer or paid work outside of the Company related to Your Company work responsibilities or work product (e.g., speaking engagement, authoring or publishing) unless You obtain written approval from Your line manager, on the basis that such work is unlikely to create an actual, apparent or potential Conflict of Interest and on the basis that any payment is not intended and could not be seen as improper influence.

For all such work, You may Receive necessary and modest travel, accommodation, Meals and other directly related, incidental expenses, with written line manager approval, on the basis that such expenses are not intended and could not be seen as improper influence.

### 8.4 You must not accept any appointment to the Board of Directors of an external organisation in the healthcare or scientific arena, unless You obtain written approval from Your line manager.

Approval should not normally be provided for directorships of Third Parties who are conducting, or may conduct, business directly within Your scope of responsibility or where You will gain a financial benefit that could be open to question or misinterpretation if publicly disclosed.

#### 8.5 You must not use non-public Company information for personal gain.

You must not pass such information to anyone else (either inside or outside the Company), who does not have a legitimate need for the information.

#### 8.6 See Section 2 of this Policy for further requirements on Conflicts of Interest.

#### 9. MEETINGS

### 9.1 Organising or supporting Meetings with External Stakeholders is part of Our business. Where doing so, You must follow the requirements listed in the Global Standard on Meetings.

The location, venue, conduct and other arrangements made for Meetings must be modest, conducive and appropriate to the purpose of the Meeting.

#### 9.2 Meetings must always have a scientific, medical education and/or other legitimate business purpose, which must be clearly stated.

The Company may Give a Contribution (See Section 5) to a Meeting organiser to support the conduct of a Meeting (e.g., a Sponsorship). Any such Contribution must meet the relevant requirements of both the *Global Standard on Contributions* and the *Global Standard on Meetings*, with respect to the substance of the Meeting as well as the conduct and arrangements made for the Meeting.

#### 9.3 See Section 2 of the Policy and the Global Standard on Meetings for further requirements on Meetings.

The Global Standard on Meetings also includes specific requirements on Company support for External Stakeholders to attend independent congresses.

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#### **10. ENGAGING THIRD PARTIES & ENSURING COMPLIANCE**

#### 10.1 The Company is committed to engaging only those Third Parties who embrace standards of ethical behavior that are consistent with Our own.

Engagement Owners are accountable for ensuring that the Third Party's reputation and conduct are consistent with the Company's ethical standards (See Section 10.5).

For the avoidance of doubt, engagements do not include informal, routine business Interactions between Employees and Third Parties, where no Services are provided and no payment is Given (e.g., informal discussions at professional Meetings or independent congresses for scientific exchange, or routine phone calls in the normal course of business).

### 10.2 Engagement Owners must engage a Third Party only where there is a genuine business need for Third Party Services and must only engage the necessary and appropriate Third Parties to provide those Services.

Engagement Owners must ensure that the selected Third Party has the relevant qualifications, expertise, reputation, knowledge, experience and ability to fulfill the genuine business need, and is the most appropriate choice to provide the Services.

External Stakeholders may be engaged by the Company (either directly or through a specifically authorised Third Party on the Company's behalf) to provide Services. Such Services include, but are not limited to: providing input and information as an Advisor or consultant, speaking at Meetings (e.g., a Promotional Speaker), acting as a clinical investigator or a study site, or educating or otherwise presenting to Representatives at Representative training or business cycle sessions. Patients and Other Third Parties may also be engaged by the Company to provide Services.

Each engagement with an External Stakeholder or Patient for Services must be documented in a signed contract. If the External Stakeholder or Patient is not accepting compensation, or payment or reimbursement of expenses, the requirement for a signed contract may be waived with documented line manager approval.

Each engagement with Other Third Parties for Services must be documented in the format required for the particular Services to be provided, such as a contract, Terms & Conditions, a Purchase Order or other required documentation of offer and acceptance of Services.

Third Parties must not provide any Service on behalf of the Company, in connection with the execution of an engagement or otherwise, unless the Service has been specifically authorised in the signed contract (or other required documentation of the engagement) between the Company and the Third Party, or has otherwise received appropriate documented approval.

You must not Give any Payments for Voluntary or Incidental Activities to any Third Party.

10.3 Our Interactions and engagements with External Stakeholders and Patients must at all times be professional exchanges, designed to enhance the practice of medicine, to benefit Patients, or to fulfill a genuine business need.

In no circumstances may the engagement of an External Stakeholder or Patient be used as a means to gain access or to disguise Promotional Activities, or create an appearance of doing so.

### 10.4 To the extent appropriate, Business Units must establish adequate Relevant Procedures to mitigate the risk of actual or apparent improper influence over individual External Stakeholders engaged to provide Services, and for monitoring compliance.

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To the extent appropriate, Business Units must establish Relevant Procedures that include Fair Market Value guidelines, as well as limits on aggregate compensation provided to individual External Stakeholders and limits on frequency of engagement of individual External Stakeholders. The scope of such guidelines and limits ultimately established will vary, based upon locality and/or function. In developing Fair Market Value guidelines, these Business Units must consider local established compensation levels, varying levels of expertise and/or prominence of Third Parties, varying types and durations of Services to be provided, and the spirit and principles of this Policy.

Third Parties must be paid compensation consistent with and no greater than Fair Market Value, taking into account individual qualifications, experience, ability and reputation, and only for the Services actually provided, consistent with the terms of the engagement.

To the extent appropriate, Business Units must establish Relevant Procedures to enable the Company to satisfy transparency obligations, with respect to payments made to External Stakeholders.

10.5 Prior to the selection and engagement of a Third Party, Engagement Owners must conduct appropriate and proportionate risk assessments, as well as associated, due diligence procedures (if necessary), according to Relevant Procedures. Engagement Owners must take these steps to ensure that the Third Party's reputation and conduct relating to the execution of the engagement are consistent with the Company's ethical standards, with respect to all relevant areas of risk.

To the extent appropriate, Business Units must establish Relevant Procedures to guide Engagement Owners on how to assess, develop, communicate, implement and enforce required compliance expectations for Third Parties. Required compliance expectations will vary, based upon the nature of the Third Party, the Services to be provided and the nature of the associated risks. Based upon the risk assessment and outcomes for a particular Third Party, Engagement Owners may be required to implement one or more of the following actions with respect to that Third Party:

a) improvement plans or action plans;

b) monitoring or auditing requirements;

c) contractual obligations, including written assurances or commitments by the Third Party;

d) provision of Global Policies, Global Standards, Relevant Procedures or other reference materials, and/or associated training;

e) prior review of the engagement or aspects of the engagement or Services from the relevant Legal and/or Compliance partner; and/or

f) other actions to mitigate identified areas of risk, such as contractual risk mitigation clauses.

At a minimum, Engagement Owners must not engage a Third Party where it is known, or where there is a reason to believe, that the Third Party has Given or Received Bribes, unless the Engagement Owner has documented his/her satisfaction with all of the following, in consultation with the relevant Legal and/or Compliance partner:

a) the actions and improvements undertaken by the Third Party to remediate the concerns and/or behaviour;

b) the current level of compliance by the Third Party; and

c) evidence of the Third Party's ability to provide strong governance and monitoring and to prevent future occurrences of such concerns and/or behaviour.

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Engagement Owners, in consultation with an appropriately senior level of management, must periodically reassess existing Third Party relationships, following the required timeframes outlined in the Relevant Procedures, and taking into account any unanticipated changes in the conduct, reputation or risks related to the particular Third Party.

### 10.6 See Section 2 of this Policy for further requirements on Engaging Third Parties. Engagement Owners must also refer to the *Global Standard on Engaging Third Parties* for further requirements, prior to entering into any engagement with a Third Party.

#### **11. PROMOTIONAL & NON-PROMOTIONAL ACTIVITIES & MATERIALS**

11.1 A key part of Our business is to provide information about Company Products and, where and when appropriate, to Promote their use. Promotional and Non-Promotional Activities and Materials must always be accurate, fair and balanced and not misleading in their content.

The Company has a duty to support the safe and effective use of Company Products. While the Company cannot provide medical advice to External Stakeholders or Patients, the Company may engage in Promotional and Non-Promotional Activities where this is appropriate and permitted by local law. For example, Promotional and Non-Promotional Activities directed to Patients (i.e., "direct to consumer" activities) may only be undertaken where this is permitted by local law.

Our activities must never undermine the relationship between HCPs and their Patients. All Promotional and Non-Promotional Activities and Materials directed to HCPs or Patients must therefore support HCPPatient Interactions and must allow the therapeutic value of Company Products to be assessed by HCPs in the interest of Patient care.

Promotional and Non-Promotional Materials about Company Products directed to Patients must be understandable, taking into account varying levels of education between and within populations. These Materials must be educational, scientific and balanced, and should encourage the Patient to seek further information from the appropriate HCP.

The Company may display Promotional or Non-Promotional exhibits, either in conjunction with a Meeting or as a stand-alone activity, according to the requirements included in Relevant Procedures. See the *Global Standard on Meetings* for further requirements on exhibits (with or without a Meeting).

### 11.2 The Company must only Promote Company Products once the time is right to do so (which will never be before the Company Product or Use has received the necessary Authorisation), and only consistent with the approved labeling.

Promotional Activities and Promotional Materials must meet all of the following requirements:

a) They must provide a fair balance between a Company Product's benefits and its risks or limitations. They must not exaggerate the benefits or downplay the risks or limitations;

b) They must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way, and must not involve false or unapproved statements about other companies' products. Company Products must only be Promoted on their own proven merits; and

c) They must be capable of substantiation by reference to the approved labeling or scientific evidence consistent with the approved labeling, and must not involve discussions of Unauthorised Company Products or Uses.

Representatives and other Employees in customer-facing roles (e.g., public relations, telemarketing, Marketing, Medical) must be trained as appropriate to their role and must do all of the following in an accurate, responsible manner:

a) They must possess sufficient Company Product and disease area knowledge to present information to External Stakeholders or Patients, as appropriate to their role; and

b) They must be able to recognise inquiries regarding Unauthorised Company Products or Uses and refer these inquiries to Scientifically Trained Personnel.

All training and educational materials must be approved through the Applicable Internal Review Procedures.

Representatives and other Employees in customer-facing roles must have available a copy of the current, approved labeling for each Company Product or Use discussion they initiate with External Stakeholders.

Any revisions to the approved labeling must be communicated to Representatives and other relevant customer-facing Employees as soon as reasonably possible.

Promotional Activities that are directed to External Stakeholders must be confined to those individuals who are recognised practitioners in the area of medicine concerning Authorised Company Products or Uses.

Promotional Activities and Promotional Materials must not be directed to External Stakeholders who have requested that they not be sent such information.

#### 11.3 Non-Promotional Activities and Materials (including those regarding disease awareness programs) must not be used to Promote Company Products. Non-Promotional Activities and Materials must be presented in an objective, balanced manner, and must be scientific in tone, language, appearance and intent.

Where local law allows the Company to respond to Company Product-related questions from Patients, any such response may only be made by Scientifically Trained Personnel or other specifically authorised Employee or Third Party, according to Relevant Procedures. Patients communicating with the Company must not be given medical advice, but must instead be referred to their HCP.

Specifically authorised Employees are permitted to proactively issue press releases or other Non-Promotional Materials, such as those relating to financial or investor information.

Scientifically Trained Personnel are permitted to proactively present scientific data or findings regarding Authorised or Unauthorised Company Products or Uses with a view to generating further scientific insight, supporting the medical community in learning about scientific/medical progress or sharing information on current medical practice, such as at scientific congresses or similar events.

All inquiries concerning Unauthorised Company Products or Uses (whether from External Stakeholders or Patients) must be referred to Scientifically Trained Personnel. All responses to such inquiries, either oral or written, must then come directly and only from such Scientifically Trained Personnel, and must meet all of the following requirements:

a) Information must only be provided in response to unsolicited inquiries;

b) Information must be accompanied by the approved labeling, as applicable;

c) All responses must be limited to the scope of the inquiry and must provide data which are appropriate to the source of the inquiry; and

d) All responses must contain (as relevant) a statement that the information requested involves an Unauthorised Company Product or Use and that the Company does not recommend Unauthorised Uses of the Company Product.

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### 11.4 Promotional Materials and Non-Promotional Materials must be approved through the Applicable Internal Review Procedures. Any modification to approved Promotional or Non-Promotional Materials must also be approved through the Applicable Internal Review Procedures.

You must not create, use or provide "home-made" or other unapproved Promotional or Non-Promotional Materials on any topic. You must not alter any approved Promotional or Non-Promotional Materials in any way, unless such creation or alteration is for the express purpose of submitting these Materials for review and approval.

Promotional and Non-Promotional Materials must be assigned an expiration date upon approval, must be monitored for expiration date and must not be used after the expiration date specified in the original approval, unless they are formally re-approved through the Applicable Internal Review Procedures.

Promotional and Non-Promotional Materials must be accompanied by the approved labeling where applicable, as required by Relevant Procedures.

#### **12. PRE-AUTHORISATION ACTIVITIES & MATERIALS**

12.1 It is permissible to engage in Pre-Authorisation Activities (i.e., Profiling, Market Access and Pre-Authorisation Training activities), and to use materials supporting such activities, to prepare for a successful commercial launch of a Company Product or Use. Pre-Authorisation Activities must not be used to disguise Pre-Authorisation Company Product Promotion, or create an appearance of doing so.

Materials used for Pre-Authorisation Activities must be approved through the Applicable Internal Review Procedures.

### 12.2 Relevant Employees (e.g., Employees in the Marketing, Medical or Sales functions) and specifically authorised Third Parties may Profile customers prior to Authorisation of a new Company Product or Use, to assist in segmentation and targeting activities.

Profiling Activities may only be conducted if all of the following requirements are met:

a) Employees engaging in Profiling must use materials (e.g., scripts) that have been approved through the Applicable Internal Review Procedures;

b) These materials must be structured to allow for a brief conversation to collect broad information about an External Stakeholder's involvement in a disease area, such as treatments and classes used (e.g., "What classes do you use to treat this disease state?"), as well as their needs and the needs of their Patients;

c) These materials must contain clear instructions on proper execution. These materials must contain a clear, prominent prohibition against engaging in Promotional Activities about the new Company Product or Use during a Profiling conversation;

d) These materials must not contain targeted questions that are specific or unique to a Company Product or Use;

e) If asked by the External Stakeholder about the purpose of the Employee's questions, Employees may objectively state that the Company has submitted a Company Product or Use for regulatory Authorisation. Employees must not proactively discuss the Company Product or Use in any further detail; and

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f) In the event that the External Stakeholder asks for more details about the Company Product or Use during a Profiling discussion, Employees (other than those in the Medical function) may provide appropriate contact information for the External Stakeholder to submit his/her own request for such information (i.e., a "professional information request"), but such Employees must not directly respond to the request or submit the request on behalf of the External Stakeholder. Employees in the Medical function may directly respond to the request and may submit a professional information request on behalf of the External Stakeholder.

During, and in support of, internal Company segmentation and targeting activities, relevant Employees may share existing knowledge and review and share prescribing data and other Company-purchased or publicly available information.

For the avoidance of doubt, Profiling activities are also permitted after Authorisation of a new Company Product or Use.

12.3 Relevant Employees other than Representatives or their first line managers (e.g., Employees in the Market Access or Medical functions) and specifically authorised Third Parties may perform Market Access activities prior to Authorisation of a new Company Product or Use, by providing Company Product or relevant disease area information to Healthcare Organisations ("HCOs") (i.e., payers) or Public Officials to support regulatory Authorisation, pricing or reimbursement discussions.

For the avoidance of doubt, Market Access activities are also permitted after Authorisation of a new Company Product or Use.

12.4 Pre-Authorisation Training on Unauthorised Company Products or Uses may be initiated as necessary to allow for sufficient time to study and understand the new information presented regarding the Company Product or Use, disease area, disease management, External Stakeholder and Patient needs and/or the current market, including the current state of medical practice, competitors and existing therapies, and treatment protocols and Guidelines.

In making the determination of the timing and sequencing of Pre-Authorisation Training for a particular new Company Product or Use (as a guideline, no longer than 60 days before the expected Authorisation date), the Reviewer must seek input from Employees in the Medical, Training, Commercial, Compliance and/or Legal functions ("contributing functions"), as applicable, and must take into account all of the following considerations:

a) whether the training will involve a new or familiar disease area;

b) whether the training will involve an Unauthorised Company Product or an Unauthorised Use of an Authorised Company Product;

c) the likelihood of receiving significant changes and comments to the proposed labeling submitted to the regulatory agency responsible for Authorisation;

d) the risks of pre-Authorisation Promotion arising from providing training on Unauthorised Company Products or Uses and/or Promotional messages; and

e) other factors deemed relevant to the particular proposed training by the Reviewer and/or contributing functions, who are evaluating the training need and the associated risks.

All Pre-Authorisation Training materials must be marked with a clear, prominent, appropriate disclaimer stating that the material is strictly for internal purposes only (e.g., "For Internal Use Only"). These materials may include information on Unauthorised Company Products or Uses or relevant disease areas, and may include relevant reprints. These materials, or the information they contain, must not be shown, discussed, or distributed outside the Company, except where an appropriate Third Party must also be trained (e.g., a contract sales force or sales force of a co-promotional partner).

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After the relevant Authorisation has been obtained, information included in Pre-Authorisation Training materials that is appropriate for discussion with External Stakeholders or Patients may be included in

Promotional and/or Non-Promotional Materials specifically designed and approved for those purposes.

#### **13. NON-INTERVENTIONAL STUDIES**

#### 13.1 Non-Interventional Studies ("NISs") must address a scientifically and medically valid question to which the Company needs the answer.

These may include: the effectiveness and/or safety of a Company Product, medical practice and drug utilisation characterisation, disease epidemiology and clinical epidemiology, burden of disease (e.g., costs and quality of life) or other Patient-reported outcomes, and compliance/adherence to a therapeutic regimen.

### 13.2 The Company must not be involved in the decision to place a particular Patient on a specific Company Product. That decision is made solely by the Patient's HCP.

An NIS must not be used to induce the use or prescription of a Company Product or to train HCPs on the use of a particular therapy.

Patients must not be given a Company Product or switched to a Company Product for the purpose of taking part in the study.

### 13.3 NISs must be observational in nature and the collected data must undergo a formal analysis by the Company or by a Third Party on the Company's behalf.

Additional diagnostic or monitoring procedures must not be applied to the Patients, and epidemiological methods must be used for the analysis of collected data.

### 13.4 See Section 2 of this Policy for further requirements on NISs. Employees must also refer to the Relevant Procedures (i.e., International Procedures) for further requirements.

All NISs must be registered and their results posted according to the requirements of the Relevant Procedures.

The decision to conduct an NIS and the selection, engagement and payment of NIS investigators must meet all of the relevant requirements of Section 10 of this Policy and the *Global Standard on Engaging Third Parties*.

Support for NISs may be Given by specifically authorised Third Parties on behalf of the Company according to the Relevant Procedures.

#### 14. INVESTIGATOR SPONSORED STUDIES

### 14.1 The Company recognises the importance of Investigator Sponsored Studies ("ISSs") in expanding scientific knowledge related to potential Uses of Company Products.

An ISS may be conducted with Authorised or Unauthorised Company Products or Uses.

All ISSs supported by the Company must be consistent with the research strategy for the relevant Company Product.

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### 14.2 The Company may provide support for an ISS, but must not be considered to be the sponsor or to have any partial sponsorship role in the study in accordance with local law.

The decision to provide support for an ISS must be based on whether the study expands scientific knowledge related to potential Uses of Company Products and/or associated disease area(s) through a properly conducted independent clinical study that will result in the publication of meaningful new data.

### 14.3 See Section 2 of this Policy for further requirements on ISSs. Employees must also refer to the Relevant Procedures (i.e., International Procedures) for further requirements.

A contract approved through the Applicable Internal Review Procedures must be negotiated and signed by authorised representatives of the Company and the sponsor and, as applicable, the investigator, prior to study initiation.

The level of financial support that may be provided will vary among countries. It must always be consistent with Fair Market Value for the activities to be conducted as part of the clinical trial, and payments must be milestone-driven.

The Company must not provide Company Product Samples for use in ISSs.

Support for ISSs may be Given by specifically authorised Third Parties on behalf of the Company according to the Relevant Procedures.

#### GLOSSARY

Advisory Boards refers to internal Meetings organised by the Company where the Company engages External Stakeholders (i.e., "Advisors") to provide the Company with independent advice and input within their area of expertise.

Advisors refers to the definition provided within the definition of Advisory Boards.

**Applicable Internal Review Procedures** refers to the review and approval requirements for Interactions and supporting materials, as set out in Relevant Procedures. These requirements include, but are not limited to, review and approval by Nominated Signatories, Scientifically Trained Personnel, the Legal Department, other specialist functions (e.g., Procurement) or line managers, as appropriate (i.e., "**Reviewers**"). Reviewers must take into account the substance, as well as the intended purpose and audience, when approving Interactions or supporting materials, and approval must be obtained in advance of any Interaction or use of supporting materials.

Authorisation or Authorised refers to approval of a Company Product or Use by the relevant local regulatory agency, to permit entry into the local market or to permit inclusion into the local approved labeling.

**Bribe** or **Bribery** refers to Giving or Receiving of something of value that is intended or could be seen as an inducement or reward for improper behaviour (i.e., behaviour that is dishonest or illegal or a breach of duty of impartiality, trust or good faith), to influence any official act or decision, or to obtain or retain business, favourable treatment or other advantage or benefit. Giving or Receiving of Bribes is a wellrecognised form of corruption (collectively referred to as "improper influence" through this Policy).

**Business Unit** refers to a distinct section of the Company, such as a consolidated legal entity, a local marketing organisation, a Senior Executive Team ("SET") function, a department or operating entity within a SET function, or, in some cases, a cross-functional unit comprising Employees with common responsibilities.

**Community Investment Contributions** refers to certain charitable Donations, Sponsorships or Partnerships Given by the Company to non-profit organisations that meet the relevant criteria described in the *Global Standard on Contributions* and the *Global Procedure and Guidance Community Investment*.

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Company or Our refers to AstraZeneca PLC and its consolidated legal entities worldwide, including MedImmune.

**Company Product** refers to any pharmaceutical or biological product or medical device that is developed and/or marketed by the Company, including investigational products/devices and co-promoted products/devices. For purposes of this Policy, references to Company Products include both Authorised and Unauthorised Company Products, unless specifically noted.

**Conflicts of Interest** refers to situations where personal, financial or other interests, activities or associations outside of the Company may influence or compromise, or could be seen to influence or compromise, the professional duties and decisions of an Employee or Third Party providing Services.

**Contributions** refers to financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or Employee time) Given by the Company to a Third Party. Contributions may be classified as either Donations, Sponsorships or Partnerships.

Cultural Courtesy Gift refers to a personal Gift traditionally given to acknowledge a significant national, cultural or religious holiday or event.

**Donations** refers to the type of Contributions Given by the Company to a non-profit or Public Sector Organisation, that may or may not be for a designated pre-defined initiative.

Employee or You(r) refers to all Company full-time and part-time directors, officers, employees and temporary staff worldwide.

Engagement Owners refers to Employees responsible for engaging with and managing the Services provided by a Third Party.

**External Stakeholders** refers to the category of Third Parties who are external customers and other relevant stakeholders, including Healthcare Professionals ("HCPs") and Healthcare Organisations ("HCOs"), Scientifically Trained Personnel engaged by the Company to provide Services, Public Officials, Patient Groups and other relevant public and private organisations and groups.

A **Facilitation Payment** (or "grease" payment) is an unofficial payment or anything else of value Given to Public Officials (including HCPs and other individuals employed by Public Sector Organisations) to secure or speed up routine actions that the recipient has a duty to perform. Examples include additional payments required to issue permits or licences, speed passage through immigration controls and release goods held at port or in customs.

**Fair Market Value** refers to the amount that a service or item would be worth to a typical buyer who is under no duty to purchase and who receives no special advantage. Fair Market Value is determined by the home country of the relevant service provider (who receives payment for the service) or relevant buyer of the item.

**Fellowships** and **Preceptorships** refer to programmes conducted at host institutions and designed to provide basic training (i.e., training necessary to obtain a degree or licence) or advanced education to HCPs or scientists in a particular specialty, therapeutic area or field of research.

Gift refers to an Item of Value that is provided as a mark of appreciation, commemoration or friendship.

Give, Giving or Given means to directly or indirectly offer, promise or give, or to authorise such actions.

**Global Policies** refers to the mandatory documents that support the Company's *Code of Conduct* by setting out the compliance commitments of the Company and the key principles to be followed to meet those commitments.

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**Global Standards** refers to the mandatory documents that support the Global Policies by describing the compliance rules to be followed to deliver the intent stated in the Global Policies or in the Company's *Code of Conduct*.

**Guidelines** refers to any of the following materials and may or may not relate to a specific disease state: practice guidelines, treatment guidelines, medication algorithms, disease definitions or Research & Development quality standards. Guidelines are not intended to refer to treatment guidelines or protocols developed by HCOs, where such development is essential to the business of the HCO (such as a formulary or benefit administrator), or those developed by HCP practices.

**Healthcare Professionals ("HCPs")** and **Healthcare Organisations ("HCOs")** refer to individuals or organisations, respectively, who may or do prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve or supply any Company Product or service, including any members of the medical, dental, pharmacy or nursing professions, and relevant associated administrative staff; and/or hospitals and other care organisations, health plans, health insurers, managed care organisations, pharmacies, formulary or benefit administrators and clinical research organisations, and relevant staff at such entities.

**Hospitality** refers to Meals, travel/accommodation, and other directly related, incidental expenses, as well as invitations or tickets to social or entertainment events. Entertainment events include sporting, theatre, music or recreational events.

Interactions refers to the business and personal interactions and activities described in this Policy.

Interacts refers to the conduct of an Interaction.

**Investigator Sponsored Study (ISS)** refers to a clinical study that is independently initiated, designed and conducted by an external investigator (who assumes both the sponsor and principal investigator role) or medical institution, collaborative research group or academic research organisation (which assumes the sponsor role and appoints principal investigator(s) for the study). For purposes of this Policy, sponsor/investigator is used as a generic term for both situations described above.

**Item of Medical Utility** refers to an Item of Value primarily designed to educate External Stakeholders or Patients or help External Stakeholders educate Patients about disease management in disease state areas relevant to Authorised Company Products or Uses.

**Items of Value** refers to Gifts, Items of Medical Utility, items used to assist in screening or diagnosis of Patients, items linked to the safe and effective administration of Company Products, logistical items, Samples (including Samples vouchers or coupons), awards and Patient Programmes.

Market Access refers to discussions with HCOs (i.e., payers) or Public Officials about regulatory Authorisation, pricing or reimbursement decisions.

**Market Research** refers to the systematic gathering and interpretation of quantitative or qualitative data on the market environment from External Stakeholders or Patients using statistical and analytical methods to gain insight and support decision-making. It does not include the gathering and interpretation of "real world evidence" or Company-purchased HCP-level data.

Meals refers to food and/or beverages.

**Meeting** refers to a planned gathering of External Stakeholders, which the Company organises or supports, either financially or non-financially. Non-financial support includes in-kind assistance, such as resources, facilities or Employee time. Meetings may be for an internal Employee audience, or for an external audience of External Stakeholders and may be held in-person or virtually.

**Non-Interventional Study (NIS)** refers, in general terms, to a study where the assignment of the Patient to a particular therapeutic strategy is not decided in advance by a study protocol but falls within the HCP's current practice, and the prescription of the Company Product is clearly separated from the decision to include the Patient in the study.

**Non-Promotional Activity** refers to any activity that is not a Promotional Activity that is intended to provide scientific or educational information about Company Products, relevant disease areas or health and medicines generally. Non-Promotional Activities may be oral or written and may be conducted through any medium, including the Internet. Non-Promotional Activities may take a number of forms, including, but not limited to, leaflets provided with Company Products, point of sale information, information regarding disease awareness programmes, responses to queries from External Stakeholders or Patients, information provided to inform the development of Guidelines or other information contributing to scientific exchange.

Non-Promotional Materials refers to materials intended to be used during Non-Promotional Activities or to support Non-Promotional Activities.

Our or Company refers to AstraZeneca PLC and its consolidated legal entities worldwide, including MedImmune.

**Other Third Parties** refers to the category of Third Parties who are not External Stakeholders or Patients, including, but not limited to, the media, suppliers, distributors, agents and joint venture, co-promotion, research and licensing partners.

**Partnerships** refers to the type of Contributions Given by the Company in collaboration with a non-profit, for-profit or Public Sector Organisation for a predefined initiative, involving substantive, active Company participation and resulting in the delivery of specific, measurable outcomes. For purposes of this Policy, Partnerships do not include research or commercial collaborations aimed at the development or marketing of Company Products or services for the Company's benefit.

Patient Groups refers to non-profit organisations formally representing the needs of Patients, theirfamilies and other caregivers.

**Patient Programmes** refers to Items of Value, specifically vouchers, rebates, coupons, co-pay assistance cards, motivational information and other programmes and materials designed to increase access and affordability of Company Products or to enhance therapy compliance.

Patients refers to the category of Third Parties who are members of the general public and who use or may use Company Products.

**Payments for Voluntary or Incidental Activities** refers to any compensation or expense reimbursement Given to an individual or organisation as a "thank you" for voluntary activities or for activities that are not necessary to address a genuine business need. They do not include payments made to Third Parties for contracted Services that address a genuine business need.

Policy refers to this AstraZeneca Global Policy on Ethical Interactions.

**Political Activities** refers to attendance or participation in public policy or other political activities, including participation in political conventions or fundraising events for Political Organisations or individual Public Officials and their causes.

**Political Organisations** refers to political parties and their employees, Political Action Committees ("PACs") and other political organisations. Political Support is distinct from Company Contributions to Public Sector Organisations (See Section 5), as well as payments to Public Officials or Public Sector Organisations (See Sections 7 and 10).

**Political Support** refers to financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or Employee time) Given to Political Organisations or individual Public Officials and their causes.

**Pre-Authorisation Activities** refers to Profiling, Market Access and Pre-Authorisation Training activities undertaken by Employees in preparation for Authorisation of a new Company Product or Use.

**Pre-Authorisation Training** refers to Company-provided education to Representatives and/or their first line managers in preparation for Authorisation of a new Company Product or Use.

**Preceptorships** and **Fellowships** refer to programmes conducted at host institutions and designed to provide basic training (i.e., training necessary to obtain a degree or licence) or advanced education to HCPs or scientists in a particular specialty, therapeutic area or field of research.

Presentation refers to each segment of a Meeting, where a distinct speaker is used and/or distinct topic is discussed.

**Presentation Materials** refers to all materials intended to be shown and/or distributed to the speaker or audience before, during or after a Presentation, including but not limited to speaker briefing documents, written summaries of Presentation objectives, slides and reference documents.

**Profiling** (also known as "disease insight visits") refers to discussions with External Stakeholders to gain an understanding of their involvement in a disease area, including therapeutic options, medical gaps, External Stakeholder needs or the needs of Patients. For the avoidance of doubt, Profiling is not considered Market Research.

Promote, Promotion or Promotional refers to the conduct of Promotional Activities.

**Promotional Activity** refers to any activity that is intended or could be seen to Promote the prescription, administration, recommendation, purchase, payment, reimbursement, authorisation, approval, supply or use of Company Products or services. Promotional Activities may be oral or written and may be conducted through any medium, including the Internet.

Promotional Materials refers to materials intended to be used during Promotional Activities or to support Promotional Activities.

**Promotional Speaker Programmes** refers to Promotional Meetings organised by the Company to Promote Authorised Company Products or Uses, where the Company engages External Stakeholders

(i.e., "Promotional Speakers") to speak to other External Stakeholders on behalf of the Company about such topics.

Promotional Speakers refers to the definition provided within the definition of Promotional Speaker Programmes.

Public Official refers to an individual who:

- Holds a legislative, administrative or judicial position of any kind, whether appointed or elected, or is a candidate for such a position, or
- Exercises a public function for a country or territory of a country, or for any Public Sector Organisation of a country or territory, at the national, regional or local level,
- Acts as an official or agent of an international Public Sector Organisation, or
- Is any other employee (including HCPs) of a Public Sector Organisation.

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**Public Sector Organisation** refers to an agency, enterprise, or other entity of a government that sets or administers public policy or exercises executive, political and/or sovereign power through customs, institutions and laws within a country or territory of a country, at the national, regional or local level. It also includes state-owned and state-controlled entities, such as a state-owned or state-controlled hospital, university, energy company, telecommunications company or other similar state-owned or statecontrolled enterprises.

Receive, Receiving or Received means to directly or indirectly solicit, agree to receive or accept, or to authorise such actions.

**Relevant Procedures** refers to the written local and/or functional policies, standards, procedures and guidelines that contain details, processes and controls for compliance with this Policy and the supporting Global Standards.

**Representatives** refers to Employees who are members of any Commercial channel who Promote Company Products directly to External Stakeholders. Representatives may be referred to as sales representatives, service team associates, inside sales agents, medical representatives or other titles, depending upon the relevant local marketing organisation. Representatives include any Third Parties fulfilling such responsibilities on the Company's behalf (i.e., a contract sales force). Representatives do not include other Employees, such as those performing marketing or market access activities.

Reviewers refers to the definition provided within the definition of Applicable Internal Review Procedures.

**Sample** refers to an Item of Value, specifically a unit of pharmaceutical Company Product that is not to be sold but is provided free of charge to an HCP to allow the HCP and appropriate Patients to determine tolerability and effectiveness of the Company Product.

**Scientifically Trained Personnel** refers to individuals employed or engaged by the Company who are highly-trained experts, who have relevant, specialised scientific and/or medical knowledge and whose responsibilities include the provision of scientific and/or medical information. This excludes anyone in the Sales, Marketing or other non-Medical Commercial functions, even if they have scientific or medical training or backgrounds.

Section refers to Sections 1 through 14 of this Policy, listed in the Table of Contents. Each Section covers a category of Interactions.

**Services** refers to the activities performed by a Third Party engaged by the Company. Services include activities performed on behalf of the Company, goods, services or information provided to the Company, or the activities performed in collaboration with the Company.

**Sponsorships** refers to the type of Contributions Given by the Company to a non-profit, for-profit or Public Sector Organisation for a pre-defined initiative, where the Company's name is associated with the initiative and/or the Company receives other substantial recognition for the Sponsorship.

Sympathy Gift refers to a personal Gift to express sympathy for bereavement or serious illness of the recipient or immediate family member.

**Third Party(ies)** refers to any person or organisation who is not the Company or an Employee, with whom Employees Interact. The various types of Third Parties are categorised as either External Stakeholders, Patients, or Other Third Parties. Where a Third Party fits into more than one category, the more restrictive rules apply.

**Uses** refers to the indications, dosing, populations and other uses of Company Products. For purposes of this Policy, references to Uses include both Authorised and Unauthorised Uses of Company Products, unless specifically noted.

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**Unauthorised** refers to a Company Product or Use that has not yet received Authorisation from the relevant local regulatory agency. An Unauthorised Company Product may also be referred to as "investigational." An Unauthorised Use (i.e., an "off-label use") is inconsistent with the local approved labeling for a Company Product.

Voluntary or Incidental Activities refers to any voluntary activities or activities that are not necessary to address a genuine business need.

You(r) or Employee refers to all Company full-time and part-time directors, officers, employees and temporary staff worldwide.

#### REFERENCES

Global Standard on Items of Value and Hospitality

http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global Compliance/effective/Global%20Standard/LDMS 001 00145832.pdf

Global Standard on Contributions <u>http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global Compliance/effective/Global%20Standard/LDMS\_001\_00145831.pdf</u>

Global Procedure and Guidance Community Investment <u>http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global Compliance/effective/Procedure/LDMS\_001\_00146359.pdf</u>

Global Guidance for Product Donations <u>http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global Compliance/Active/Guidance%20Materials/LDMS 001 00146361.pdf</u>

Global Standard on Meetings <u>http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global Compliance/effective/Global%20Standard/LDMS 001 00145768.pdf</u>

Global Standard on Engaging Third Parties

http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global Compliance/effective/Global%20Standard/LDMS 001 00145830.pdf

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#### Exhibit G

#### **Initial Members of the JSC**

#### AstraZeneca

Fouzia Laghrissi Thode, Vice President, Global Product Portfolio Strategy

Elisabeth Björk, Global Product Vice President, Global Medicines Development

Howard Hutchinson, Vice President for Product Licensing, Global Medicines Development

Peter Honig, VP Global Regulatory Affairs, Global Regulatory Affairs

David Snow, President, China & Hong Kong, Global Commercial

AstraZeneca Secretariat: Joseph McCullough

#### FibroGen

Frank Valone

Peony Yu

Al Lin

Michael Lowenstein

Chris Chung

FibroGen Secretariat: Kirara Tsuboi

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#### Schedule G (a)

### Until the date when the JDC has been formed, the JSC delegates the following responsibilities to the Core Joint Project Team. Unless otherwise directed by the JSC, the Core JPT shall:

(i) provide regular reports to the JSC regarding the development of the Product, and discuss, prepare and submit to the JSC for approval annual and interim amendments to the Development Plan (and the Development Budget) for each Product;

(ii) discuss and manage the implementation of the Initial Development Plan;

(iii) discuss the audited final report from the Carcinogenicity Studies, including whether or not a Technical Product Failure has occurred, and provide input thereon to the JSC;

(iv) propose to the JSC particular studies to be conducted;

(v) create, propose for JSC review and approval, and implement the Development Strategy for Development in the Territory and the design of all Clinical Trials and Nonclinical Studies conducted under each Development Plan, including Phase 4 Clinical Trials;

(vi) create and propose the CMC related development plan for JSC review and approval, and oversee any CMC related development activities according to the plan, e.g. stability studies or packaging development, as well as other activities to prepare for supply of drug substance and finished Product for Commercialization, including to oversee the selection process for, and select (pursuant to Section 6.4), a contract manufacturer to be used by FibroGen for commercial supplies;

(vii) allocate budgeted resources and determine priorities for each Clinical Trial and Nonclinical Study under each Development Plan, including Phase 4 Clinical Trials;

(viii) supervise, with regular oversight by the JSC, the conduct of all Clinical Trials and Nonclinical Studies under each Development Plan, including Phase 4 Clinical Trials;

(ix) endorse the selection of Third Party contractors to conduct Clinical Trials of Products;

(x) facilitate, with regular oversight by the JSC, the flow of Information between the Parties with respect to the Development of Products, including Development Data and Astellas Data pursuant to Section 3.10, as well as any other Information related to the Astellas Collaboration that has a material impact on AstraZeneca's rights under this Agreement;

(xi) discuss the priority of life cycle management Development of Products for other indications and propose any such indications to the

JSC;

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(xii) propose to the JSC for approval allocation of primary responsibility as between the Parties for tasks relating to Development of Products where not already specified in the Development Plan;

(xiii) discuss the requirements for Regulatory Approval in the Territory and oversee and coordinate regulatory matters with respect to Products in the Territory, including to review and approve material regulatory filings (other than the filing of an NDA in the U.S., which shall be approved by the JSC) prior to submission thereof;

(xiv) propose to the JSC for approval and implement a publication strategy for publications and presentations related to Products in the Territory and review and approve all such publications in accordance with Section 12.5, provided that the responsibilities under this subsection (xvi) with respect to a certain Product shall transition from the JDC to the JCC following the first NDA approval of such Product in the U.S., the more precise timing of such transition to be mutually agreed by the Parties;

(xv) facilitate the flow of Information between the Parties with respect to obtaining Regulatory Approval for Products; and

(xvi) perform such other functions as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

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#### Schedule G (b)

### Until the date when the JCC has been formed, the JSC delegates the following responsibilities to Core Joint Project Team. Unless otherwise directed by the JSC, the Core JPT shall:

(xvii) regularly report to the JSC regarding the Commercialization of the Products, and discuss, prepare and submit for approval to the JSC the U.S. Commercialization Plan for each Product in the U.S., including any amendments thereto;

(xviii) coordinate the Commercialization activities of FibroGen and AstraZeneca with respect to Products, including pre-launch and post-launch activities;

(xix) propose to the JSC for approval the allocation of primary responsibility as between the Parties for tasks relating to Commercialization of Products in the U.S.;

(xx) propose to the JSC for approval the amount of Product to be distributed free of charge annually for regulatory or marketing purposes or investigator-initiated trials (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7); and

(xxi) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

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#### FG-4592 Initial Development Plan

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#### Exhibit I

#### **U.S. Co-Commercialization Terms**

Unless the Parties agree in writing upon an alternate allocation of responsibility, the Parties shall have the following rights and obligations with respect to the operational responsibilities for the Commercialization of Products in the U.S. under each U.S. Commercialization Plan, under the direction of the JCC as specified in Section 2.4 and Article 5. [\*]

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#### Exhibit J

#### **Development Supply Terms**

The supply from FibroGen to AstraZeneca, or to FibroGen internally where FibroGen has been assigned (either by the JDC or under the terms of the Agreement) the lead responsibility for the conduct of a Clinical Trial for which the supply is intended, shall include those GMP quantities of Product, and those development activities, in either case, approved by the JDC. As of the Effective Date, the JDC has not been convened. Therefore, the Parties have agreed that the following provisions shall govern the manufacture and delivery of the supplies necessary to conduct the Clinical Trials under the Development Plan.

FibroGen shall manufacture and supply an appropriate amount (currently estimated at up to approximately 3 million units of Product (i.e. 3 million tablets of active drug) and approximately 1.5 million tablets of placebo) for the conduct of the Phase 3 Clinical Trials sponsored by AstraZeneca as well as the amount required to support FibroGen's studies and regulatory submissions. The Parties shall agree upon more exact quantities as soon as possible. Such unit numbers shall include varying drug strengths for the Clinical Trials and shall be delivered at least four (4) months ahead of the start of the Clinical Trials, subject to Section 6.2.

FibroGen shall continue its already started development of a solid formulation, e.g. tablet, aimed at enabling attributes such as commercially viable shelf-life and use of standard primary packages, a dosage unit size to enable an attractive intake by patients as well as deemed possible to manufacture by conventional manufacturing technology in a cost effective manner and that does not reduce the clinical effectiveness or increase a hypothetical adverse event profile of the Product. FibroGen shall initiate *in vivo* testing as needed and according to timelines agreed by the JDC.

The supplies and activities set forth in this Exhibit J may be amended from time to time by the JDC or the JSC.

FibroGen shall report the progress of the items listed above to AstraZeneca's appointed Pharmaceutical Development contacts on a regular and reasonable basis. FibroGen shall also consult AstraZeneca prior to making any critical decisions with material impact on further development, e.g. choice of solid state form, particle size control methodology, choice of excipients, process technology and packaging materials, stability testing protocols, quality specifications and analytical testing methodology, choice of starting materials and sourcing.

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#### Exhibit K

#### Main Terms for Supply Agreement and Quality Agreement

The Supply Agreement ("SA") and Quality Agreement ("QA") referenced at Section 6.3 of the Agreement shall contain the following main terms and conditions. Capitalized terms used but not defined in this Exhibit K shall have the meaning ascribed to such terms in the Agreement.

#### Supply

- <u>Effective Date of SA/QA</u>: The SA and the QA will provide for an effective date which is earlier than the execution date, in case supply of Product is required prior to execution of the SA and the QA.
- <u>Conflict:</u> In the event of a conflict between the Agreement and the SA or the QA, the SA once executed will control with respect to supply matters, and the QA, once executed, will control with respect to quality matters.
- Forecasting, Ordering and Delivery: Terms relating to forecasting and ordering shall be set forth in the SA. The Parties shall agree and include in the SA, a mechanism for defining the lead-times for all Products ordered by AstraZeneca. Delivery of Product shall be EXW INCOTERMS 2010 to an address specified by AstraZeneca. Title shall pass to AstraZeneca on delivery to AstraZeneca or its designee.
- <u>Failure to Supply</u>: The SA will include remedies and other consequences for supply failure (to be defined in the SA) including: (i) rights for AstraZeneca to access relevant information in the possession of FibroGen and its affiliates relating to the manufacturing processes for the Product; and (ii) rights for AstraZeneca to contact FibroGen's suppliers (including suppliers of the active pharmaceutical ingredient for the Product), both (i) and (ii) to assess the feasibility of (including contracting with) such suppliers manufacturing and supplying the Product to AstraZeneca, solely in the event of a supply failure by FibroGen.
- <u>Insurance and Risk</u>: The agreement will contain provisions requiring FibroGen to maintain insurance coverage of the types and in the amounts typically carried by providers of manufacturing services in the pharmaceutical or chemical area. FibroGen shall bear the risk of loss of materials (including API) and Product while within FibroGen's or its subcontractor's control.
- <u>Subcontractors</u>: FibroGen may engage subcontractors ("Subcontractors") that meet the quality standards agreed by the Parties. No such subcontract shall release FibroGen from any of its obligations under the SA or the QA except to the extent such obligations are satisfactorily performed by such Subcontractor in accordance with the SA and the QA. To the extent that AstraZeneca has genuine concerns and can demonstrate with reasonable documentation to FibroGen the basis for its concern with respect to the performance of the work for which the Subcontractor is to be engaged, the choice of such Subcontractor shall be subject to AstraZeneca's approval.

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- <u>Formulation</u>: In the event the Parties decide that AstraZeneca will carry out formulation of the Product, such activities will be included in the SA and any applicable terms will be added to the SA to account for AstraZeneca's role in the formulation activities.
- <u>Non-Conforming Product</u>: The agreement will contain provisions relating to the determination and replacement of nonconforming product and the use of a Third Party testing laboratory to resolve disputes relating to nonconforming product.
- <u>Shortfalls</u>: The SA will include consequences relating to any failure or inability to supply full quantities of Product in compliance with the applicable product specifications ordered by AstraZeneca, including an obligation that in the event of a shortage, FibroGen will allocate an amount of its remaining manufacturing capacity in an equitable manner to be set forth in the Supply Agreement.
- <u>Pricing and Payment</u>: The pricing provisions set out in Section 6.5 of the Agreement shall be incorporated into the terms of the SA. AstraZeneca shall pay invoices in accordance with the terms set forth in the Agreement.
- <u>Legal and Regulatory Requirements</u>: Appropriate provisions shall be included in the SA to ensure that each Party complies with all relevant local, national and international legal or regulatory requirements and other relevant requirements applicable to the manufacture, handing, transport and storage of all Products at all times.
- <u>Governance</u>: The SA will include governance and reporting provisions specific to the manufacturing activities, which governance provisions will be designed to provide AstraZeneca transparency into the activities under such agreement, including subcontracting and CMO arrangements, and to facilitate effective management of the supply chain.
- <u>Health and Safety</u>: FibroGen shall be wholly accountable and liable for the safety, health and environmental aspects of all work performed on its or any
  of its subcontractor's premises.
- <u>AstraZeneca Policies</u>: The SA will include provisions required to comply with applicable AstraZeneca standard policies, including with respect to responsible procurement, product security and waste handling.
- <u>Document Retention</u>: Appropriate provisions shall be included in the SA with regard to maintaining appropriate documentation for patent and regulatory purposes and in full compliance with all applicable laws.
- <u>Technology Transfer</u>: The technology transfer provisions in the Agreement will remain in effect during the term of the SA (and any post-expiration or termination supply period, as described above in Section 13.6(e) or (g)), even after the Agreement has terminated or expired.

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<u>Liability and Indemnity</u>: The SA will include provisions relating to liability and indemnification that are consistent with the principles of allocation of liability described in the Agreement.

<u>Warranties</u>: FibroGen will be required to provide customary representations and warranties within the SA, including (but not limited to) as to the following:

(a) that it has full power and authority, and has taken all necessary actions and has obtained all necessary authorizations, licenses, consents and approvals required, to execute and perform the SA, and

(b) that its retention as a supplier by AstraZeneca and its performance of the SA do not, and shall not, breach any agreement with any other third party.

Generally:

- The SA shall include such terms as are reasonable and customary for similar supply agreements.
- Each of the Parties agree and acknowledge that the SA will contain a number of provisions which shall be consistent with provisions in the body of the Agreement, including Confidentiality, Assignment, Governing Law and Dispute Resolution.

#### Quality

- <u>General</u>: A Quality Agreement shall be negotiated in good faith between the Parties and shall include all appropriate provisions as would normally be contained in such an agreement. Any breach of the QA shall be deemed a breach of the SA.
- The QA shall include:
  - Notice to AstraZeneca of inspections by regulatory authorities and access to such inspections
  - Notice to AstraZeneca of and access to all investigations concerning the manufacture of Products
  - Provision by FibroGen of documentation required by AstraZeneca
  - Maintenance of a change control system which allows for the pre-approval of major changes
  - Rights for AstraZeneca to conduct quality audits on FibroGen or any Subcontractor
  - Agreed procedures on a product recall

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Each of the Parties agrees and acknowledges that the Products must satisfy appropriate specifications and associated tests, details of which shall be set out in the QA, and a mechanism for handling any defective products shall be agreed and included in the QA.

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#### Exhibit L

#### **Invoicing Requirements**

Subject to any separate instructions to be agreed between the Parties regarding payments to health care professionals or health care organizations in the Territory, as required by applicable laws and regulations, invoices should be sent to:

AstraZeneca AB AstraZeneca R&D Mölndal Att. Christina Wågestrand CVGI iMed Strategy 431 83 Mölndal Sweden

Invoices shall contain the following information:

- a. AstraZeneca's Agreement ID: Elisabeth Björk, Global Product Vice President, Global Medicines Development, ECHO Project ID 10007956
- b. the number and date of invoice
- c. the latest date of payment according to Agreement
- d. description of services
- e. name and address of FibroGen, Inc.
- f. FibroGen, Inc. VAT registration number or EIN/TaxID,
- g. AstraZeneca's VAT registration number SE556011748201 (in EC),
- h. VAT rate (%), if any,
- i. taxable amount per VAT rate, if any,
- j. VAT amount, if any
- k. legal reference or explanation when VAT is excluded,
- l. invoice amount and currency,
- m. bank details, preferably IBAN code, otherwise account number and bank code, and
- n. SWIFT-address.

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#### Patents that may be Extended

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#### Exhibit N

#### ASTRAZENECA AND FIBROGEN COLLABORATE TO DEVELOP AND COMMERCIALISE FG-4592, A TREATMENT FOR ANAEMIA IN CHRONIC KIDNEY DISEASE AND END-STAGE RENAL DISEASE

#### Collaboration to include US, China and selected other markets

#### 31 July 2013

AstraZeneca and FibroGen today announced that they have entered into a strategic collaboration to develop and commercialise FG-4592, a first-in-class oral compound in late stage development for the treatment of anaemia associated with chronic kidney disease (CKD) and end-stage renal disease (ESRD).

This broad collaboration focuses on the US, China and all major markets excluding Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa, which are covered by an existing agreement between FibroGen and Astellas Pharma Inc. The AstraZeneca-FibroGen joint effort will be focused on the development of FG-4592 to treat anaemia in CKD and ESRD, and may be extended to other anaemia indications.

FG-4592 is a small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase. HIF is a protein that responds to oxygen changes in the cellular environment and meets the body's demands for oxygen by inducing erythropoiesis, the process by which red blood cells are produced. FG-4592 has the potential to address the considerable unmet medical need for an effective treatment for anaemia that offers the convenience of oral administration and an improved safety profile as compared to current standards of care. At present, treatment options involve a combination of injectable erythropoiesis-stimulating agents (ESAs) and iron supplements. FG-4592 works through the body's natural oxygen-sensing and response system to help produce red blood cells. This can be compared to the body's natural response to conditions at high altitude, where oxygen levels are low, which is to produce more red blood cells.

In Phase II clinical studies, FG-4592 met its primary objective of demonstrating anaemia correction in treatment-naïve CKD patients not on dialysis as well as maintenance of haemoglobin levels and anaemia correction in patients on dialysis. FG-4592 has demonstrated this efficacy combined with an acceptable safety profile in clinical trials, and has been shown to achieve anaemia correction in the absence of intravenous iron supplementation.

The companies plan to undertake an extensive FG-4592 phase III development programme for the US, and to initiate phase III trials in China, with anticipated regulatory filings in China in 2015 and in the US in 2017.

AstraZeneca will pay FibroGen committed upfront and subsequent non-contingent payments totalling \$350 million, as well as potential future development related milestone payments of up to \$465 million, and potential future sales related milestone payments in addition to tiered royalty payments on future sales on FG-4592 in the low 20% range. Additional development milestones will be payable for any subsequent indications which the companies choose to pursue.

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AstraZeneca will be responsible for the US commercialisation of FG-4592, with FibroGen undertaking specified promotional activities in the ESRD segment in this market. The companies will also co-commercialise FG-4592 in China where FibroGen will be responsible for clinical trials, regulatory matters, manufacturing and medical affairs, and AstraZeneca will oversee promotional activities and commercial distribution.

Pascal Soriot, Chief Executive Officer, AstraZeneca, said: "Our collaboration with FibroGen on FG-4592 is an important addition to AstraZeneca's growing late-stage portfolio in cardiovascular and metabolic disease, one of our core therapy areas. We know from our research into complications of renal disease that anaemia continues to be a challenge for patients with chronic kidney disease, due in part to the inconvenience and complexity of existing injectable and intravenous therapies and the safety concerns associated with them. The science behind this compound is compelling. Through our collaboration with FibroGen we aim to offer a first-in-class, convenient treatment option for doctors and patients."

Thomas B. Neff, Chief Executive Officer, FibroGen, said: "FG-4592 has the potential to offer anaemia patients an oral therapy that provides coordinated erythropoiesis, that increases natural erythropoietin within the normal physiological range, and that is effective without intravenous iron supplementation and without an increased risk for hypertension. We are especially pleased that AstraZeneca will share our commitment to making China the first-to-launch country for FG-4592 and join our effort to bring important innovation in anaemia therapy to CKD and ESRD patients in the US and other countries. This agreement secures proper development and commercialisation resources for FG-4592, and ensures US clinical trial efforts are fully funded."

– ENDS –

#### NOTES TO EDITORS

#### About chronic kidney disease and anaemia

Diabetes, high blood pressure, and other conditions can cause significant damage to the kidneys. If left untreated, those can result in chronic kidney disease and progress to kidney failure. Such deterioration can lead to patients needing a kidney transplant or being placed on dialysis to remove excess fluid and toxins that build up in the body. The progression of CKD also increases the prevalence of anaemia, a condition associated with having fewer of the red blood cells that carry oxygen through the body, and/or lower levels of haemoglobin, the protein that enables red blood cells to carry oxygen. As haemoglobin falls, the lower oxygen-carrying capacity of an anaemic patients' blood results in various symptoms including fatigue, loss of energy, breathlessness, and angina. Anaemia in CKD patients has been associated with increased hospitalisation rates, increased mortality, and reduced quality of life.

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CKD is a worldwide critical healthcare problem that affects millions of people and drives significant healthcare cost. In the US, prevalence of CKD has increased dramatically in the past 20 years, from 10% of the adult population (or approximately 20 million US adults) as stated in the National Health and Nutrition Evaluation Survey (NHANES) 1988-1994, to 15% (or approximately 30 million adults) in NHANES 2003-2006. In 2009, total Medicare costs for CKD patients were \$34 billion. China has an estimated 125 million CKD patients, or 5 times the number of CKD patients in the US [Lancet April 2012].

#### About FG-4592

FG-4592 is an orally administered small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase activity, in development for the treatment of anaemia in patients with chronic kidney disease (CKD). HIF is a protein transcription factor that induces the natural physiological response to conditions of low oxygen, "turning on" erythropoiesis (the process by which red blood cells are produced) and other protective pathways. FG-4592 has been shown to correct anaemia and maintain haemoglobin levels without the need for supplementation with intravenous iron in CKD patients not yet receiving dialysis and in end-stage renal disease patients receiving dialysis. An Independent Data Monitoring Committee has found no signals or trends to date to suggest that treatment with FG-4592 is associated with increased risk of cardiovascular events, thrombosis, or increases in blood pressure requiring initiation or intensification of antihypertensive medications.

Under a licensing agreement between FibroGen, Inc. and Astellas Pharma Inc., Astellas is developing FG-4592 for the treatment of anaemia in CKD and ESRD patients in Europe, Japan, the Commonwealth of Independent States, the Middle East, and South Africa.

#### About FibroGen

FibroGen, Inc., is a privately-held biotechnology company focused on the discovery, development, and commercialization of therapeutic agents for treatment of fibrosis, anaemia, cancer, and other serious unmet medical needs. FibroGen's FG-3019 monoclonal antibody is in early-stage clinical development for treatment of idiopathic pulmonary fibrosis and other proliferative diseases, including pancreatic cancer and liver fibrosis, and FG-4592 is a small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase currently in clinical development for the treatment of anaemia. FibroGen is also currently pursuing the use of proprietary recombinant human type III collagens in synthetic corneas for treatment of corneal blindness. For more information please visit: www.fibrogen.com

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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#### CONTACTS

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#### CERTIFICATION

I, Thomas B. Neff, certify that;

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q/A of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 13, 2017

/s/ Thomas B. Neff

Thomas B. Neff Chairman of the Board and Chief Executive Officer (Principal Executive Officer)

#### CERTIFICATION

I, Pat Cotroneo, certify that;

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q/A of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 13, 2017

/s/ Pat Cotroneo

Pat Cotroneo Vice President, Finance and Chief Financial Officer (Principal Financial Officer)