

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 13, 2020

**FibroGen, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-36740  
(Commission  
File Number)

77-0357827  
(IRS Employer  
Identification No.)

FibroGen, Inc.  
409 Illinois Street  
San Francisco, CA 94158  
(Address of principal executive offices, including zip code)

(415) 978-1200  
(Registrant's telephone number, including area code)

Not Applicable  
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.01 par value	FGEN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

**Item 7.01 Regulation FD Disclosure**

Beginning January 13, 2020, FibroGen, Inc. (the Company) intends to conduct meetings with existing and prospective investors and analysts in which its corporate slide presentation will be presented. A copy of the presentation materials, including a slide setting forth certain cautionary statements intended to qualify the forward-looking statements therein, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 7.01 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">FibroGen, Inc. Presentation Materials dated January 2020</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**FIBROGEN, INC.**

Dated: January 13, 2020

By: /s/ Michael Lowenstein  
Michael Lowenstein  
Chief Legal Officer

# FibroGen, Inc. Corporate Presentation

January 2020



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# Forward-Looking Statements

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This presentation contains “forward-looking” statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, business strategy, and plans, and objectives of management for future operations, are forward looking statements. These forward-looking statements can generally be identified by terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “contemplate,” “intend,” “target,” “project,” “should,” “plan,” “expect,” “predict,” “could,” “or potentially,” or by the negative of these terms or other similar expressions. Forward-looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses, or current expectations concerning, among other things, our ongoing and planned development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for roxadustat, pamrevlumab, and our other product candidates, the potential safety, efficacy, reimbursement, convenience, or clinical and pharmaco-economic benefits of our product candidates, including in China, the potential markets for any of our product candidates, our ability to develop commercial functions, or our ability to operate in China, expectations regarding clinical trial data, our results of operations, cash needs, spending of proceeds from our public offerings, financial condition, liquidity, prospects, growth, and strategies, the industry in which we operate, and the trends that may affect the industry or us.

Forward-looking statements involve known and unknown risks, uncertainties, assumptions, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements, including the other risks and uncertainties that are described in the Risk Factors section of our most recent annual report on Form 10-K or quarterly report on Form 10-Q filed with the Securities and Exchange Commission. Forward-looking statements represent our management’s beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

# Company Overview

**San Francisco** headquarters with subsidiary in Beijing

- Company Mission - developing innovative, first-in-class medicines for the treatment of chronic and life-threatening or debilitating conditions



Enrique Conterno appointed CEO January 2020

**500+** employees worldwide

- 300+ U.S.
- 200+ ex-U.S.

**3Q Year End 2019 cash guidance estimated ~\$650-\$660 million**

- Range includes the \$50 million U.S. NDA milestone
- Substantial milestone payments in near-term
- No debt

# Enrique Conterno – CEO

- Former Senior Vice President for Eli Lilly and Company, serving as President, Lilly USA, President, Lilly Diabetes, and a member of Lilly's corporate executive committee.
- Nearly three decades of experience in the global healthcare industry include multiple strategic leadership roles and the oversight of several significant product launches, including the diabetes field's first-ever cardiovascular approval.
- Re-established Lilly's leadership position in diabetes, growing the business from approximately \$3 billion to over \$10 billion in annual revenue.
- Extremely qualified to lead FibroGen as we prepare for the global commercialization of roxadustat and continue the advancement of our clinical programs.



# Strategy: FIRST-IN-CLASS PRODUCT PROGRAMS ADDRESSING SIGNIFICANT UNMET MEDICAL AND PATIENT NEED

## ROXADUSTAT

### Anemia Associated with CKD

- Approved in China for NDD-CKD and DD-CKD
- Approved in Japan for DD-CKD
  - NDD sNDA submission planned for early 2020
- U.S. NDA submitted 4Q 2019
- EU MAA submission anticipated 1H 2020

### PARTNERED with Astellas / AstraZeneca

- Astellas: Europe, Japan, Middle East, CIS, South Africa,
- AstraZeneca: U.S./ROW and China

## PAMREVLUMAB

### Idiopathic Pulmonary Fibrosis

- ZEPHYRUS Phase 3 study enrolling

### Pancreatic Cancer

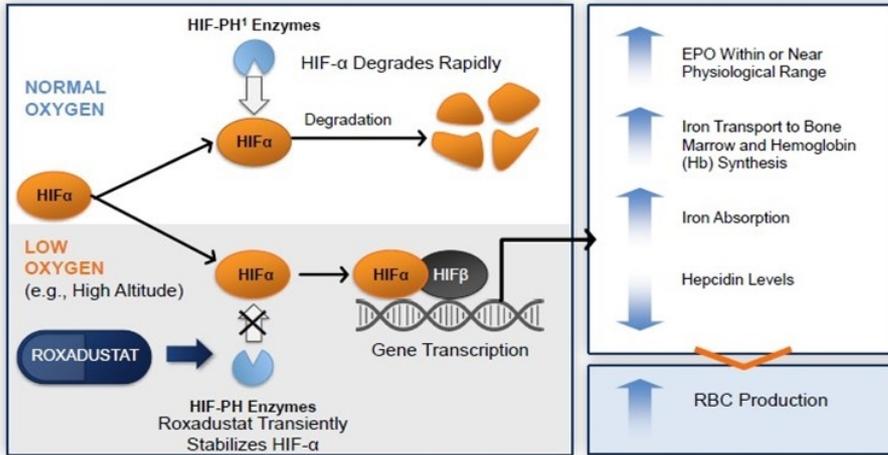
- LAPIS Phase 3 study enrolling

### Duchenne's Muscular Dystrophy

- Discussion with regulatory agencies (FDA/EMA) ongoing regarding pivotal program design; preparing for initiation of pivotal program in 2020

# Roxadustat: Novel, First-in-class Treatment for CKD Anemia

- Roxadustat – oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI)
  - 2019 Nobel Prize winning science is the foundation of roxadustat
  - Increases hemoglobin (Hb) by mimicking the body's natural response to low oxygen
  - Studied for treatment of anemia in Stage 3 to 5 CKD patients, both on and not on dialysis



<sup>1</sup>hypoxia-inducible factor prolyl hydroxylase (HIF-PH)

## 2019 Nobel Prize In Physiology or Medicine

*"for their discoveries of how cells sense and adapt to oxygen availability."*

*Awarded jointly to:*

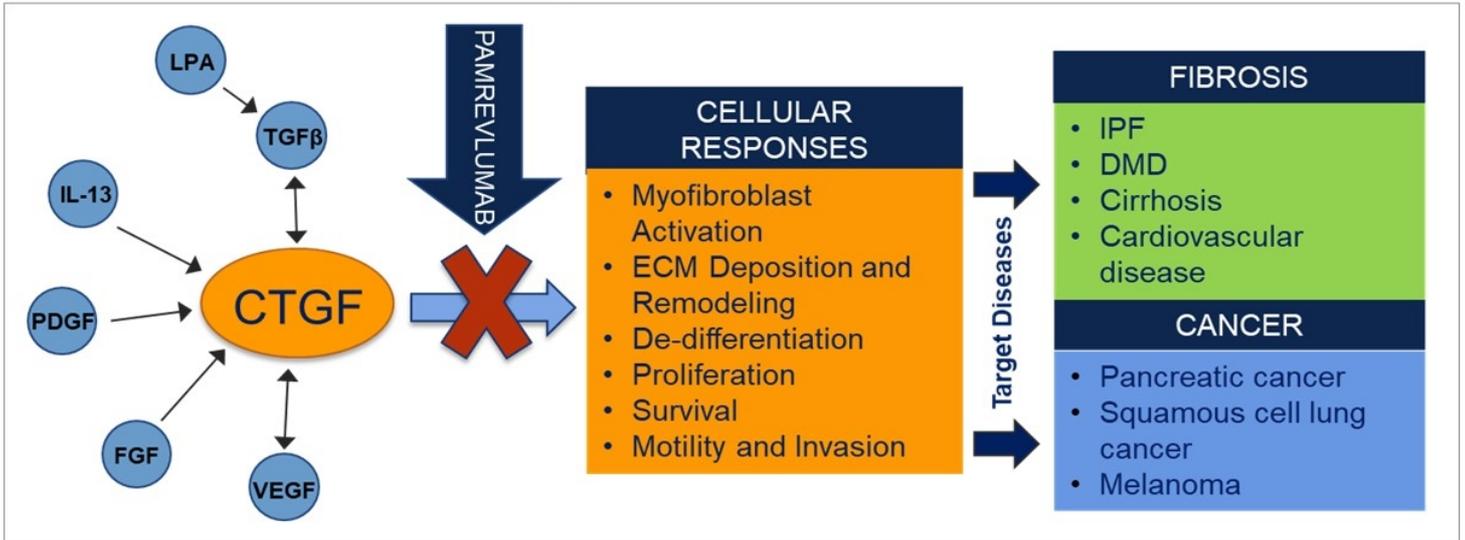
**William G. Kaelin Jr.**  
Harvard University

**Gregg L. Semenza**  
Johns Hopkins University

**Peter J. Ratcliffe**  
Francis Crick Institute  
London



# Pamrevlumab: Innovative Treatment for Fibrosis and Fibroproliferative Disease



**PAMREVLUMAB -- fully humanized monoclonal antibody targeting activity of connective tissue growth factor, a central factor in fibrosis and in various proliferative diseases**

# FibroGen Marketed and Late Stage Portfolio with Blockbuster Portfolio



Partnered

Wholly Owned



<sup>1</sup>Dialysis-dependent NDA approved in Japan; non-dialysis dependent trials are ongoing  
Partnerships: Astellas: Europe, Middle East, CIS, South Africa, Japan; AstraZeneca: U.S./ROW and China



# Roxadustat

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Anemia

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# Roxadustat: An Innovative Approach to Addressing Anemia

## + ROXADUSTAT HAS BEEN SHOWN TO BE MORE THAN AN ORAL ALTERNATIVE TO ESAs

- Superiority to ESAs has been shown in hemoglobin change from baseline and reduction in risk of blood cell transfusion
- CV safety demonstrated in pooled analyses
- Overcomes suppressive effects of inflammation on erythropoiesis
- Coordinate erythropoiesis, encompasses iron mobilization, and hepcidin reduction

## >> ADVANCED BY FIBROGEN FROM DISCOVERY THROUGH LATE-STAGE CLINICAL DEVELOPMENT AND APPROVAL

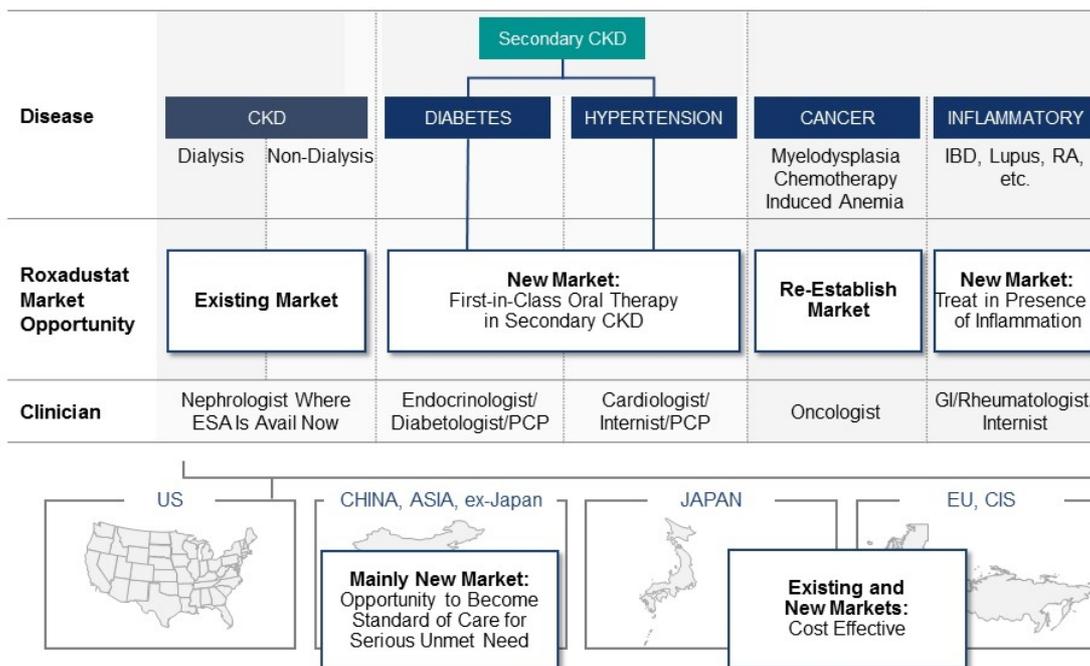
- Dialysis-dependent and non-dialysis-dependent CKD patients – Registration and Approval
- Anemia associated with myelodysplastic syndromes (MDS) – Phase 3
- Anemia associated with chemotherapy induced anemia (CIA) – Phase 2



## PARTNERED WITH ASTRAZENECA AND ASTELLAS

- Astellas: Europe, Middle East, CIS, South Africa, Japan
- AstraZeneca: U.S./ROW and China
  - Strong and established presence in renal, diabetes and hypertension markets

# Potential Global Multi-Billion Dollar Markets for Anemia



# Chronic Kidney Disease (CKD) is a Serious Health Burden Worldwide

## CKD Worldwide

**850  
million**  
people worldwide  
have CKD<sup>1</sup>

CKD causes  
**2.4  
million**  
deaths each year<sup>2</sup>

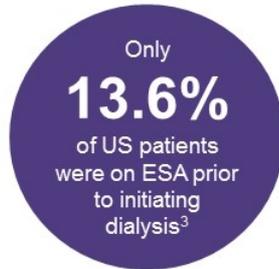
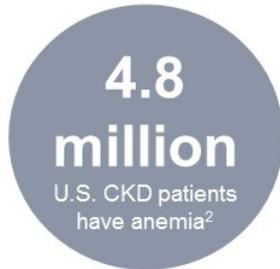
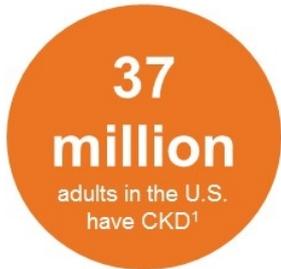
CKD is the  
**6th**  
fastest growing  
cause of death<sup>2</sup>

## Anemia increases risk of significant health consequence in CKD patients

- Increased risk of hospitalization, cardiovascular complications and death
- Frequently causing significant fatigue, cognitive dysfunction and reduced quality of life.

# CKD Anemia Patients Not On Dialysis are Undertreated

Despite associated health risks, anemia is often left untreated in CKD patients not on dialysis (NDD)



## Contributing factors of undertreatment

- Limited use of ESA outside dialysis care
- Delayed referral to nephrologists
- Inconvenience of frequent visits to receive ESA therapy
- Patients not comfortable in ESA self-injections
- Storage and transportation requirements with ESA

Sources: <sup>1</sup>U.S. Department of Health and Human Services Centers for Disease Control and Prevention website [www.cdc.gov/kidneydisease](http://www.cdc.gov/kidneydisease). Accessed January 10, 2020. <sup>2</sup>Stauffer ME, Fan T. Prevalence of anemia in chronic kidney disease in the United States. *PLoS ONE* 2014;9(1):e84943. <sup>3</sup>United States Renal Data System (USRDS) Annual Data Report 2019 estimate as of Year End 2017

# While Dialysis-Dependent Patients Typically Receive Anemia Therapy, Unmet Need Persists with Current SoC

## Opportunity for therapies that can overcome the limitations of current SoC

### DD-CKD population continues growing

In the US, over 520K patients are on dialysis as of Dec 2017 vs. 370K in Dec 2007 (CAGR 3.4%)<sup>1</sup>

In China, over 600K patients are currently on dialysis. Double digit growth Y/Y due to rapid increase of diabetes and hypertension, the two leading causes of CKD

Over 90% DD-CKD patients require anemia therapy

### Significant morbidity and mortality risks during the first year on dialysis

Patients on dialysis for less than 12 months represents 20-25% of total US DD-CKD patients each year.

Patients face significant increased risks of death, CV events and hospitalizations during the first year on dialysis.

### Limitations of Current Anemia SoC with ESA

Most patients start receiving anemia therapy when the dialysis therapy is initiated.

Limitations of ESA include:

- Often requires concomitant use of IV iron
- Patients with inflammation are often hyporesponsive to ESA



<sup>1</sup>United States Renal Data System (USRDS) Annual Data Report 2019 estimate as of Year End 2017

# Roxadustat Opportunity in Treatment of CKD Anemia

Roxadustat, the potential first in class, orally administered small molecule HIF-PH inhibitor, has the potential to revolutionize the treatment paradigm in CKD anemia

## Past

Only option was transfusion

- Transfusion was the only option when iron alone was not enough

## Present

Treated as EPO deficiency<sup>1</sup>

- With supplemental EPO combined with extra iron supplements for red blood cell production

## Future

Treat CKD anemia by enabling the body to stimulate coordinated erythropoiesis

- Activating HIF pathway has the potential to stimulate endogenous production of red blood cells

# Roxadustat NDD and DD Program: One of the Largest CKD Anemia Clinical Development Programs

## Phase 3 CKD non-dialysis-dependent (NDD) Pool

D5740C00001	FGCL-4592-060	1517-CL-0608	NDD Pooled	
<b>OLYMPUS</b>	<b>ANDES</b>	<b>ALPS</b>		
AstraZeneca	FibroGen	Astellas	<b>Roxa</b>	<b>Placebo</b>
<b>N=2761</b>	<b>N=922</b>	<b>N=594</b>	<b>N=2391</b>	<b>N=1886</b>
R 1:1	R 2:1	R 2:1	<b>1.62</b>	<b>1.23</b>
			<b>Avg PEY</b>	<b>Avg PEY</b>

**Number of patients: 4277**  
**Patient exposure years: 6194**

## Phase 3 CKD dialysis-dependent (DD) Pool

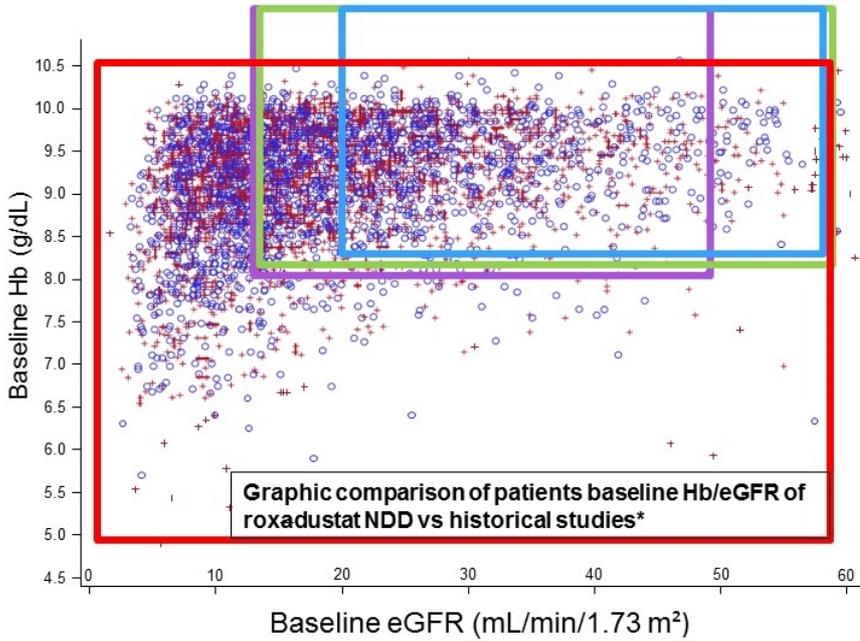
D5740C00002	FGCL-4592-064	FGCL-4592-063	DD Pooled	
<b>ROCKIES</b>	<b>SIERRAS</b>	<b>HIMALAYAS</b>		
AstraZeneca	FibroGen	FibroGen	<b>Roxa</b>	<b>EPO</b>
<b>N=2106</b>	<b>N=741</b>	<b>N=1043</b>	<b>N=1943</b>	<b>N=1947</b>
R 1:1	R 1:1	R 1:1		
Correction & maintenance Early & Stable DD	Maintenance Early & Stable DD	Correction DD Vintage<4mos Only (Early)	<b>1.71</b>	<b>1.92</b>
			<b>Avg PEY</b>	<b>Avg PEY</b>

**Number of patients: 3880**  
**Patient exposure years: 7059**



EPO, epoetin alfa; Hb, hemoglobin; PEY, patient exposure year; R, Randomization; Roxa, roxadustat

# NDD Roxadustat Program: Evaluation of Anemia Therapy In A Broad Range of Patients Not Included In Prior CKD Anemia Trials



**Roxadustat NDD Patient Features**  
 Advanced CKD: **42% CKD 5**  
 Low Iron stores: **40% non-iron replete**  
 Low Mean Baseline Hb: **9.1**

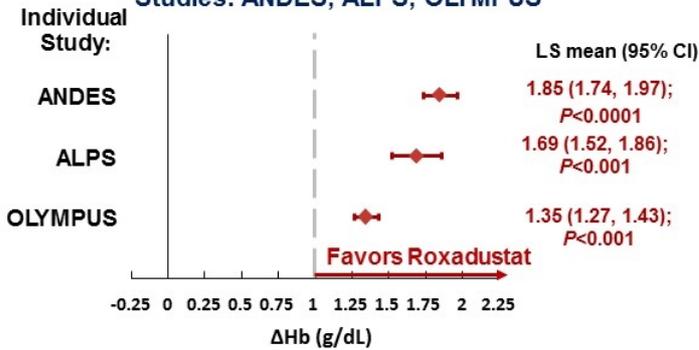
CHOIR (2006)	ARCTOS Mircera (2008)
TREAT (2009)	Roxadustat NDD
Actual Pooled Treatment 1 for Period ○ Placebo + Roxadustat	

**FibroGen** \*Historical study patients' baseline Hb & eGFR characteristics in figure is based on approximations from published manuscripts  
 eGFR, estimated glomerular filtration rate

# NDD: Roxadustat is Superior to Placebo, Regardless of iron-repletion

**Primary efficacy endpoint (change in Hb from baseline to Hb averaged over Weeks 28–52) was met in individual studies and pooled analyses**

Hb change from baseline to Week 28–52  
Studies: ANDES, ALPS, OLYMPUS

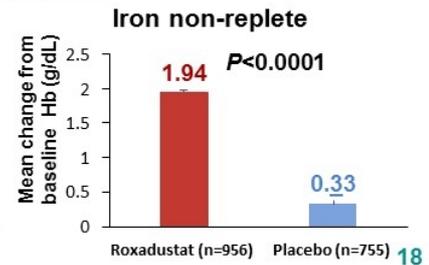
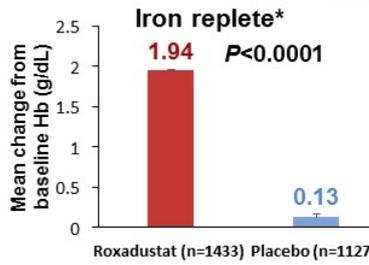
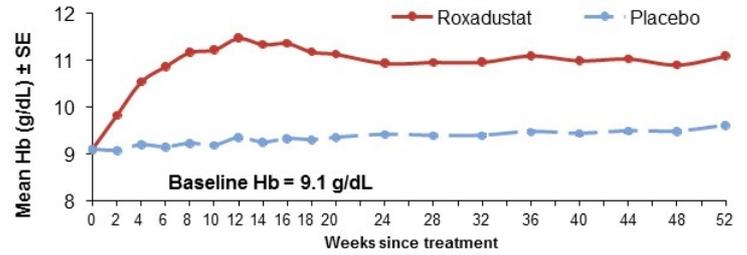


\*Iron Replete: TSAT  $\geq 20\%$  and ferritin  $\geq 100$  ng/mL

CI, confidence interval; LS, least squares; SE, standard error



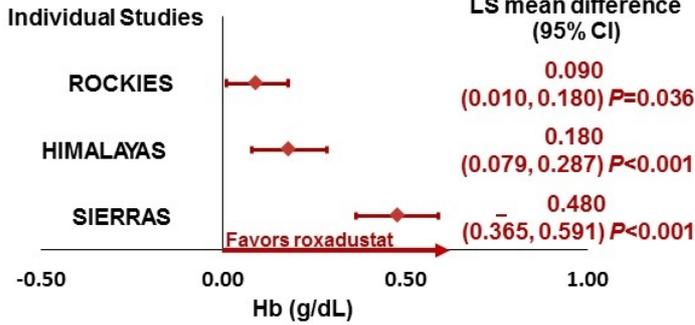
NDD (N=4277): Mean Hb over time up to Week 52 (g/dL)  
Hb change to Week 28–52: 1.85 (Roxa) vs 0.13 (Placebo)  $P < 0.001$



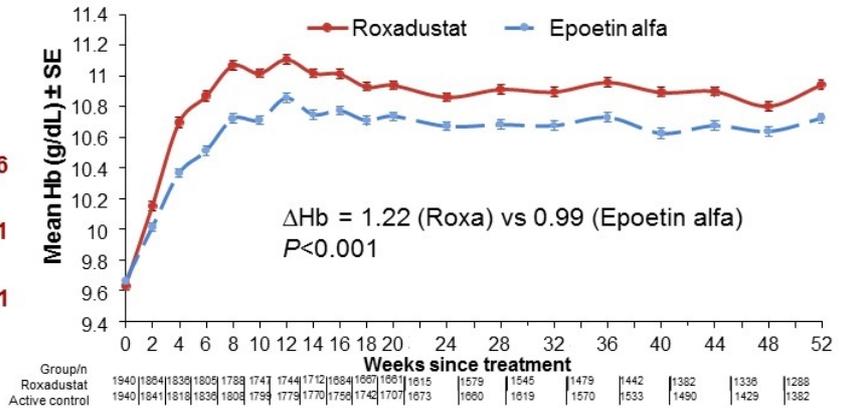
# DD: Roxadustat Efficacious, Larger Hb Increase Than EPO in Individual Studies and In Pooled Analysis

**Primary efficacy endpoint (change in Hb from baseline to Hb averaged over Weeks 28 to 52): Roxadustat achieved larger Hb increase over epoetin alfa in individual studies & in pooled DD**

Hb (g/dL) change from baseline to Week 28–52



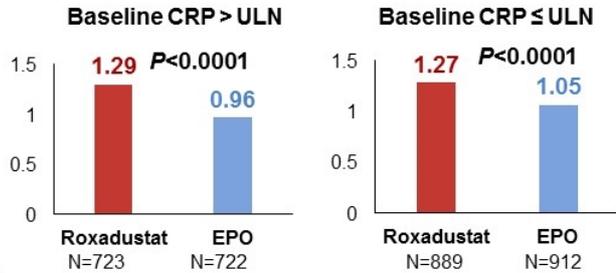
DD (N=3857): mean Hb (g/dL) over time



# DD: Roxadustat Efficacious Regardless of Inflammation, Requires Less IV iron than Epoetin Alfa

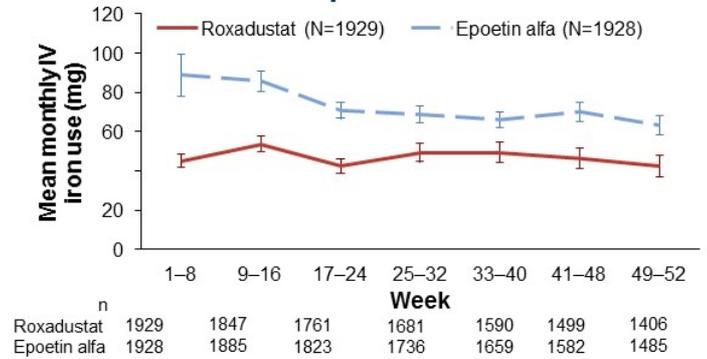
- Roxadustat achieved higher Hb increase in patients with inflammation (CRP > ULN) and in patients without inflammation (CRP ≤ ULN), compared to epoetin alfa
- Less IV iron was required in roxadustat patients than in patients on epoetin alfa

## DD: Hb (g/dL) change from baseline to Weeks 28–52



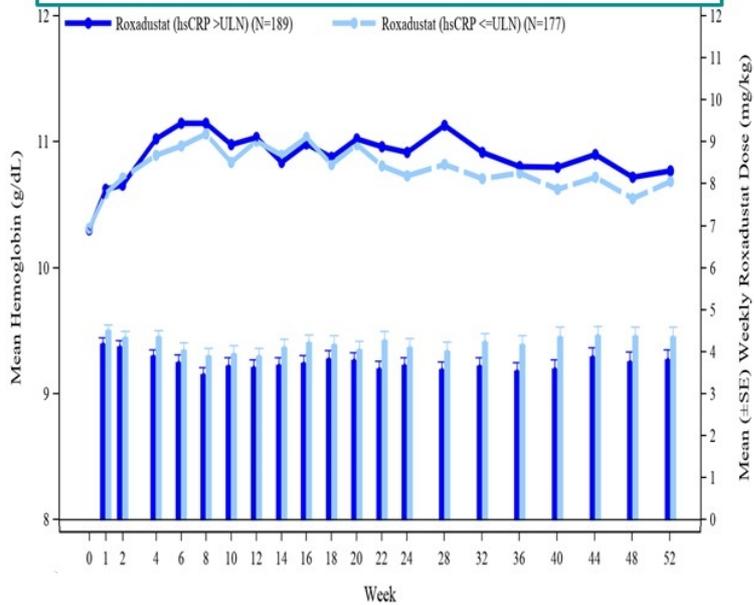
IV, intravenous; ULN, upper limit of normal

## DD: Less Monthly IV Iron Use in Roxadustat Patients Than in Epoetin Alfa Patients

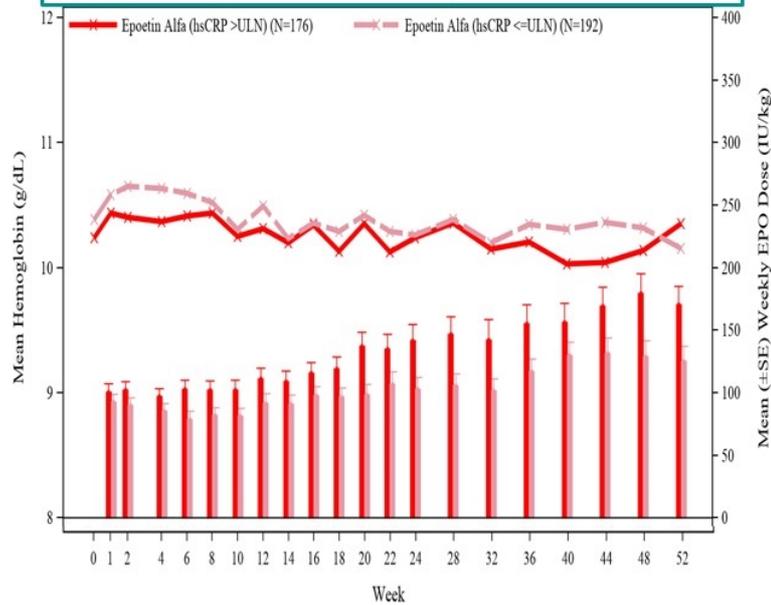


# SIERRAS (064) US-Only Study in Stable Dialysis Patients: Roxadustat Efficacy Unaffected by Inflammation & Durable Over Time

Roxadustat patients with or without inflammation achieved comparable Hb levels with comparable average doses, and stable over 52 weeks.

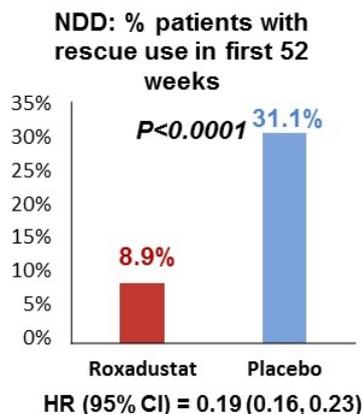


EPO patients with inflammation (CRP>ULN) required higher doses than patients without inflammation (low CRP), and avg dose increased by ~50% over 52 weeks.

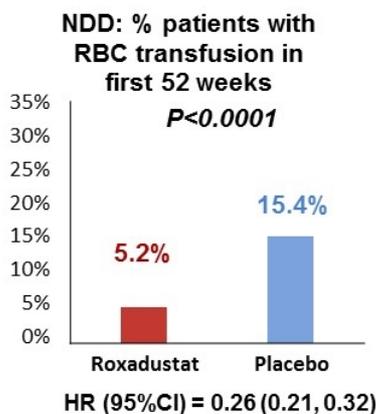


# Roxadustat Lowers Use of Rescue\* Therapies in NDD; Reduction in RBC Transfusion in NDD (vs Placebo) and in DD (vs Epoetin Alfa)

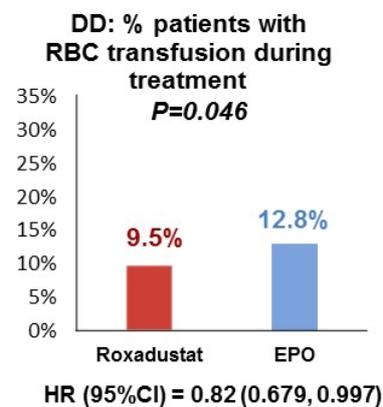
## NDD: Rescue Use



## NDD: RBC Transfusion



## DD: RBC Transfusion

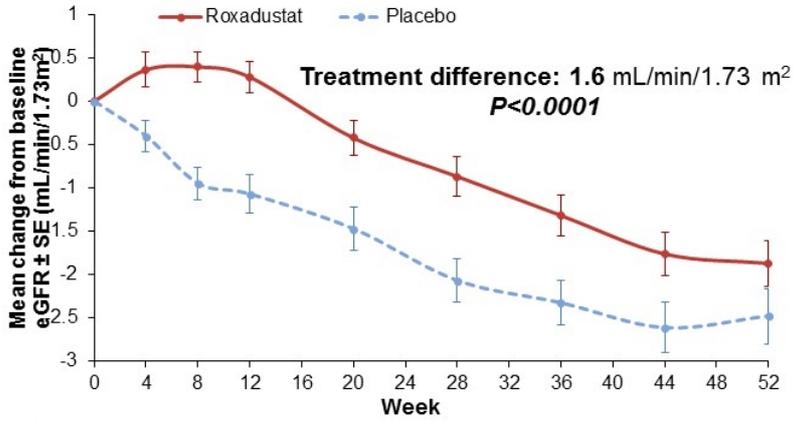


\*Rescue = RBC transfusion, ESA, or IV iron  
HR, hazard ratio; RBC, red blood cell

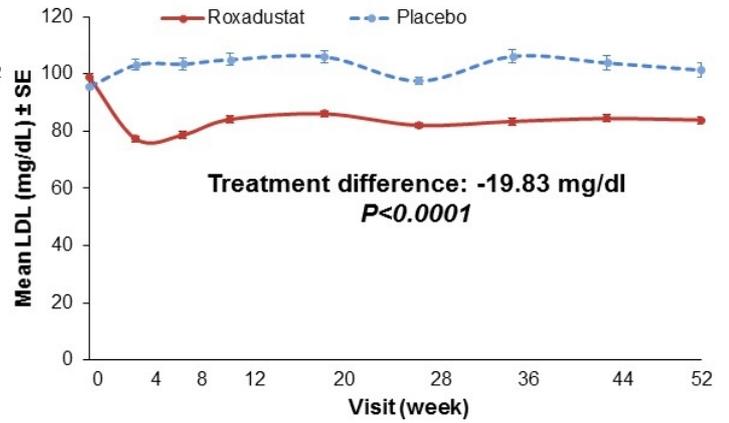
# Roxadustat: Potential Additional Benefits in NDD

## Change in eGFR from Baseline

Patients with baseline eGFR  $\geq 15$  mL/min/1.73 m<sup>2</sup> (N=2438)



## Mean LDL (mg/dL) over time up to Week 52



Group/n	0	4	8	12	20	28	36	44	52
Roxadustat	1373	1311	1269	1236	1189	1150	1086	1038	990
Placebo	1065	1017	979	936	863	819	760	706	657

LDL, low-density lipoprotein



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# Cardiovascular Safety Endpoint Pooled Analyses

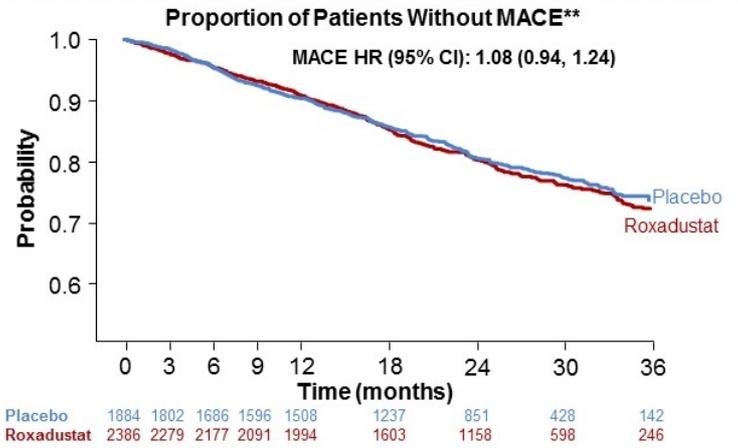
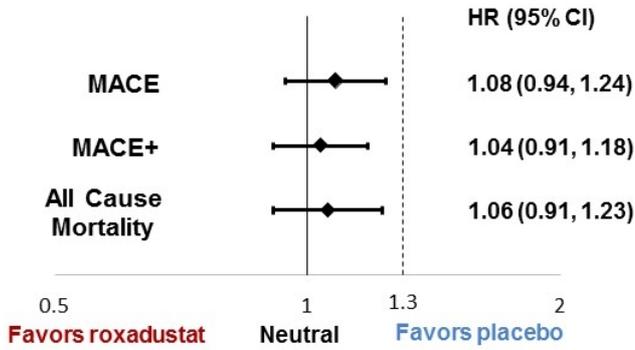
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- Cardiovascular (CV) safety endpoints analyzed in **NDD pool** and in **DD pool**
- *Key safety endpoints:*
  - **Time to first MACE**
    - MACE (Major Adverse Cardiovascular Events) include: all-cause mortality, myocardial infarction, and stroke
  - **Time to first MACE+**
    - MACE+ includes MACE, unstable angina requiring hospitalization, and congestive heart failure requiring hospitalization
  - **Time to all-cause mortality**
- CV events were **centrally adjudicated** by independent experts blinded to treatment assignment

# NDD: Pooled Cardiovascular Safety Endpoints MACE, MACE+, All-Cause Mortality

**Risks of MACE, MACE+, or all-cause mortality in roxadustat patients were comparable to placebo in NDD patients\***

Time to event endpoints using Cox model, ITT analysis\*\*  
NDD (OLYMPUS, ANDES, ALPS), N=4270



\*"comparable" based on hazard ratio (HR) upper bound of 95% confidence interval (95%CI) below reference non-inferiority margin of 1.3

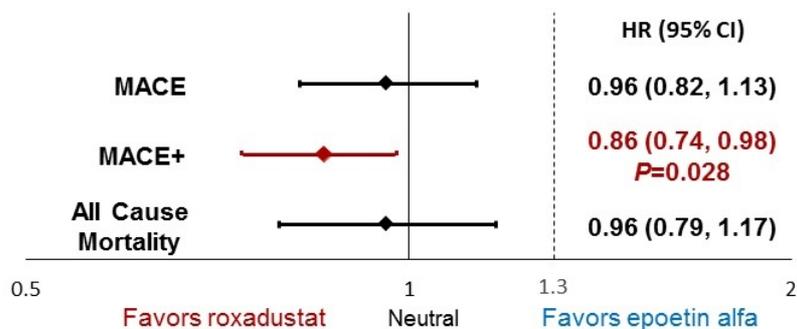
\*\*ITT analysis = Intent to treat analysis evaluation period to include on-treatment and off-treatment long term follow-up, until end of study



# DD: Pooled Cardiovascular Safety Endpoints

- Risk of MACE and all-cause mortality in roxadustat patients were not increased compared to epoetin alfa in DD patients\*
- Roxadustat patients had a lower risk of MACE+ than epoetin alfa patients

Time to event endpoints using Cox model†  
DD (ROCKIES, HIMALAYAS, SIERRAS), N=3880



MACE+ Components Incidence Rates, N (%)		
Events	Roxadustat	Epoetin alfa
n	1940	1940
Death (all-cause mortality)	207 (10.7%)	232 (12.0%)
Myocardial infarction	103 (5.3%)	109 (5.6%)
Stroke	45 (2.3%)	50 (2.6%)
Unstable angina	18 (0.9%)	22 (1.1%)
Congestive heart failure	120 (6.2%)	166 (8.6%)

\*"risk not increased" based on hazard ratio (HR) upper bound of 95% confidence interval (95%CI) below reference non-inferiority margin of 1.3.

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# Roxadustat Efficacy

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- **Roxadustat efficacy was demonstrated**
  - **Achieved primary efficacy endpoint (change in Hb) in individual studies and pooled analyses**
    - **NDD:** roxadustat was superior to placebo and efficacious regardless of iron-repletion
    - **DD:** roxadustat achieved larger mean Hb increase than epoetin alfa, including in patients with inflammation, and less IV iron was required in roxadustat arm than in epoetin alfa.
  - **Lower RBC transfusion risk**
    - **NDD:** In roxadustat patients compared with placebo
    - **DD:** In roxadustat patients compared with epoetin alfa
  - **Other potential benefits in NDD**
    - Reduced LDL cholesterol
    - Less decline in eGFR

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## Roxadustat CV Safety

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- **CV safety was demonstrated in all study populations**

- **Non-dialysis:** Risk of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to placebo in NDD patients
- **Incident dialysis:** Roxadustat had 30% lower risk of MACE and 34% lower risk of MACE+ than epoetin alfa, and with a trend towards lower all-cause mortality relative to epoetin alfa
- **Dialysis-dependent:**
  - Roxadustat patients had a lower risk of MACE+ than epoetin alfa patients
  - Risk of MACE and all-cause mortality in roxadustat patients were not increased compared to epoetin alfa in DD patients

# Oncology Anemia Market Opportunity

## ADDRESSING UNDERSERVED PATIENT POPULATIONS

### Chemotherapy Induced Anemia (CIA)

**1.3 million** patients undergo chemotherapy each year in the U.S.

- 30%-90% cancer patients receiving chemotherapy develop anemia.<sup>3</sup>
- Anemia rate varies by tumor type, and increases with each successive chemotherapy round

**80%-90%** ESA oncology use reduced since 2006

- Three RCTs in cancer populations published, leading to Box warning by the US FDA in 2007. US ESA oncology sales was approximately \$4 billion as of 2006.



<sup>2</sup>National Cancer Institute estimates of annual diagnoses from 2007 to 2011. <sup>3</sup>Anemia defined as Hb<12g/dL.

### Myelodysplastic Syndromes (MDS)

**60K-170K** US Prevalence

- Annual incident rate: 4.9/100K adults in U.S.<sup>2</sup>; 1.51/100K adult in China.
- Anemia is the most common clinical presentation in MDS, leading to frequent red blood cell transfusions and related risks such as iron overload, impairment of QOL, and shorter lifespan

**5x** ESA dose typically used vs. CKD dose

- ESA response rate as low as 20%-32% in lower risk MDS
- Majority patients are transfusion dependent and face associated risks of transfusions

# Roxadustat Collaboration Economics



- Royalty/Transfer Price in low 20% in US/EU + ROW
  - China 50/50 profit split
- Development Costs + Further Commercialization paid by partners
- Total Milestones of \$2.5 Billion
- \$425 million payable upon achievement of milestones relating to submission and approval of roxadustat in DD-CKD and NDD-CKD in the U.S. and Europe.
  - \$180 million of milestones on NDA and EMA submission
  - \$245 million on approval and first sale

\$ Millions	Astellas Japan, EU, etc.	AstraZeneca U.S., China, ROW	Payments Rec'd through Sep 30, 2019
Equity Investment in FibroGen	\$81	\$20	\$101
Upfront, Non-Contingent	\$360	\$402	\$762
Development and Reg. Milestones	\$543	\$571	\$170
Commercial Milestones	\$15	\$653	\$0
<b>POTENTIAL TOTAL</b>	<b>\$918M</b>	<b>\$1,626M</b>	<b>\$932M of \$2,544M</b>

Low 20% (Astellas) – Low-Mid 20% (AZ)  
Transfer Price (AST) – Net Sales Royalty/Transfer Price (AZ)

<b>All FibroGen R&amp;D Costs Reimbursed, ex-China</b>
<b>All Commercial Costs Covered by Partners, ex-China</b>
<b>CHINA PARTNERSHIP</b> 50% Profit Sharing 50% Development and Launch Costs

# FibroGen China

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# China: Roxadustat Commercialization Underway

## FibroGen

- FibroGen is Innovator and Marketing Authorization Holder (MAH)
- Roxadustat is sold under the FibroGen name

## FibroGen-AZ Roxadustat China Partnership



## AstraZeneca

- AstraZeneca China is largest multinational pharma in China, with annual revenue exceeding \$4 billion
- 15,000 staff in China
- Track record of commercial success



50/50 profit share

# China: Positive Momentum and Upwards Trajectory

## NDA Approval

Dialysis (DD)  
approved Dec 2018

Non-Dialysis (NDD)  
approved Aug 2019

## Reimbursement

Admitted into  
National Reimbursement  
Drug List  
Dec 2019

Covers DD and NDD

## Pricing

~\$2,000 patient price per year

~\$1,500 ex-factory per year

95.5 RMB per 50mg capsule

## KOL Endorsement

Indication of strong support  
from top KOLs

## Significant Awards

Dushu Lake Award  
Sept 2019

Health China Forum  
Top 10 Innovative Drug  
of 2019 Award  
Jan 2020

## Large Dedicated Field Team

300+ dedicated sales  
30+ dedicated MSLS  
and  
expanding

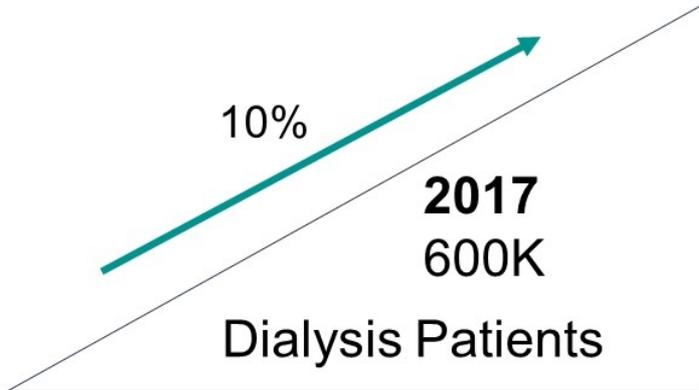
# China: Potential Markets - Differentiated Solution

**~120 million people in China are living with CKD**

**LARGEST DIALYSIS MARKET IN THE WORLD**

Convert Installed Base – *Substitute ESA*

Win Incident Patients – *Direct to HIF-PHI instead of ESA*



Anemia Treatment Rate - 90%

Treatment Rate with ESA - 90%



**NON-DIALYSIS**

- **NDD-CKD**

- CKD patients in stage 3 and stage 4, as well as stage 5 who are not eligible for dialysis.
- Largely untreated with ESAs

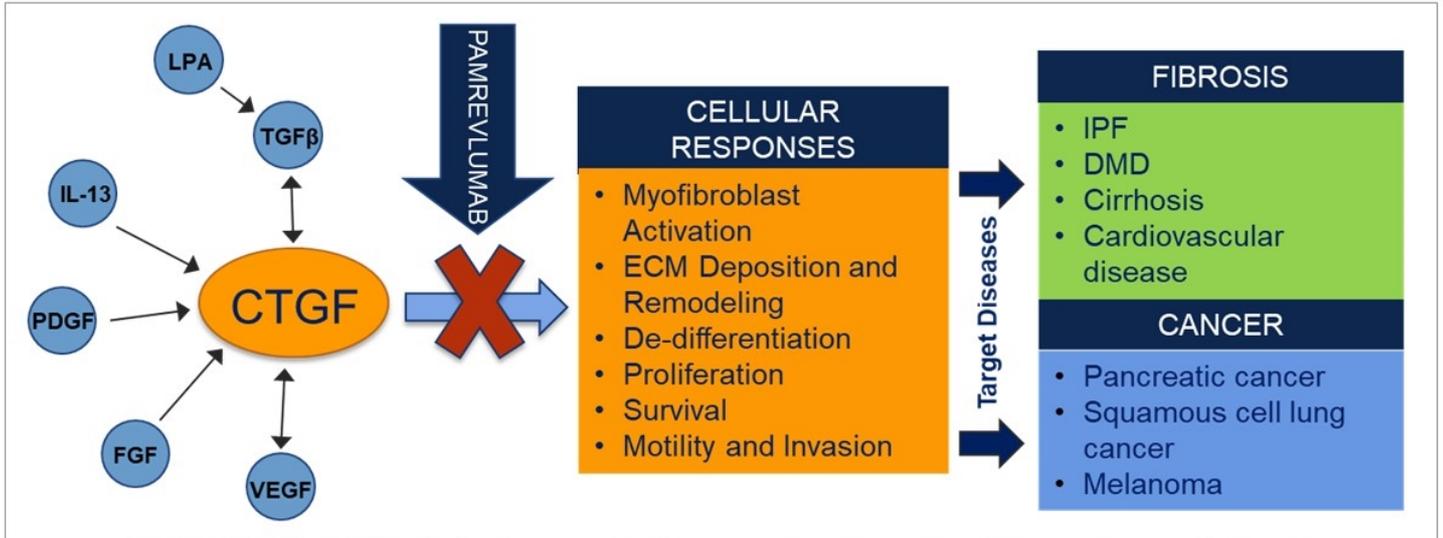
- **Dialysis-Eligible NDD Population**

- China has a large population of Dialysis-Eligible NDD-CKD patients
- These patient qualify for dialysis under treatment guidelines but are not dialyzed
- Estimated at 1-2 million patients
- At risk for severe anemia

# Pamrevlumab

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# Pamrevlumab: Innovative Treatment for Fibrosis and Fibroproliferative Disease



**PAMREVLUMAB -- fully humanized monoclonal antibody targeting activity of connective tissue growth factor, a central factor in fibrosis and in various proliferative diseases**

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# Pamrevlumab: Targeting 3 High Need Medical Indications

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## Idiopathic Pulmonary Fibrosis (IPF)

- FDA Fast Track and Orphan Drug Designation
- Randomized placebo-controlled, double-blind Phase 3 study enrolling
- Primary endpoint of change in forced vital capacity (FVC) from baseline

## Pancreatic Cancer (LAPC)

- FDA Fast Track and Orphan Drug Designation
- Randomized placebo-controlled, double-blind Phase 3 study enrolling

## Duchenne Muscular Dystrophy (DMD)

- FDA Orphan Drug Designation
- EMA Orphan Medicinal Product Designation
- Discussion with regulatory agencies (FDA/EMA) ongoing regarding pivotal program design; preparing for initiation of pivotal program in 2020

# IPF Patients Need New Therapeutic Options



## ORPHAN DISEASE

- U.S. prevalence of ~44,000 to 135,000<sup>1</sup>
- U.S. incidence of ~21,000 to 52,000<sup>1</sup> cases per year
- Incident and mortality are on the rise, and prevalence is expected to increase with the aging population<sup>2</sup>



## PROGRESSIVE

- Leads to irreversible loss of lung function with high morbidity and mortality rates
- Median survival of 3-5 years following diagnosis

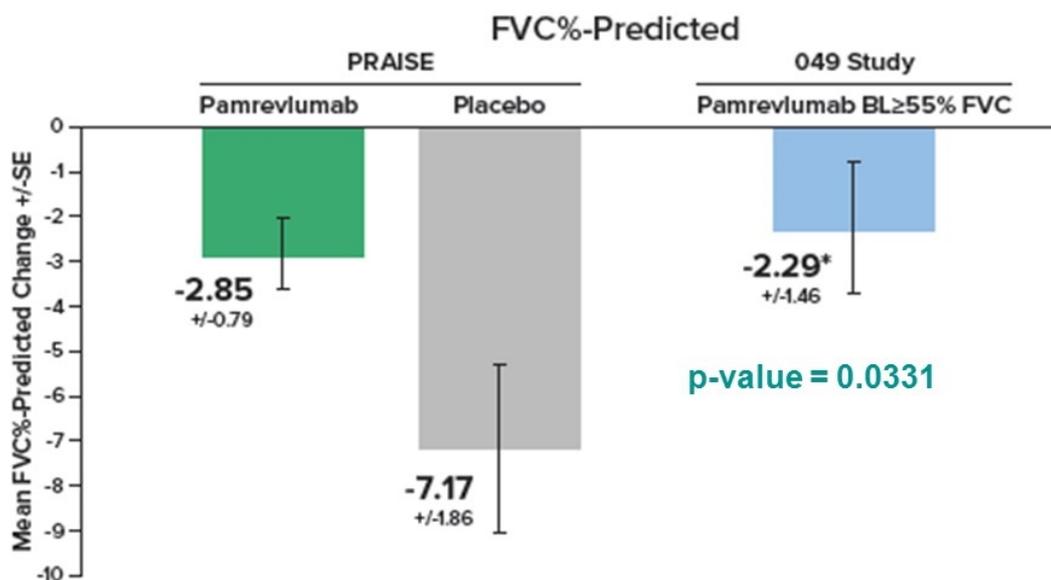


## CURRENT TREATMENTS

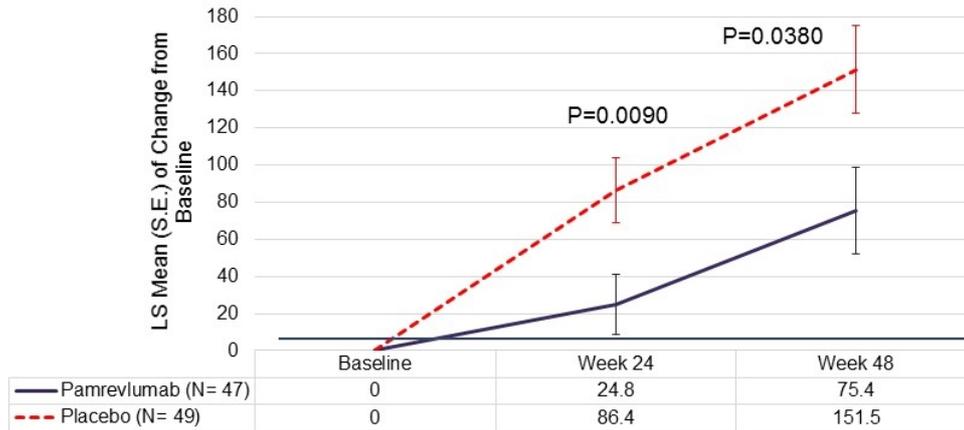
- Slow pulmonary function loss
- Modest effect on slowing disease progression
- No demonstration of reversal
- Require side effect management
- ~\$2B 2018 sales

# Met Primary Efficacy Endpoint by Slowing Decline in FVC Percent Predicted

Consistent with Results from Phase 2 Open-Label Study (Study 049)



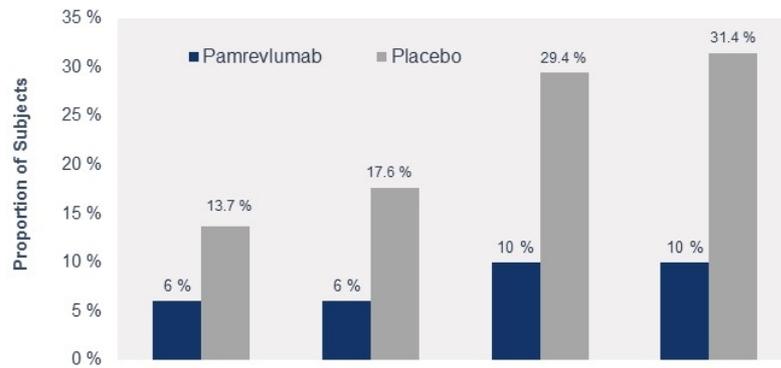
# Pamrevlumab Attenuated Fibrosis Progression



- Absolute differences in QLF changes from baseline to Weeks 24 and 48 between pamrevlumab arm and placebo were 61.6 ml and 76.2 ml, respectively
- First reported statistically significant results for attenuation of fibrosis by qHRCT
- Change in fibrosis (lung structure) correlates with change in FVC % predicted (lung function), primary endpoint of study (Spearman’s correlation coefficient of -0.64, p=0.0001)

# Reduced IPF Disease Progression

## IPF Disease Progression (FVC% Predicted Decline $\geq 10\%$ or Death) vs. Placebo



**Relative Difference 68%**

### ITT Analysis

Visit (Weeks)	12w	24w	36w	48w
<b>P-value*</b>	0.1235	0.0527	0.0172	0.0103
<b>Pamrevlumab, n (%)</b>	3 (6.0%)	3 (6.0%)	5 (10.0%)	5 (10.0%)
<b>Placebo, n (%)</b>	7 (13.7%)	9 (17.6%)	15 (29.4%)	16 (31.4%)
<b>Difference (%)</b>		<b>-11.6%</b>		<b>-21.4%</b>
<b>Relative Difference</b>	-56%	-66%	-66%	-68%

# ZEPHYRUS Pamrevlumab IPF Phase 3 Study

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## Patient Population

- IPF patients who are not currently being treated with approved therapies
- IPF diagnosis according to ATS/ERS/JRS/ALAT guidelines\*

## Study Design

- Placebo-controlled, double-blind
  - Similar to PRAISE Phase 2b study
- Enroll ~565 patients
- Randomization 3:2 pamrevlumab or placebo

## Primary Endpoint

- Change in forced vital capacity (FVC) from baseline

## Secondary Endpoints

- Composite clinical outcome of disease progression
- Patient-reported outcomes
- Quantitative changes in lung fibrosis volume from baseline
- Additional endpoints



# ZEPHYRUS

NCT03955146

# LAPC Patient Population Lacks Treatment Options

## ADDRESSING UNDERSERVED, GROWING, AND EMERGENT PATIENT POPULATIONS



### 55K new U.S. patients Dx annually<sup>1</sup>

- **~27,700** (50%) present with no detectable metastases
- **~9,700** (15-20%) classified as resectable
- **~18,000** (30-35%) with locally advanced disease that precludes resection



### Clinical significance of resection

#### Locally advanced disease

- **50%** survive 8-12 months
  - **~8%** survive 5 years
  - Survival rate similar to metastatic disease

#### Borderline and resectable disease

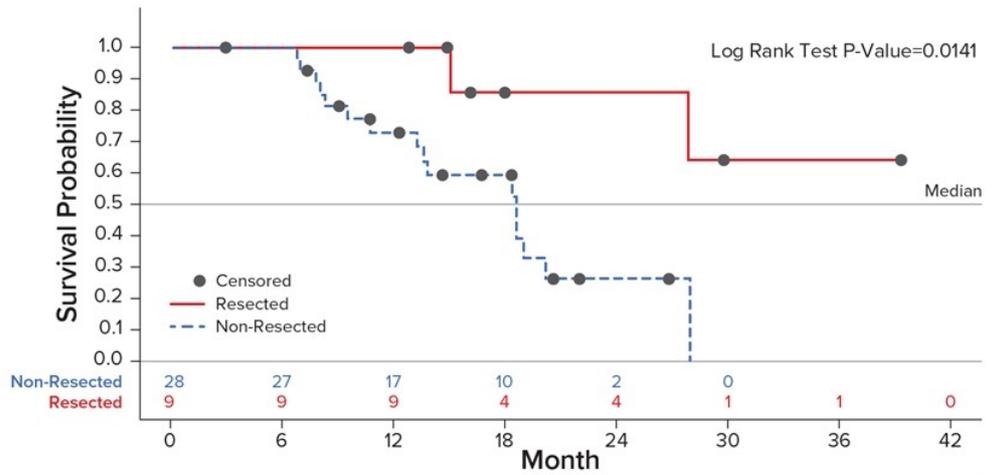
- **50%** survive 17-27 months
- **~20%** survive 5 years

# Survival Benefit Reported at ASCO 2018

## Resection Increases Survival

- Statistically Significant Improvement in Median Survival p-value=0.0141
- Statistically significant improvement of median survival in those who undergo resection
- Median survival for patients with non-resected tumors was 18.6 months
- Median survival for patients with resected tumors was >40 months

## Overall Survival (OS) By Resection



	N	Event	Censored	Median (95% CI)
Non-Resected	28	16 (57.1%)	12 (42.9%)	18.56 (13.27, 20.21)
Resected	9	2 (22.2%)	7 (77.8%)	NE (15.01, NE)

# LAPIS Pamrevlumab LAPC Phase 3 Study



LAPIS  
NCT03941093

## Patient Population

- Locally advanced, unresectable pancreatic cancer
- ECOG 0-1 (health status of patient)
- No prior therapy

## Study Design

- Double-blind, placebo-controlled
- Enroll ~260 subjects at 40-60 sites globally
- Randomization 1:1 pamrevlumab + gemcitabine/nab-paclitaxel or placebo + gemcitabine/nab-paclitaxel
- Six cycles of neoadjuvant treatment followed by evaluation for surgical eligibility and possible resection
- Long-term overall survival follow-up for all subjects

**Primary Endpoint:** Overall Survival (OS)

## Secondary Endpoints:

- Progression-free survival
- Patient-reported outcomes

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## DMD Background

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- Affects ~1 in every 5,000 newborn boys
- About 20,000 children are diagnosed with DMD globally each year
- A fatal disease caused by genetic mutations leading to the absence or defect of dystrophin, a protein necessary for normal muscle function
  - The absence of dystrophin results in muscle weakness, muscle loss, fibrosis, and inflammation
- Patients with DMD are often non-ambulatory before the age of 12, and their progressive muscle weakness may lead to serious medical problems relating to diminished function of respiratory and cardiac muscles

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# Pamrevlumab DMD Program

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## Design

- Open-label, single-arm study in 21 non-ambulatory boys, 12 years of age and older

## Endpoints

- Change from baseline in:
  - Pulmonary function tests
  - Upper body muscle function tests
  - Muscle and cardiac fibrosis by MRI imaging

## One-Year Administrative Analysis

- Results show potential to mitigate decline in:
  - FVC
  - Cardiac function
  - Muscle function
- Positive comparison to natural disease history
- Preparing for initiation of pivotal program in 2020

# Upcoming 2020 Milestones

## ROXADUSTAT

- MAA submission to EMA for the treatment of anemia in dialysis-dependent and non-dialysis-dependent CKD patients anticipated 1H 2020
- Japan NDD sNDA submission early 2020
- China roxadustat launch ongoing
- Publication of Phase 3 roxadustat Data
- Potential roxadustat US approval

## PAMREVLUMAB

- Idiopathic Pulmonary Fibrosis (IPF) Phase 3 trial enrolling
- Locally Advanced Pancreatic Cancer (LAPC) Phase 3 trial enrolling
- Duchenne Muscular Dystrophy (DMD) - preparing for initiation of pivotal program in 2020

# Thank you

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For more information contact at [IR@fibrogen.com](mailto:IR@fibrogen.com)

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