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): June 25, 2021

FibroGen, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36740**	**77-0357827**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 8.01 Other Events.

On June 25, 2021, FibroGen, Inc. and its collaboration partner, Astellas Pharma Inc., issued a press release in which they announced the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency has adopted a positive opinion, recommending the granting of marketing authorization for the medicinal product Evrenzo (roxadustat), intended for the treatment of anemia symptoms in patients with chronic kidney disease.

A copy of such press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "Astellas Receives Positive CHMP Opinion for EVRENZO™ (roxadustat) for Adult Patients with Symptomatic Anemia of Chronic Kidney Disease" dated June 25, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Dated: June 25, 2021

FIBROGEN, INC.

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

Exhibit 99.1

Press Release

Astellas Receives Positive CHMP Opinion for EVRENZO™ (roxadustat) for Adult Patients with Symptomatic Anemia of Chronic Kidney Disease

TOKYO, June 25, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and FibroGen, Inc. (Nasdaq: FGEN, CEO: Enrique Conterno, "FibroGen") today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion relating to the use of roxadustat for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD).[1] CKD impacts one in 10 people globally, of whom one in five are affected by anemia.[2, 3] Anemia of CKD is associated with significant impairment in quality of life and progression to adverse cardiovascular (CV) and renal outcomes.[4-6] Anemia of CKD is often untreated or not treated to target.[4-6]

If approved by the European Commission (EC), roxadustat will be the first orally administered inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase (PH) available in Europe. Roxadustat increases hemoglobin (Hb) levels through a different mechanism of action compared to erythropoiesis-stimulating agents (ESAs). As a HIF-PH inhibitor, roxadustat activates the body's natural response to reduced oxygen levels in the blood. This response involves the regulation of multiple, coordinated processes that lead to the correction of anemia with a reduced need for intravenous iron.

“Anemia of CKD remains an under recognized and undertreated condition. Today’s positive CHMP opinion marks a significant step in providing patients with a new and important treatment option for anemia associated with CKD, regardless of dialysis status,” said Bernhardt G. Zeiher, M.D., Chief Medical Officer, Astellas. “We look forward to the review and assessment by the European Commission which, if positive, would make roxadustat the first HIF-PH inhibitor approved in Europe to treat symptomatic anemia in adult patients with CKD.”

The positive CHMP opinion is based on the results from a comprehensive pivotal Phase 3 program comprising of eight multicenter and randomized studies, which involved 9,600 patients worldwide.[7-12] The results of this program support roxadustat as efficacious in achieving and maintaining target Hb levels (10-12g/dL) in patients with symptomatic anemia of CKD regardless of dialysis status and irrespective of prior ESA treatment.[7-11] The safety profile observed in the roxadustat development program is reflective of the CKD populations studied and comparable to ESAs.[7-12]

“Anemia of CKD significantly affects the daily lives of those living with the condition,” said Mark Eisner, M.D., M.P.H, Chief Medical Officer, FibroGen. “Roxadustat’s novel mechanism of action and oral administration provide physicians with the opportunity to help re-define the management of symptomatic anemia of CKD.”

The positive opinion from the CHMP will now be reviewed by the EC, which has the authority to approve medicines for European Union member states, as well as Iceland, Norway, Liechtenstein and Northern Ireland.[13] The EC has 67 days from the CHMP opinion to issue a final decision.

About CKD and Anemia of CKD
Chronic kidney disease (CKD) is a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure or end-stage renal disease, requiring dialysis or kidney transplant.[14] Many patients with CKD die of cardiovascular complications before progressing to kidney failure and as such the prevalence of early kidney disease is much greater than end-stage disease.[14, 15] CKD impacts one in 10 people globally and is predicted to become the fifth most common cause of premature death globally by 2040.[2, 16]

Anemia, a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, is a common early complication of CKD affecting approximately 20% of CKD patients.[3, 17] Anemia of CKD is associated with an increased risk of hospitalization, cardiovascular complications and death, and can also cause significant fatigue, cognitive dysfunction and reduced quality of life.[5, 18] Blood transfusions are used for treating severe anemia, however, they may reduce a patient's opportunity for kidney transplant and can increase the risk of infection and/or complications such as heart failure and allergic reactions.[19, 20]

About Roxadustat
Roxadustat, an oral medicine, is the first in a new class of medicines, HIF-PH inhibitors, that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin; improved iron absorption and mobilization; and downregulation of hepcidin. Roxadustat is also in Phase 3 clinical development for anemia associated with myelodysplastic syndromes (MDS) and Phase 2 for chemotherapy-induced anemia (CIA).

Roxadustat is approved in Japan, China and Chile for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). In the U.S., the New Drug Application is under review by the U.S. Food and Drug Administration. Several other licensing applications for roxadustat have been submitted by Astellas and AstraZeneca to regulatory authorities across the globe and are currently in review.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia of CKD in territories including Japan, Europe, Turkey, Russia and the Commonwealth of Independent States, the Middle East, and South Africa. FibroGen and AstraZeneca are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia of CKD in the U.S., China, other markets in the Americas, in Australia/New Zealand, and Southeast Asia.

About Astellas
Astellas Pharma Inc., is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at https://www.astellas.com/en.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For more information, please visit www.fibrogen.com.

Astellas Cautionary Notes
In this press release, statements made with respect to current plans, estimates, strategies and beliefs, and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual

results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) that is included in this press release is not intended to constitute an advertisement or medical advice.

FibroGen Forward-Looking Statements
This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the development and commercialization of the Company's product candidates, the prevalence of CKD and anemia, the potential safety and efficacy profile of our product candidates, our clinical and regulatory events. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may", "will", "should", "on track", "could", "expect", "plan", "anticipate", "believe", "estimate", "predict", "potential", "continue" and similar words, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to continued progress and timing of our various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year that ended December 31, 2020 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

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References

1. European Medicines Agency. Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) June 2021 Available from: https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-21-24-june-2021 TBC [Accessed June 2021]

2. Nephrology ISo. Chronic kidney disease. Global kidney health atlas 2019 [Accessed June 2021]. Available from: https://www.theisn.org/wp-content/uploads/2021/05/GKHAtlas_2019_WebFIle-1.pdf.

3. Dmitrieva O, de Lusignan S, Macdougall IC, Gallagher H, Tomson C, Harris K, et al. Association of anaemia in primary care patients with chronic kidney disease: cross sectional study of quality improvement in chronic kidney disease (QICKD) trial data. BMC Nephrol. 2013;14:24.

4. Wong MMY, Tu C, Li Y, Perlman RL, Pecoits-Filho R, Lopes AA, et al. Anemia and iron deficiency among chronic kidney disease Stages 3-5ND patients in the Chronic Kidney Disease Outcomes and Practice Patterns Study: often unmeasured, variably treated. Clin Kidney J. 2020;13(4):613-24.

5. Schmidt RJ, Dalton CL. Treating anemia of chronic kidney disease in the primary care setting: cardiovascular outcomes and management recommendations. Osteopath Med Prim Care. 2007;1:14.

6. Stauffer ME, Fan T. Prevalence of anemia in chronic kidney disease in the United States. PLoS One. 2014;9(1):e84943.

7. Clinicaltrials.Gov. Roxadustat in the Treatment of Anemia in End Stage Renal Disease (ESRD) Patients on Stable Dialysis (Pyrenees). NCT02278341. Available from: https://clinicaltrials.gov/ct2/show/NCT02278341 [Accessed June 2021]

8. Shutov E, Sułowicz W, Esposito C, Tataradze A, Andric B, Reusch M, et al. Roxadustat for the treatment of anemia in chronic kidney disease patients not on dialysis: a phase 3, randomized, double-blind, placebo-controlled study (ALPS). Nephrol Dial Transplant. 2021.

9. Coyne DW, Roger SD, Shin SK, Kim SG, Cadena AA, Moustafa MA, et al. Roxadustat for CKD-related Anemia in Non-dialysis Patients. Kidney Int Rep. 2021;6(3):624-35.

10. Provenzano R, Shutov E, Eremeeva L, Korneyeva S, Poole L, Saha G, et al. Roxadustat for anemia in patients with end-stage renal disease incident to dialysis. Nephrol Dial Transplant. 2021.

11. Fishbane S, El-Shahawy MA, Pecoits-Filho R, Van BP, Houser MT, Frison L, et al. Roxadustat for Treating Anemia in Patients with CKD Not on Dialysis: Results from a Randomized Phase 3 Study. J Am Soc Nephrol. 2021;32(3):737-55.

12. Barratt J, Andric B, Tataradze A, Schömig M, Reusch M, Valluri U, et al. Roxadustat for the treatment of anaemia in chronic kidney disease patients not on dialysis: a phase 3, randomised, open-label, active-controlled study (DOLOMITES). Nephrol Dial Transplant. 2021.

13. European Medicines Agency. Authorizations of Medicines. Available from: https://www.ema.europa.eu/about-us/what-we-do/authorisation-medicines [Accessed June 2021]

14. Ojo A. Addressing the global burden of chronic kidney disease through clinical and translational research. Trans Am Clin Climatol Assoc. 2014;125:229-43; discussion 43-6.

15. Subbiah AK, Chhabra YK, Mahajan S. Cardiovascular disease in patients with chronic kidney disease: a neglected subgroup. Heart Asia. 2016;8(2):56-61.

16. Institute for Health Metrics and Evaluation (IHME). Findings from the Global Burden of Disease Study 2017 2018. Available from: http://www.healthdata.org/sites/default/files/files/policy_report/2019/GBD_2017_Booklet.pdf. [Accessed June 2021]

17. National Kidney Foundation. Anemia and Chronic Kidney Disease. Available from: https://www.kidney.org/atoz/content/what_anemia_ckd. [Accessed June 2021]

18. Eriksson D, Goldsmith D, Teitsson S, Jackson J, van Nooten F. Cross-sectional survey in CKD patients across Europe describing the association between quality of life and anaemia. BMC Nephrol. 2016;17(1):97.

19. Disease NIoDaDaK. Anemia in Chronic Kidney Disease: National Institute of Diabetes and Digestive and Kidney Disease. Available from: https://www.niddk.nih.gov/health-information/kidney-disease/anemia. [Accessed June 2021]

20. Sahu S, Hemlata, Verma A. Adverse events related to blood transfusion. Indian J Anaesth. 2014;58(5):543-51.