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): May 18, 2023

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.)**
409 Illinois Street **San Francisco, California**		**94158**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 415 978-1200

(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(s)**	**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 May 18, 2023, FibroGen, Inc. issued a press release in which it reported positive topline results from its Phase 3 study in China of roxadustat for the treatment of chemotherapy-induced anemia.

A copy of such press release is furnished 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 "FibroGen Announces Positive Topline Results from China Pivotal Phase 3 Clinical Trial of Roxadustat for the Treatment of Chemotherapy Induced Anemia," dated May 18, 2023
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.

FIBROGEN, INC.

Date: May 18, 2023

By: /s/ Michael Lowenstein

Michael Lowenstein
Chief Legal Officer

FibroGen Announces Positive Topline Results from China Pivotal Phase 3 Clinical Trial of Roxadustat for the Treatment of Chemotherapy Induced Anemia

- *Met primary endpoint of noninferiority of roxadustat to erythropoietin alfa*
- *Plan to file supplemental New Drug Application in China*

SAN FRANCISCO and BEIJING, May 18, 2023 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) and its subsidiary, FibroGen (China) Medical Technology Development Co., Ltd. today announced positive topline data from Company's Phase 3 clinical study of roxadustat for treatment of anemia in patients receiving concurrent chemotherapy treatment for non-myeloid malignancies in China.

Roxadustat (□®) demonstrated non-inferiority compared to recombinant erythropoietin alfa (SEPO®) on the primary endpoint of change in hemoglobin (Hb) level from baseline to the average level during weeks 9-13.

In the preliminary safety analysis, the adverse event profile of roxadustat was generally consistent with previous findings and supportive of a positive benefit risk in this patient population.

"Roxadustat is a promising potential new oral drug for treating chemotherapy-induced anemia, which complicates the treatment of many cancer patients," said Mark D. Eisner, MD, MPH, Chief Medical Officer, FibroGen. "Chemotherapy-induced anemia remains an unmet medical need in China, and we believe that roxadustat has potential to improve the lives of these patients."

A total of one-hundred fifty-nine (159) patients with non-myeloid malignancy (solid tumor) with a baseline hemoglobin level at or below 10 g/dL were enrolled into this Phase 3, randomized, open-label, active-controlled study investigating the efficacy and safety of roxadustat for treatment of chemotherapy-induced anemia (CIA). Patients were randomly assigned roxadustat or erythropoietin alfa three times per week (TIW), during a treatment period of 12 weeks, with an additional 4-week follow-up period. The primary endpoint of the study was change in hemoglobin level from baseline to the average level during weeks 9-13. For more information regarding this study, please visit www.clinicaltrials.gov (NCT05301517).

Detailed results from the study will be submitted for presentation at an upcoming medical conference.

This Phase 3 study is sponsored and conducted by FibroGen and is part of the collaboration with AstraZeneca. FibroGen will work with AstraZeneca and the China Health Authority to file the supplemental New Drug Application.

About Chemotherapy-Induced Anemia
Although chemotherapy-induced anemia is one of the most common side effects of chemotherapy, it is often not recognized and is frequently undertreated. CIA can adversely affect long-term patient outcomes, as anemia limits both quality of life and efficacy of chemotherapy treatment. The incidence and severity of CIA depends on a variety of factors. This includes the type of cancer and the treatment, including the type of chemotherapy, schedule, and intensity of therapy. It also depends on whether the patient has received prior myelosuppressive chemotherapy, radiation therapy, or both. An estimated 30% to 90% of cancer patients receiving chemotherapy develop anemia; and in China the figure approaches 80%[1]. Approximately 650,000 cancer patients undergo chemotherapy every year in the United States. In China, over 3 million cancer patients undergo chemotherapy[2].

About Roxadustat
Roxadustat, an oral medication, is the first in a new class of medicines comprising 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 in clinical development for chemotherapy-induced anemia (CIA) in China.

Roxadustat is approved in China, Europe, Japan, and numerous other countries for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). Several other licensing applications for roxadustat have been submitted by partners, Astellas and AstraZeneca to regulatory authorities across the globe, and are currently under review. Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia 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 in the U.S., China, and other markets not licensed to Astellas.

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 connective tissue growth factor (CTGF) biology and hypoxia-inducible factor (HIF) to advance innovative medicines for the treatment of unmet needs. 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), metastatic pancreatic cancer, and Duchenne muscular dystrophy (DMD). Roxadustat (□®, EVRENZO™) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in CKD patients on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia (CIA) in China. FibroGen recently expanded its research and development portfolio to include product candidates in the immuno-oncology space. For more information, please visit www.fibrogen.com.

Forward-Looking Statements
This release contains forward-looking statements regarding FibroGen's strategy, future plans and prospects, the development and commercialization of the company's product candidates, the potential safety and efficacy profile of its product candidates, and the potential impact of clinical data. These forward-looking statements include, but are not limited to, statements about FibroGen's plans and objectives 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. FibroGen's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of its 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 ended December 31, 2022 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, each as 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 FibroGen undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

References:

1. □□□ et al. Medical Information Medicine & Surgery. Sep. 2009. Vol. 22 No.9
2. International Agency for Research on Cancer (WHO) https://gco.iarc.fr/today/

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