



## FibroGen Reports Financial Results for the First Quarter of 2016

May 9, 2016

**Continued Progress in Roxadustat Phase 3 Studies; Promising Interim Pancreatic Cancer Data**

**–Webcast Conference Call Scheduled for 4:30pm EST Today–**

SAN FRANCISCO, May 09, 2016 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ:FGEN) ("FibroGen"), a research-based biopharmaceutical company, today reported financial results for the quarter ended March 31, 2016.

"We are pleased with the progress of our major development programs across the board," said Thomas B. Neff, chief executive officer of FibroGen. "FibroGen and our collaboration partners continue to advance the roxadustat global Phase 3 program in anemia of chronic kidney disease with the hope of providing a safer and more accessible option for patients. We remain on track to initiate new drug application submissions in 2016 for China and in 2018 for the United States. Data from our ongoing Phase 2 programs relating to FG-3019 continue to support the development of this antibody as a potential therapy for devastating and difficult-to-treat diseases."

### Program Updates

#### ***Anemia in Chronic Kidney Disease (CKD): roxadustat (FG-4592)***

- Timelines for roxadustat remain on track. The company expects to initiate new drug application submissions for roxadustat in 2016 for China and in 2018 for the U.S.
- FibroGen and partners AstraZeneca and Astellas are conducting a total of seven Phase 3 trials for registration in the U.S., Europe, and other territories. FibroGen has completed target enrollment for two out of the three FibroGen-sponsored studies, and we have achieved over 80% of target enrollment in the third study.
- The independent data safety monitoring board overseeing roxadustat U.S. and Europe Phase 3 studies met in April 2016 to review the roxadustat safety data, and confirmed that the trials should proceed with current Phase 3 protocols without modification.
- In China, we are conducting two pivotal Phase 3 trials with roxadustat. We are over 80% enrolled in our 300 patient dialysis study, for which the primary efficacy endpoint is 26 weeks, and expect to complete enrollment this month. We are approximately one-third enrolled in our 150 patient non-dialysis study, for which the primary efficacy endpoint is eight weeks, and expect to complete enrollment in the third quarter of 2016. We expect to be able to report data in both studies by year-end.

#### ***Fibrosis and Other Fibroproliferative Disease: FG-3019***

- In idiopathic pulmonary fibrosis (IPF), promising data from our open-label, single-arm dose-finding trial in subjects with moderate to severe IPF were presented in a manuscript published in the European Respiratory Journal (on-line publication in March, and in-print publication in May of this year). Results of the study showed that after 48 weeks of treatment 35% of the subjects receiving FG-3019 had stable or improved lung fibrosis, 24% had improved fibrosis, both as measured by quantitative high resolution computed tomography. For subjects in the high dose group with baseline forced vital capacity (FVC)  $\geq 55\%$  predicted, 37% showed improvement in pulmonary function (as measured by FVC) at the end of the initial 48 week treatment portion of the study. An accompanying editorial noted that, to the best of current knowledge, neither of the two currently approved IPF treatments are targeting connective tissue growth factor (CTGF), posing a promising basis for a future placebo-controlled trial combining our anti-CTGF antibody FG-3019 with pirfenidone or nintedanib.
- We continue to see promising preliminary data from our ongoing open-label Phase 2 study in patients with inoperable Stage 3 pancreatic cancer. Subjects entering the trial must have failed resection scoring, i.e., been found to have unresectable tumors, and thus not eligible for surgery. At present, of nine patients randomized to receive FG-3019 plus chemotherapy (standard-of-care) three patients continue on treatment, one discontinued treatment early due to a chemotherapy-related serious adverse event and five patients completed six months of treatment. All five who completed treatment were reassessed as eligible for resection based on standard scoring criteria set forth in the protocol. Seven patients have been randomized to the comparator arm with only standard of care chemotherapy. Of the seven patients, three experienced disease progression prior to completing treatment and four completed the treatment regimen, of which only one was reassessed as eligible for tumor removal.
- We continue to enroll subjects and add sites in our open-label Phase 2 study of FG-3019 in non-ambulatory Duchenne muscular dystrophy (DMD) patients.

### Financial Highlights

- Net loss per basic and diluted share for the quarter ended March 31, 2016, was \$0.45 per share, an improvement of \$0.33 per share as compared to the same period last year.
- At March 31, 2016, FibroGen had \$309.9 million of cash, cash equivalents, investments, receivables and restricted cash.
- For the quarter ended March 31, 2016, revenue increased 74% and research and development expenses decreased 14% as compared to the same period last year, largely due to the fact that we had reached the 50/50 spending cap with AstraZeneca during the fourth quarter of 2015 on our initial funding obligations for roxadustat. Under an agreement between FibroGen and AstraZeneca, FibroGen's total funding obligations for roxadustat development in CKD outside China are limited to \$116.5 million. As of the end of the fourth quarter of 2015, the \$116.5 million cap on our share of development costs for roxadustat has been reached. Therefore starting in the first quarter of 2016, we no longer share 50% of the development costs compared to the prior periods, as, Astellas and AstraZeneca are now responsible for funding future development and commercialization costs for roxadustat in CKD through launch for all territories, excluding China, where AstraZeneca pays 50% of development costs.

## Conference Call Details

FibroGen will host a conference call and webcast today, May 9, 2016, at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time), to discuss financial results and provide a business update. Interested parties may access a live audio webcast of the conference call via the investor section of the FibroGen website, [www.fibrogen.com](http://www.fibrogen.com). To access the conference call by telephone, please dial (888) 771-4371 (U.S. and Canada) or (847) 585-4405 (international), reference the FibroGen Q1 2016 conference call, and use the passcode 42409340. It is recommended that listeners register 15 minutes before the scheduled start time to ensure a timely connection. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial (888) 843-7419 (domestic) or (630) 652-3042 (international), and use the passcode 42409340#.

## About FibroGen

FibroGen is a research-based biopharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics to treat serious unmet medical needs. The company utilizes its extensive experience in fibrosis and hypoxia-inducible factor (HIF) biology to generate development programs in multiple therapeutic areas. Its most advanced product candidate, roxadustat (FG-4592) is an oral small molecule inhibitor of HIF prolyl hydroxylases (HIF-PHs) in Phase 3 clinical development for the treatment of anemia in CKD. A second product candidate, FG-3019, our fully-human monoclonal antibody that inhibits the activity of CTGF, is in Phase 2 clinical development for the treatment of IPF, pancreatic cancer, and DMD. For more information please visit: [www.fibrogen.com](http://www.fibrogen.com).

## Forward-Looking Statements

This release contains forward-looking statements, including statements regarding our potential milestones, clinical plans, the potential mechanism of action of certain drugs, and financial projections. Our 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 our various clinical programs, including enrollment of the Phase 3 clinical trials for roxadustat in CKD, the continued progress of our plans and programs in China, the outcome of regulatory filings for anemia associated with myelodysplastic syndrome, the enrollment and results from ongoing clinical trials for FG-3019 in IPF, pancreatic cancer, and DMD, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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.

## Condensed Consolidated Balance Sheets

(In thousands)

|                                           | March 31, 2016<br>(Unaudited) | December 31,<br>2015<br>(1) |
|-------------------------------------------|-------------------------------|-----------------------------|
| <b>Assets</b>                             |                               |                             |
| Current assets:                           |                               |                             |
| Cash and cash equivalents                 | \$ 140,959                    | \$ 153,324                  |
| Short-term investments                    | 32,454                        | 27,847                      |
| Accounts receivable                       | 5,937                         | 15,405                      |
| Prepaid expenses and other current assets | 4,651                         | 3,988                       |
| Total current assets                      | 184,001                       | 200,564                     |
| Restricted cash                           | 7,254                         | 7,254                       |
| Long-term investments                     | 122,009                       | 131,720                     |

|                             |                   |                   |
|-----------------------------|-------------------|-------------------|
| Property and equipment, net | 127,613           | 129,020           |
| Other assets                | 1,658             | 2,016             |
| <b>Total assets</b>         | <b>\$ 442,535</b> | <b>\$ 470,574</b> |

#### **Liabilities, stockholders' equity and non-controlling interests**

##### **Current liabilities:**

|                                  |               |               |
|----------------------------------|---------------|---------------|
| Accounts payable                 | \$ 1,543      | \$ 6,521      |
| Accrued liabilities              | 44,038        | 47,932        |
| Deferred revenue                 | 12,722        | 12,728        |
| <b>Total current liabilities</b> | <b>58,303</b> | <b>67,181</b> |

|                                                  |                |                |
|--------------------------------------------------|----------------|----------------|
| Long-term portion of lease financing obligations | 97,077         | 97,042         |
| Product development obligations                  | 15,786         | 15,085         |
| Deferred rent                                    | 4,581          | 4,702          |
| Deferred revenue, net of current                 | 85,328         | 85,132         |
| Other long-term liabilities                      | 5,237          | 4,607          |
| <b>Total liabilities</b>                         | <b>266,312</b> | <b>273,749</b> |

|                            |                |                |
|----------------------------|----------------|----------------|
| Total stockholders' equity | 156,952        | 177,554        |
| Non-controlling interests  | 19,271         | 19,271         |
| <b>Total equity</b>        | <b>176,223</b> | <b>196,825</b> |

|                                                                              |                   |                   |
|------------------------------------------------------------------------------|-------------------|-------------------|
| <b>Total liabilities, stockholders' equity and non-controlling interests</b> | <b>\$ 442,535</b> | <b>\$ 470,574</b> |
|------------------------------------------------------------------------------|-------------------|-------------------|

(1) The condensed consolidated balance sheet amounts at December 31, 2015 are derived from audited financial statements.

#### **Condensed Consolidated Statements of Operations**

(In thousands, except per share data)

|                                            | <b>Three Months Ended March 31,</b> |                    |
|--------------------------------------------|-------------------------------------|--------------------|
|                                            | <b>2016</b>                         | <b>2015</b>        |
|                                            | <b>(Unaudited)</b>                  |                    |
| <b>Revenue:</b>                            |                                     |                    |
| License and milestone revenue              | \$ 19,738                           | \$ 11,506          |
| Collaboration services and other revenue   | 8,544                               | 4,792              |
| <b>Total revenue</b>                       | <b>28,282</b>                       | <b>16,298</b>      |
| <b>Operating expenses:</b>                 |                                     |                    |
| Research and development                   | 43,650                              | 50,539             |
| General and administrative                 | 11,417                              | 10,482             |
| <b>Total operating expenses</b>            | <b>55,067</b>                       | <b>61,021</b>      |
| <b>Loss from operations</b>                | <b>(26,785)</b>                     | <b>(44,723)</b>    |
| <b>Interest and other, net:</b>            |                                     |                    |
| Interest expense                           | (2,777)                             | (2,758)            |
| Interest income and other, net             | 1,416                               | 843                |
| <b>Total interest and other, net</b>       | <b>(1,361)</b>                      | <b>(1,915)</b>     |
| <b>Loss before income taxes</b>            | <b>(28,146)</b>                     | <b>(46,638)</b>    |
| Benefit from income taxes                  | (305)                               | (271)              |
| <b>Net loss</b>                            | <b>\$ (27,841)</b>                  | <b>\$ (46,367)</b> |
| <br>Net loss per share - basic and diluted | <br>\$ (0.45)                       | <br>\$ (0.78)      |

Weighted average number of common shares  
used to calculate net loss per share - basic and  
diluted

62,184

59,197

Contact ☐  
Leanne Price  
415.978.1200 ☐  
[lprice@fibrogen.com](mailto:lprice@fibrogen.com)

**FIBROGEN**

FibroGen, Inc.