
**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): February 16, 2017

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))
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Item 7.01 Regulation FD Disclosure

Beginning February 16, 2017, 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 | FibroGen, Inc. Presentation Materials dated February 16, 2017 |

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: February 16, 2017

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

INDEX TO EXHIBITS

Exhibit
No.

Description

99.1 FibroGen, Inc. Presentation Materials dated February 16, 2017

FIBROGEN

Corporate Overview

February 2017

This presentation, the accompanying modules, and in each case the oral commentary contain “forward-looking” statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, the accompanying modules, and in each case the oral commentary, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward looking statements. In some cases, you can identify forward-looking statements 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, the accompanying modules, and in each case the accompanying oral commentary and include statements regarding our intentions, beliefs, projections, outlook, analyses, or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to initiate or enroll clinical trials, and our ability to make regulatory filings and obtain and maintain regulatory approvals for roxadustat, pamrevlumab, and our other product candidates, our intellectual property position, the potential safety, efficacy, reimbursement, convenience, or clinical and pharmaco-economic benefits of our product candidates, commercial opportunities, including potential market sizes and segments, 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, including all of the foregoing as it pertains to our collaboration partners AstraZeneca, AB, and Astellas Pharma Inc., including cost-sharing, our results of operations, cash needs, 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. Forward-looking statements represent our management’s beliefs and assumptions only as of the date of this presentation, the accompanying modules, and in each case the oral commentary. 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.

- Late-stage first-in-class therapeutics targeting multiple indications and multi-billion dollar markets
- Roxadustat: Oral HIF-PH Inhibitor in WW Phase 3 development
 - Potential safety advantages over ESAs
 - Anemia in CKD patients and in cancer patients
 - Phase 3 trials CKD Anemia in four regulatory pathways
 - China, U.S., EU, Japan
 - Positive China Phase 3 topline data reported in early 2017
 - Partnered with Astellas (Europe and other territories, Japan) and AstraZeneca (U.S./ROW, China)

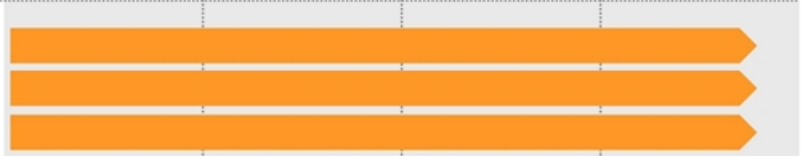
- Pamrevlumab: Disease-modifying anti-CTGF antibody
 - Fibrotic disease therapeutic with multiple potential indications
 - Idiopathic pulmonary fibrosis (IPF)
 - Pancreatic cancer
 - Duchenne Muscular Dystrophy (DMD)
 - Monotherapy and/or combination cancer therapy
- Strong balance sheet, near-term cash flow, and retain long term revenue potential
 - Q3 2016 cash balance of ~\$356.8M
 - >\$800M in upfront and milestone partner payments received to date
 - R&D reimbursed by partners globally; 50-50 cost-sharing in China
 - Significant participation in roxadustat product sales ($\geq 20\%$)

HIF PLATFORM

PRECLINICAL PHASE 1 PHASE 2 PHASE 3

Roxadustat (HIF-PH Inhibitor for CKD anemia)

- United States / Europe
- China
- Japan



FIBROTIC DISEASE PLATFORM

PRECLINICAL PHASE 1 PHASE 2 PHASE 3

FG-3019 (Anti-CTGF Antibody)

- Idiopathic Pulmonary Fibrosis
- Pancreatic Cancer
- Duchenne Muscular Dystrophy



BIOSYNTHETIC CORNEA

PILOT

PIVOTAL

FG-5200 (Corneal Blindness)¹



Partnered

Wholly-owned therapeutic

Wholly-owned Medical Device

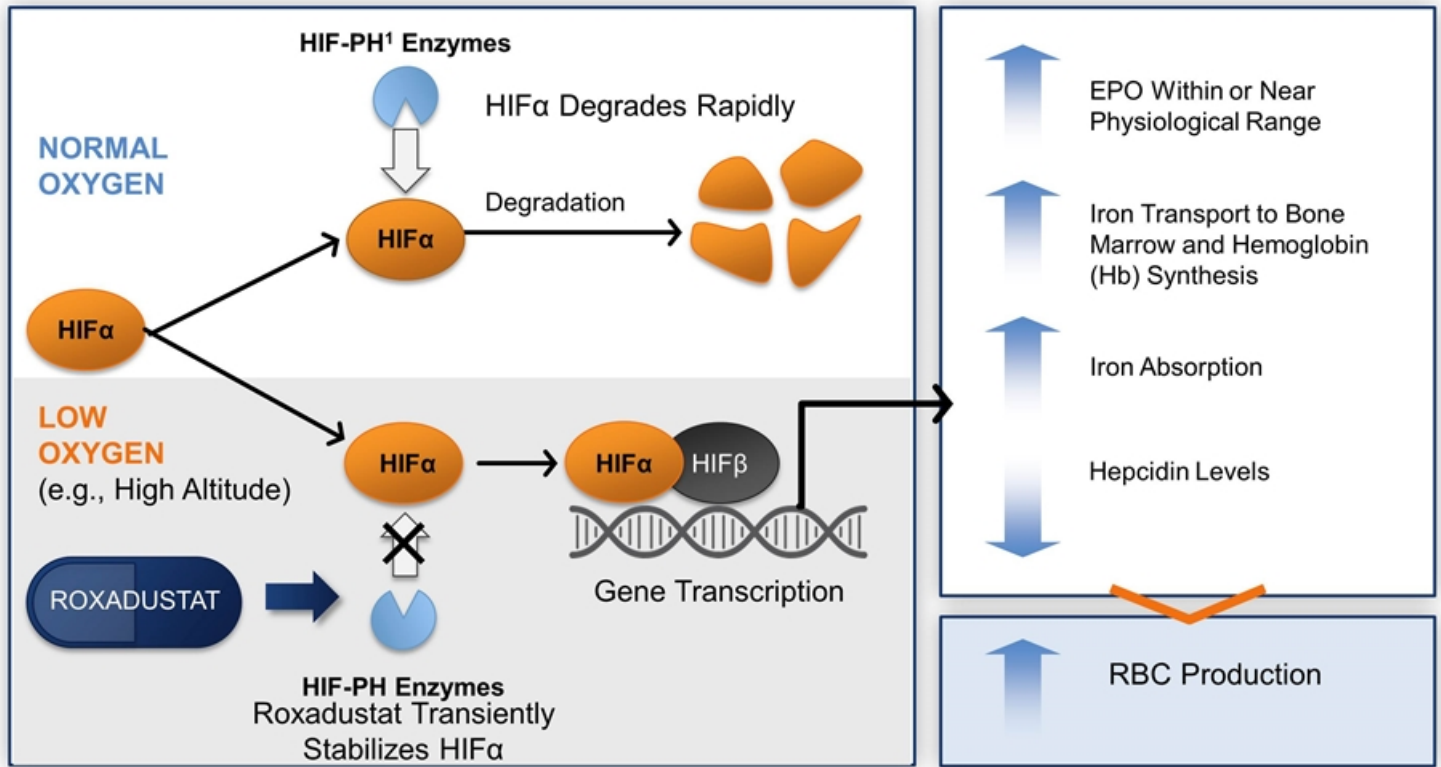
¹ 5-year POC study in 10 patients completed; filed as device in China.

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Roxadustat (FG-4592)

Activates RBC Production via Natural Pathway

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¹hypoxia-inducible factor prolyl hydroxylase (HIF-PH)

ESAs¹: Current SOC



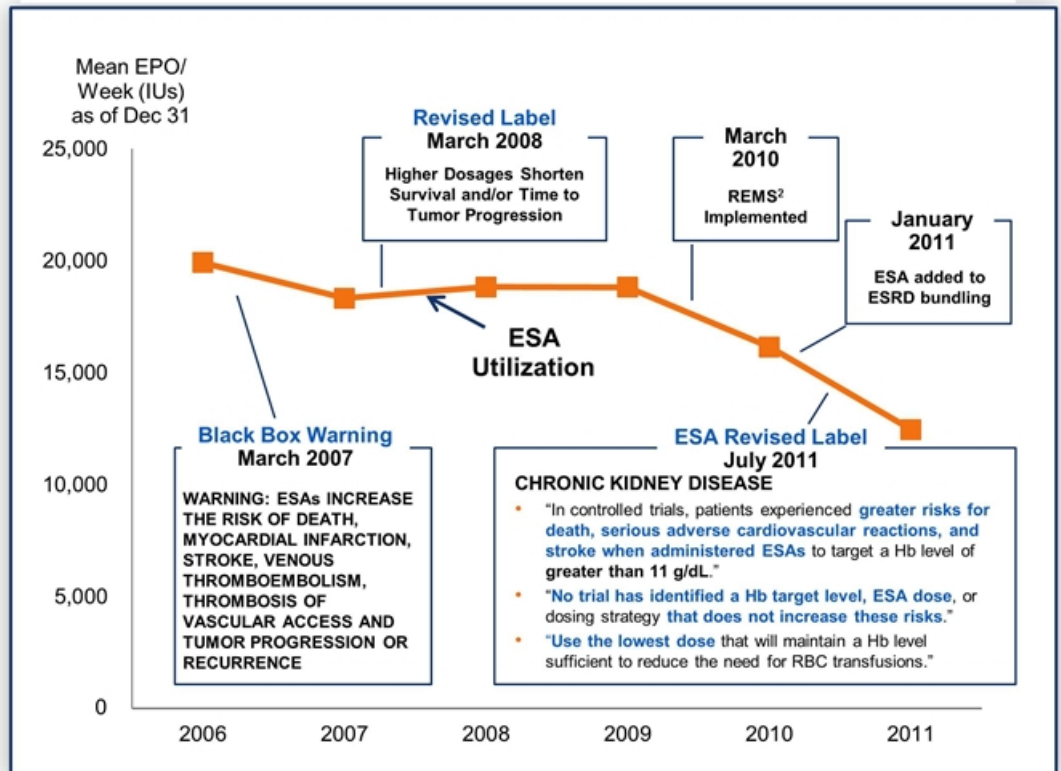
\$8.6B Global Sales

- Intravenous/subcutaneous
- Doses well above physiologic range required
- IV iron required in dialysis

ESA Safety Issues

- Major cardiac AEs
- Tumor progression
- Mortality and anaphylaxis risks with IV iron³

Post-FDA Actions: ESA Declining but Substantial



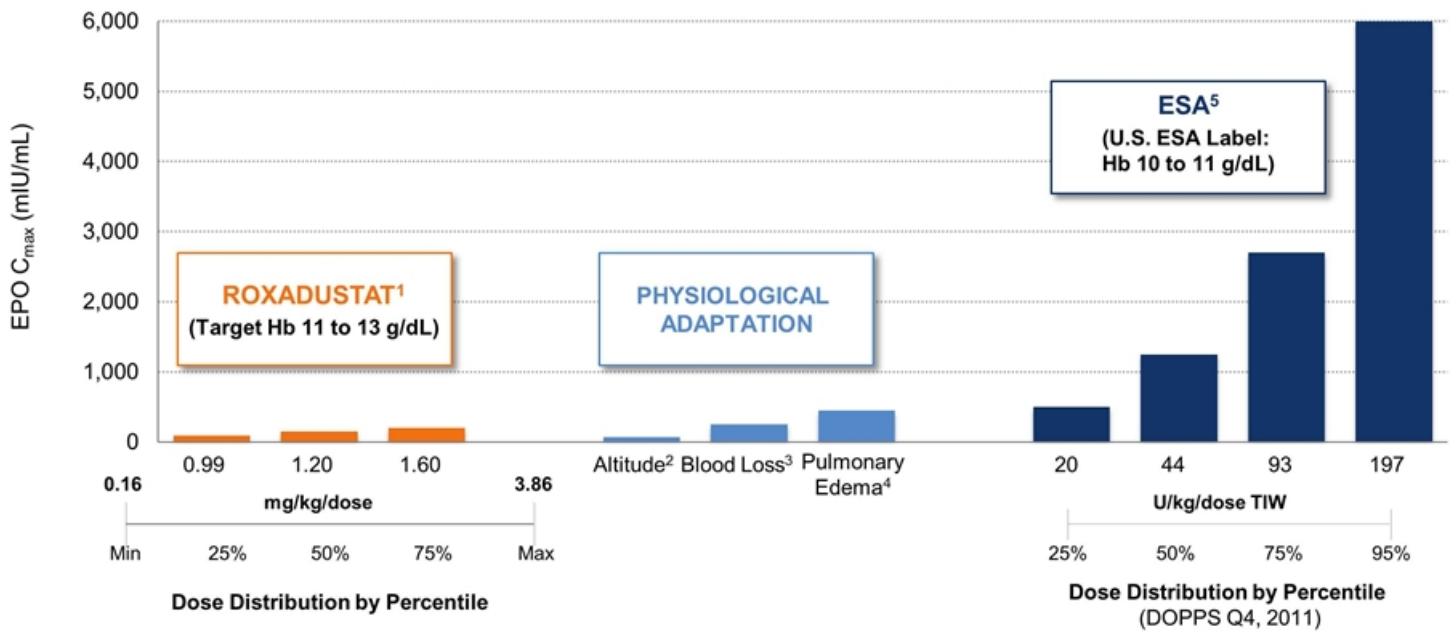
¹ Erythropoiesis-stimulating agents such as Epogen®, Aranesp® and Procrit®.

² Risk Evaluation and Mitigation Strategies. FDA can require a sponsor to implement REMS if the agency determines that safety measures above and beyond product labeling are needed.

³ GR Baillie et al., Association between IV iron dose and mortality: the DOPPS, Kidney International, 2014.

Effective With eEPO Within or Near Physiological Range

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¹ C_{max} data for roxadustat estimated for a subset of 243 patients who achieved Hb response and were dosed at expected therapeutic doses.

² Milledge & Cotes (1985) J Appl Physiol 59:360.

³ Goldberg et al. (1993), Clin Biochem 26:183, Maeda et al. (1992) Int J Hematol 55:111.

⁴ Kato et al. (1994) Ren Fail 16:645.

⁵ Based on Flaherty et al. (1990) Clin Pharmacol Ther 47:557.

| 8 Completed ¹ Phase 2 Studies | Patient Population | # of Patients | Treatment Duration |
|---|--------------------|---------------|--------------------|
| 017 – US | NDD-CKD | 116 | 4 weeks |
| 041 – US | NDD-CKD | 145 | 16, 24 weeks |
| 047 – China | NDD-CKD | 91 | 8 weeks |
| *CL-303 – Japan | NDD-CKD | 107 | 24 weeks |
| 040 – US | Stable dialysis | 161 | 6, 19 weeks |
| 053 – Global | Incident dialysis | 60 | 12 weeks |
| 048 – China | Stable dialysis | 96 | 6 weeks |
| *CL-304 – Japan | Dialysis | 130 | 24 weeks |

- Anemia correction in NDD-CKD and DD-CKD patients
- Anemia correction in incident dialysis patients
- Maintains hemoglobin levels upon conversion from ESA

- Hb correction
 - Regardless of inflammation
 - No IV iron supplementation required
 - Potential to avoid high-dose ESA risk
- Favorable safety profile vs. ESAs
 - No hypertensive effect
 - No thrombocytosis
- Other effects observed
 - Reduced hepcidin
 - Reduced cholesterol
- Optimal dosing regimen for correction and maintenance
 - Dose titration
 - Weight-based dosing

¹ Including Phase 2 dialysis and non-dialysis studies conducted in Japan by partner Astellas*

Global Phase 3 Program 4 Regulatory Pathways **FIBROGEN**

U.S./EU Global Phase 3 with target 2018 NDA submission

| Dialysis Studies | | Initial N | Enrollment Status | Non-Dialysis Studies | | Initial N | Enrollment Status |
|----------------------------------|--------|-------------|-------------------------------------|---------------------------|--------|-------------|-------------------------------------|
| Himalayas – FG Incident dialysis | 063 | 750 | Ongoing (N exceeded initial target) | Andes – FG | 060 | 600 | Ongoing (N exceeded initial target) |
| Sierra – FG Stable dialysis | 064 | 600 | Ongoing (N exceeded initial target) | Olympus – AZ | 001 | 2600 | Ongoing |
| Rockies – AZ Dialysis | 002 | 1425 | Ongoing | Alps – AST | CL-608 | 600 | Completed |
| Pyrenees – AST Stable dialysis | CL-613 | 750 | Completed | Non-dialysis Total | | 3800 | |
| Dialysis Total | | 3525 | | | | | |

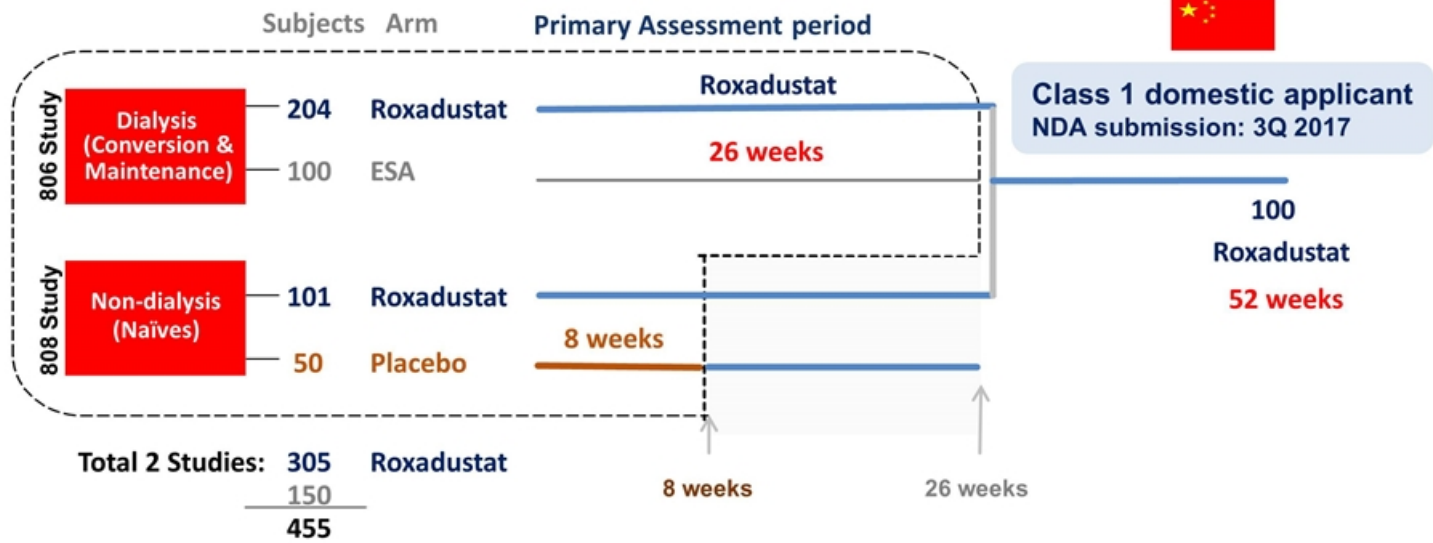
- Astellas Japan Phase 3 (4 DD-CKD; 2 NDD-CKD): all studies underway
- FibroGen China Phase 3 (1 DD-CKD; 1 NDD-CKD): topline data reported in early 2017

*AST's Dolomite CL-610 NDD-CKD, darbepoetin comparator, for EU reimbursement; ongoing

China Phase 3 Studies – Primary Endpoints Met

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FIBROGEN CHINA
 法博进(中国)医药技术开发有限公司



Commercial Opportunity

- Dialysis-CKD: ~400,000 patients; ~equal to U.S.; double-digit Y/Y growth rate since 2011
- NDD-CKD: large patient population, severe anemia, limited treatment
- CKD anemia: "severe disease" reimbursement classification
- AZ with strong presence in China; will lead marketing, sales, and distribution
- First launch anticipated in China

Roxadustat – More Efficacious Than Kirin EPO (Active Control) in Maintaining Hb levels in Stable CKD-Dialysis Patients (Study 806)

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Roxadustat further corrects and maintain Hb (g/L) in stable CKD-dialysis patients

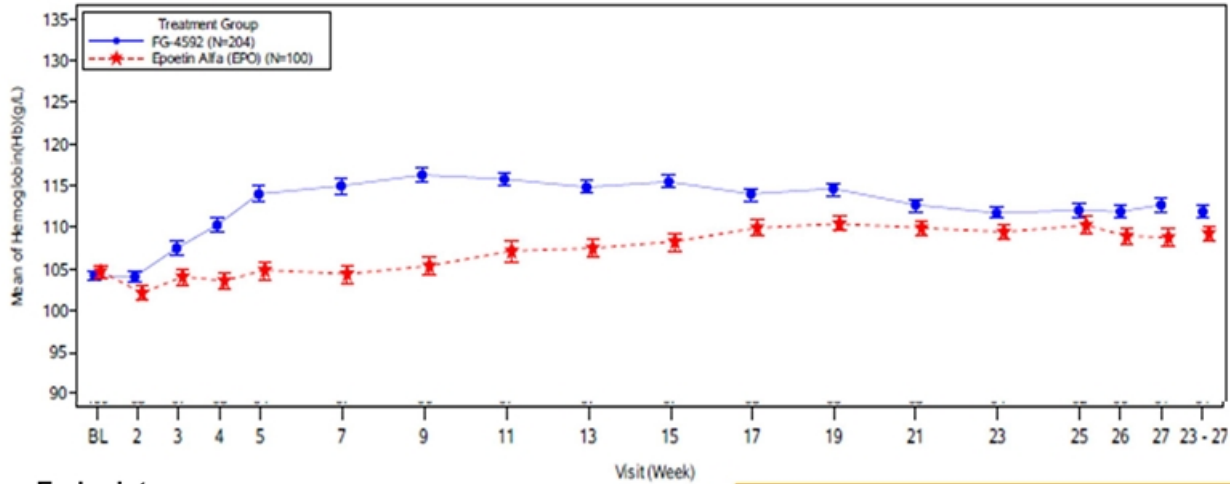


Figure 14.2-2.1a

Primary Endpoint:

Mean change in Hb from baseline, averaged over Weeks 23-27.

| PPS Mean (SD) Hb Values (g/dL) | Roxadustat (n=196) | Kirin EPO (n=98) |
|---|-------------------------|------------------|
| Baseline | 10.4 (0.7) | 10.4 (0.7) |
| Week 23-27 | 11.2 (0.9) | 10.9 (0.8) |
| Change from baseline | 0.75 (1.1) | 0.46 (1.0) |
| Treatment difference LS Mean (SE) [CI]* | 0.26 (0.12) [0.02, 0.5] | |
| P-value/superiority comparison | 0.0368 | |

Primary Endpoint

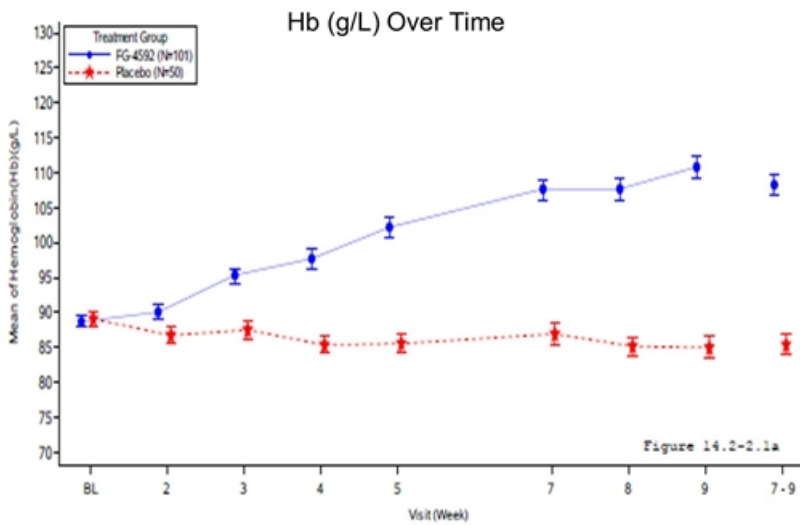
- **Non-inferiority** : roxadustat met the pre-defined non-inferiority criterion.
- **Superiority**: roxadustat achieved a greater increase in Hb level than did Kirin EPO in PPS analysis.

Kirin EPO – active comparator used in study 806

- Premium priced vs. local EPO
- Imported product from Kirin, Japan, sold by Kyowa Hakko Kirin
- Regarded as premium product
- Used by only 6.6% of patients prior to study; the rest used local Chinese EPO

Roxadustat Corrects Anemia In CKD-NDD Patients (Study 808)

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Primary Efficacy Endpoint

Mean change in Hb, averaged over Weeks 7-9, from baseline

| Mean (SD) Hb Values (g/dL) | Roxadustat (n=101) | Placebo (n=50) |
|----------------------------|----------------------------|----------------|
| Baseline Hb mean (SD) | 8.9 (0.8) | 8.9 (0.7) |
| Week 7-9 Hb, mean (SD) | 10.8 (1.4) | 8.5 (0.98) |
| Change in Hb from baseline | 1.9 (1.2) | -0.4 (0.8) |
| Difference (SE), P-value | 2.25 (0.19); $p < 0.00001$ | |

Secondary Endpoints

- Cumulative proportion of patients who achieved a Hb response (Hb increase ≥ 1.0 g/dL from baseline) in the first eight weeks (by Week 9)

| Roxadustat (n=101) | Placebo (n=50) | P-value |
|--------------------|----------------|---------------|
| 84.2% | 0% | $p < 0.00001$ |

- Proportion of patients with mean Hb ≥ 10.0 g/dL, averaged over Weeks 7-9

| Roxadustat (n=101) | Placebo (n=50) | P-value |
|--------------------|----------------|---------------|
| 67.3% | 6.0% | $p < 0.00001$ |

Global Phase 3 Development Program

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| STUDY # | COMPARATOR | TARGET # | LOCATIONS | CHINA | EUROPE | U.S | SPONSOR |
|----------------------------------|-----------------|------------|---|-----------|---------|---------|----------|
| Phase 3 Trials in Process | | | | | | | |
| Stable Dialysis | | | | | | | |
| CL-0613 | Epoetin α/Darbe | 750 | EU, MEA ³ | | 36+ wks | 52+ wks | Astellas |
| FG-064 | Epoetin α | Up to 750 | US+/-Global | | 36+ wks | 52+ wks | FibroGen |
| FG-806 | Epoetin α | 300 | China | 26-52 wks | | | FibroGen |
| Stable/Incident Dialysis | | | | | | | |
| FG-063 | Epoetin α | 750 (+150) | Global | | 36+ wks | 52+ wks | FibroGen |
| AZ-002 | Epoetin α | 1425 | Global | | | 52+ wks | AZ |
| Non-Dialysis | | | | | | | |
| FG-060 | Placebo | 600 (+300) | US, LA ² , APAC ³ | | 36+ wks | 52+ wks | FibroGen |
| CL-0608 | Placebo | 450-600 | EU, MEA ⁴ | | 36+ wks | 52+ wks | Astellas |
| FG-808 | Placebo | 150 | China | 26-52 wks | | | FibroGen |
| AZ-001 | Placebo | ~2,600 | Global | | | 52+ wks | AZ |
| EU Reimbursement Study | | | | | | | |
| CL-0610 | Darbepoetin | 570 | EU, MEA | | 36+ wks | N/A | Astellas |

¹Plan to support US regulatory approval with 7 studies (4 DD and 3 NDD), 5 of which (3DD and 2 NDD, highlighted) will also be used in the European package that contains a total of 6 studies (3 DD and 3 NDD)

²LA - Latin America; ³APAC - Asia-Pacific; ⁴MEA - Middle East & Africa

* Phase 3 program additionally includes six Phase 3 studies in Japan sponsored by partner Astellas (not listed)

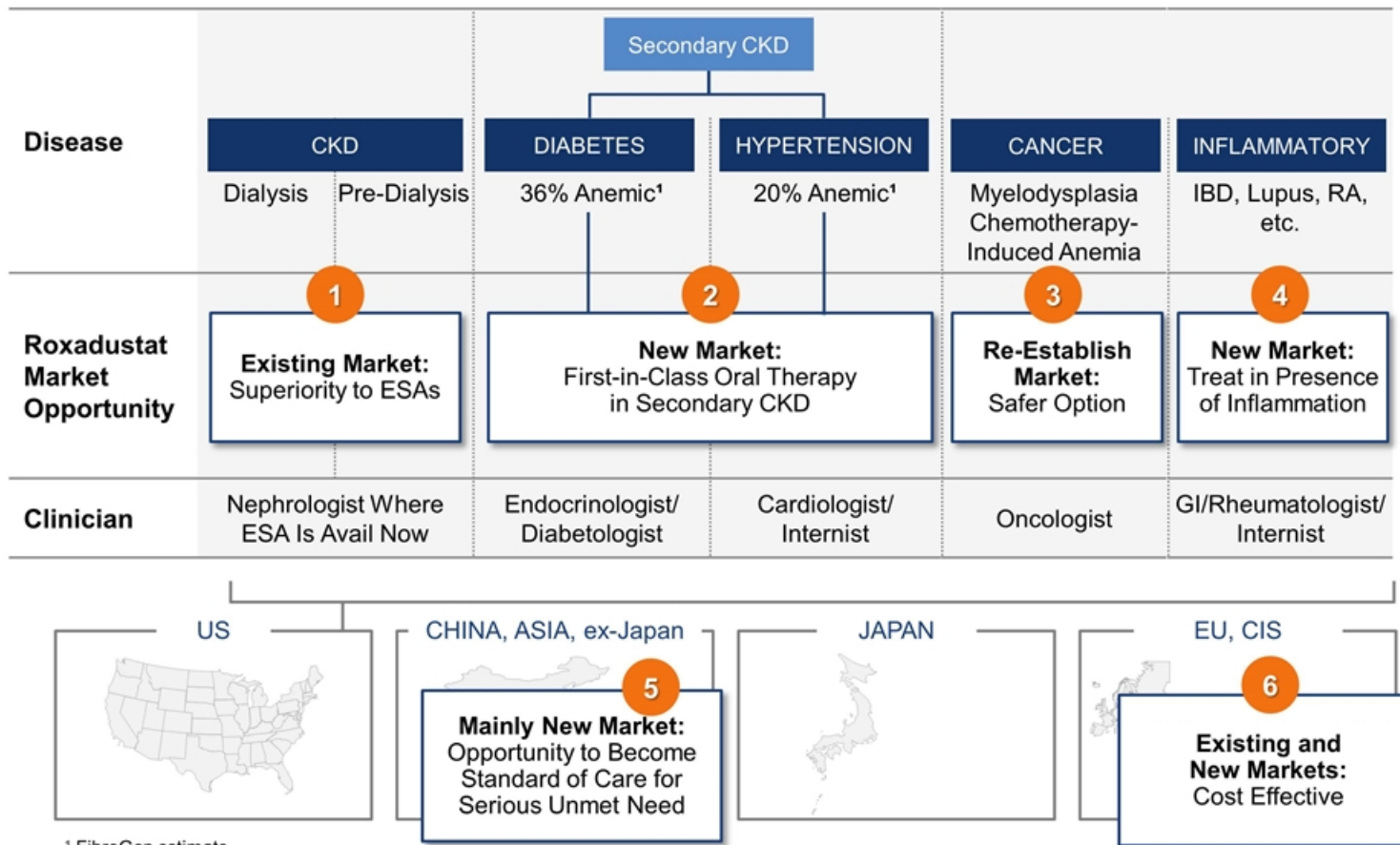
Roxadustat Has Potential to Address Unmet Need in Multiple Markets

| | CKD | | DIABETES | HYPERTENSION | CANCER | INFLAMMATORY |
|-------------------------------------|-------------------------------------|--------------|---|----------------------------|---|---------------------------------|
| Disease | Dialysis | Pre-Dialysis | 36% Anemic ¹ | 20% Anemic ¹ | Myelodysplasia Chemotherapy Induced Anemia | IBD, Lupus, RA, etc. |
| Limitations on ESA Treatment | FDA Safety Issues | | Not Referred to Nephrologists 'Delayed Referral' | | Safety Issues (Higher ESA doses required v CKD) Transfusion Mkt | ESAs Not Demonstrated to Work |
| Clinician | Nephrologist Where ESA Is Avail Now | | Endocrinologist/ Diabetologist | Cardiologist/ Internist | Oncologist | GI/Rheumatologist/ Internist |



¹ FibroGen estimate

Potential Multiple Global, Multi-Billion Dollar Markets for Anemia



¹ FibroGen estimate

- China
 - Significant unmet need in oncology-related anemias
 - Anemia associated with MDS and chemotherapy-induced anemia
 - Severe blood shortage in China
 - CFDA reviewing CTA for MDS anemia placebo-controlled Phase 2/3 study
- U.S.
 - FDA accepted Phase 3 study IND for anemia in MDS patients
 - Anticipate trial initiation in Q2 2017

Roxadustat Global Anemia Partnerships

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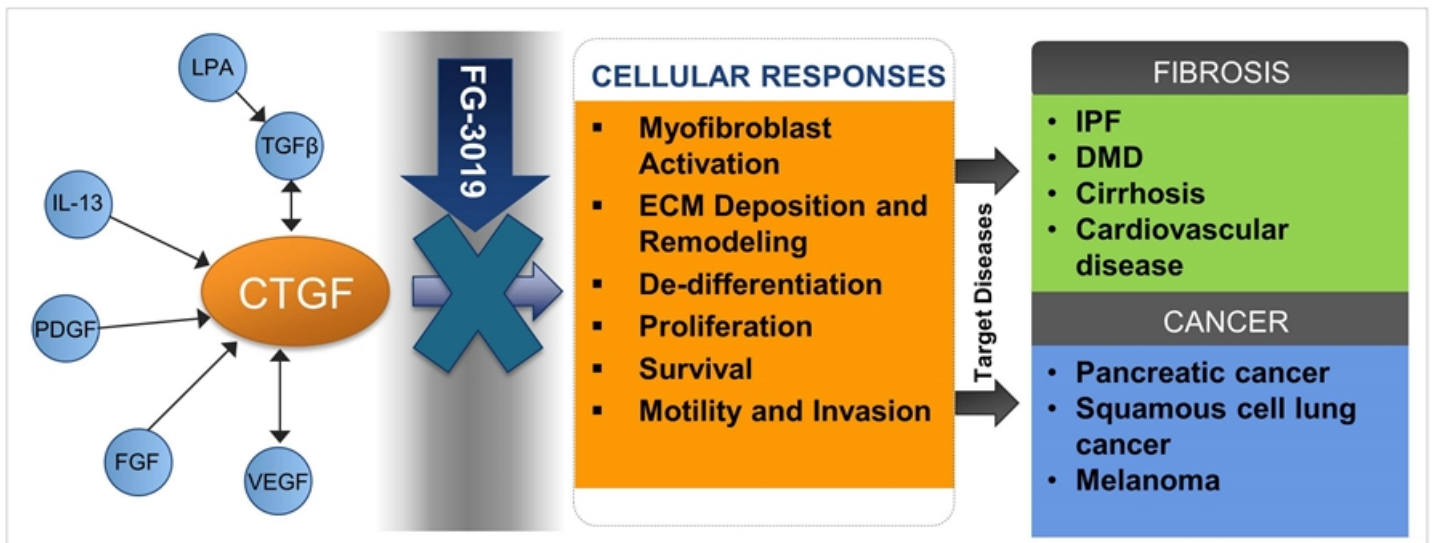
| | \$ Millions | JAPAN, EU, ETC. | U.S., CHINA, ROW | Payments Received to Date |
|-------------------------|---|--------------------|---------------------|------------------------------|
| PAYMENTS TO FIBROGEN | Equity Investment in FibroGen | \$81 | \$20 | \$101 |
| | Upfront, Non-Contingent | \$360 | \$402 | \$762 |
| | Development & Reg. Milestones | \$543 | \$571 | \$128 |
| | Commercial Milestones | \$15 | \$653 | \$0 |
| | POTENTIAL TOTAL | \$918M | \$1,626M | \$890M of \$2,544M |
| | Low 20% (Astellas) – Low-Mid 20% (AZ) Transfer Price (AST) Net Sales Royalty/Transfer Price (AZ) | | | |
| DEVELOPMENT FUNDING | FibroGen R&D Costs Reimbursed, ex-China | | | |
| LAUNCH FUNDING | Commercial Costs Covered by Partners, ex-China | | | |
| | CHINA PARTNERSHIP 50% Profit Sharing 50% Development and Launch Costs | | | |

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Pamrevlumab (FG-3019)

Central Role of Connective Tissue Growth Factor (CTGF) in Fibrosis

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LEADERSHIP IN FIBROSIS

IPF

- **Completed open-label Phase 2**
 - Reversal of fibrosis, stable or improved fibrosis by HRCT, correlating to FVC data, also observed in extension study beyond 48 weeks
 - Well tolerated
- **Ongoing Phase 2 (enrollment completed), data Q3 2017**
 - Randomized placebo-controlled trial (48 weeks), N=103
 - Sub-study: combination with pirfenidone or nintedanib (24 weeks), N=57
 - Key endpoints: change in FVC from baseline; fibrosis by HRCT

PANCREATIC CANCER

- **Completed Phase 2 in advanced disease**
 - Positive data on median survival and one-year survival
- **Ongoing Phase 2 locally advanced inoperable disease; data in Q1 2017**
 - Randomized (pamrevlumab + gemcitabine + nab-paclitaxel) vs. (gemcitabine + nab-paclitaxel)
 - Treatment duration six months, target N=42
 - Key endpoints: evaluate conversion rate to operable state, surgical margin (cancer removal), survival

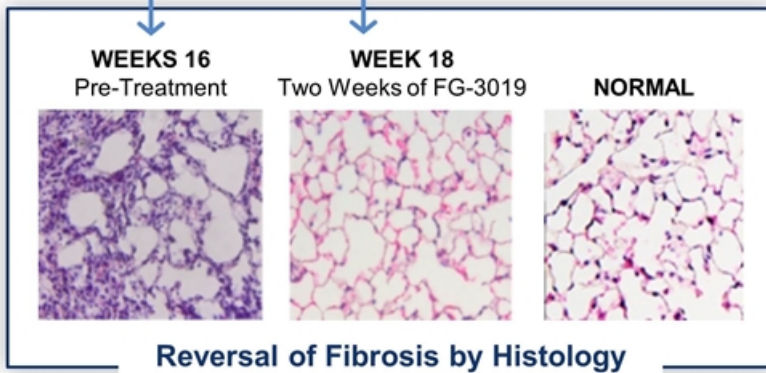
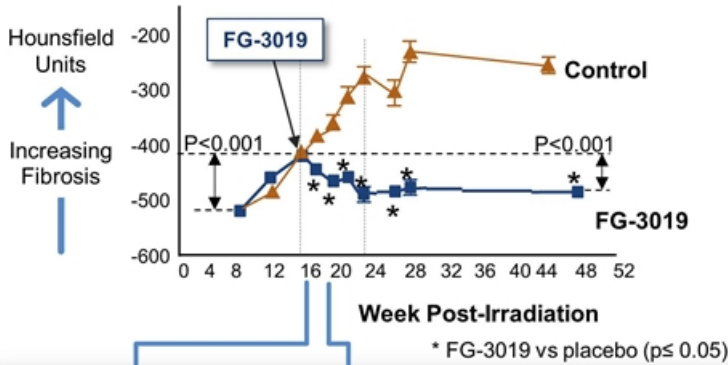
DMD

- **Ongoing open-label study in non-ambulatory patients**
 - Treatment duration 52 weeks, N=22
 - Key endpoints: change in FVC (% pred) and other measures of pulmonary function, measures of upper body muscle function, and cardiac MRI

Improved Fibrosis Shown in Preclinical Data and Open-Label Phase 2 Study

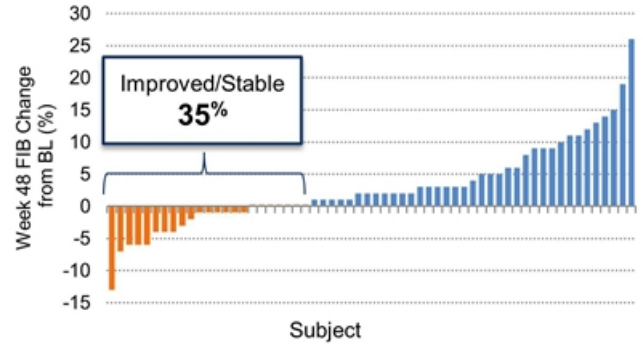
Radiation-Induced Mouse Model of Lung Fibrosis

Reversal of Fibrosis by Micro-CT Imaging

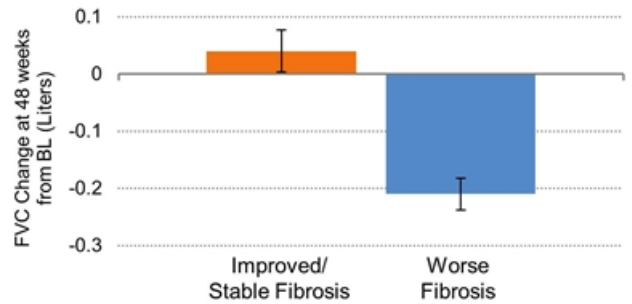


Phase 2A IPF Clinical Trial

Reversal of Lung Fibrosis by HRCT at Week 48



Improved / Stable Fibrosis Correlates with Improved Lung Function



- Orphan disease: U.S. prevalence 106,400 (2014); ~120,800 (2019) ¹
- Progressive disease can result in irreversible loss of lung function with high morbidity and mortality rates
- Median survival of 3-5 years following diagnosis
- Pirfenidone and nintedanib approved by FDA in 2014 and EMA in 2011 (pirfenidone) and 2015 (nintedanib):
 - Slow pulmonary function loss
 - Modest effect on slowing disease progression
 - No demonstration of reversal
 - Require management of side effects

¹Decision Resources 2015

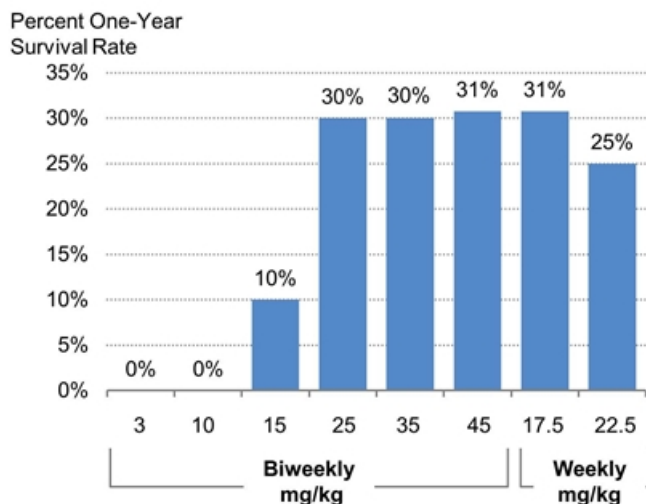
- Ongoing Phase 2 trial
 - Completed enrollment
 - Placebo-controlled portion of study with 103 patients
 - Sub-study combining pamrevlumab with pirfenidone or nintedanib
 - Expect topline data for both study arms in third quarter
- Presented data from open-label extension study at ICLAF 2016
 - No safety issues observed during prolonged treatment
 - 37 patients initially enrolled from the original open label Phase 2 study
 - Some patients treated for up to five years
 - Improved or stable pulmonary function and stable fibrosis observed during initial trial and seen in first year of extension study

Phase 2 Dose-Dependent Survival in Advanced Pancreatic Cancer

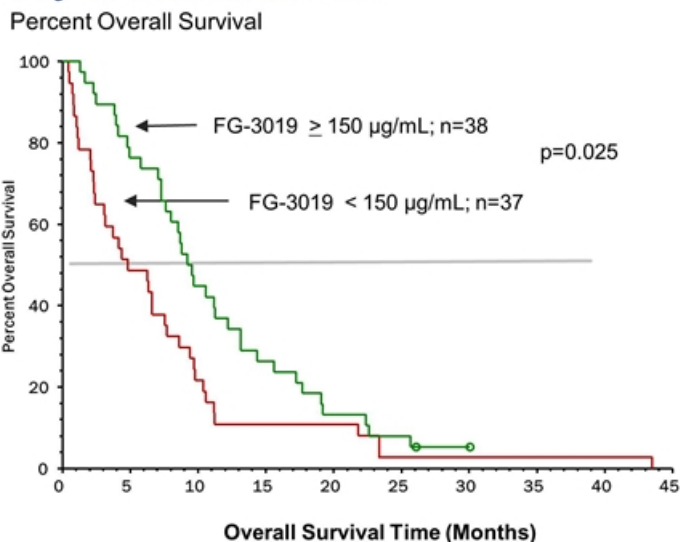
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FG-3019 in Combination with Gemcitabine and Erlotinib (N=75)

Relationship of One-Year Survival to Dose



Relationship of Survival to FG-3019 Day-15 Plasma Levels



KEY FINDINGS

- Dose-related increase in survival
- Day 15 minimum FG-3019 plasma level \geq 150 μ g/mL
 - 2x Median survival (9.4 vs. 4.8 months) (p=0.025)
 - 3x One-year survival (37% vs. 11%) (p=0.01)

- 53,000 new cases per year in U.S.¹
- ~26,500 (50%) patients have no detectable metastases at presentation
 - ~8,000 (15-20%) classified as resectable¹
 - ~18,500 (30-35%) with pancreatic cancer that precludes resection¹
- Differential outcomes and clinical significance of pancreatic resection
 - Non-resectable
 - 50% survive 8-12 months post-diagnosis
 - Few report 5-year survival
 - Similar to metastatic cases
 - Resectable
 - 50% survive 17-27 months post diagnosis
 - ~20% report 5-year survival

¹U.S. National Cancer Institute Cancer, 2016

Randomized Open-Label Phase 1/2 Trial in Pancreatic Cancer

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- Subjects with locally advanced inoperable pancreatic cancer
 - Randomized 2:1 (N=42): chemotherapy vs. chemotherapy+pamrevlumab
 - Treatment duration six months
 - Re-assess for surgery eligibility and surgical outcome
- Results reported January 2017 at ASCO-GI

| | ITT N | Still on treatment | Completed 6-month course of therapy | Rescored eligible for resection | R0 (no residual disease) | R1 (microscopic residual disease) | Unresectable (upon exploration) |
|--|-------|--------------------|-------------------------------------|---------------------------------|--------------------------|-----------------------------------|---------------------------------|
| SOC alone (gemcitabine + nab-paclitaxel) | 11 | 0 | 6 | 1 | 1 | 0 | - |
| FG-3019 + SOC | 22 | 10 | 9 | 7 | 3 | 1 | 3 |

- SOC alone: 1/11 resectable (1R0); 5 disease progression; 4 deaths
- Pamrevlumab+SOC: 4/12 resected (3 R0, 1 R1); 2 disease progression, 2 deaths

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Biosynthetic Cornea Program

U.S. (Canada and EU)

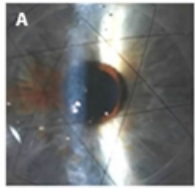
- 42,000 transplants/year in U.S.
- Established donor banking system
- Requires long-term corticosteroid use
- 5-year rejection rate of 35%

China (and Other Emerging Markets)

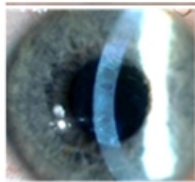
- Cadaver transplants limited
- Lack institutionalized tissue banking
- Approximately 4-5 million patients with corneal blindness
- ~200,000 new cases annually
- ~3,000 corneal implant surgeries/year
- Procedure reimbursed by government



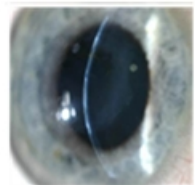
FG-5200 Biosynthetic Cornea
Proprietary Recombinant
Human Collagen Type III (RHC III)



Day 1



2 YEARS



4 YEARS

Recombinant Human Collagen III Corneas Implanted by Deep Anterior Lamellar Keratoplasty (DALK)

Subjects

- Single center, 10 subjects
- Inclusion criteria: patients on wait list for cornea transplant
- Diagnosis: keratoconus - 9; corneal scar - 1

Results

- Good tissue integration: suture removal at 4-7 weeks vs. 4-8 months for human donor tissue
- Local corticosteroid use <7 weeks vs. human donor tissue typically requiring long-term use of immuno-suppressants
- Four-year follow-up:
 - Stable, no long-term steroid immunosuppression, no tissue rejection
 - Transparency maintained
 - Nerve regeneration started at 3-6 months

Favorable Compared to Historical Data on Donor Corneas

- Visual improvement, best corrective visual acuity comparable to allograft
- Higher nerve growth rate than allograft
- Restoration of corneal touch reflex better than allograft (p=0.04)

Fagerholm, etc, Science Translational Medicine, August 2010; Volume 2 Issue 46

Fagerholm, etc, Biomaterials, 2013

Ljunggren MK, Elizondo RA, Edin J, et al. Trans Vis Sci Tech. 2014;3(2):6

FIBROGEN CHINA

珐博进(中国)医药技术开发有限公司

Regulatory Strategy

- Designated Chinese Domestic Class 3 medical device
- Seek marketing approval in China first
- Seek CE mark and export from China

Manufacturing Capability

- Domestic strategy requires manufacturing preclinical, clinical and commercial material in China by FibroGen
- Manufacturing facility construction, qualification, and aseptic operation validation completed in 2016

Program Status

- Clinical study-enabling evaluation in 2017 with GMP facility-produced cornea
 - Physical chemical testing, biologic evaluations, and preclinical studies
- Pivotal clinical trial anticipated in 2018

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Upcoming Milestones

- **Roxadustat in China**
 - Anemia associated with CKD in both DD-CKD and NDD-CKD
 - Phase 3 topline data (January 2017)
 - NDA submission Q3 2017
 - Anemia associated with MDS
 - Phase 2/3 clinical trial application under review by CFDA

- **Roxadustat U.S./ROW**
 - Large ongoing global CKD anemia program (NDA submission 2018)
 - Preparing to initiate Phase 3 clinical study in anemia associated with MDS

- Pamrevlumab
 - Phase 2 placebo-controlled IPF clinical data (Q3 2017)
 - Phase 2 pancreatic cancer study results (YE 2017/Q1 2018)

- FG-5200 biosynthetic cornea
 - Complete preclinical testing of cornea from GMP facility (2017)
 - Initiate clinical evaluation of novel medical device (2018)

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Thank you