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

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**FORM 8-K**

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**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 11, 2015**

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**FibroGen, Inc.**

(Exact name of registrant as specified in its charter)

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**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.)

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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 11, 2015, 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 2015

**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 11, 2015

By: /s/ Michael Lowenstein  
Michael Lowenstein  
VP, Legal Affairs

**INDEX TO EXHIBITS**

Exhibit  
No.

Description

99.1 FibroGen, Inc. Presentation Materials dated February 2015

# FIBROGEN

## Discussion Materials

February 2015

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,” “potentially” or 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, FG-3019 and our other product candidates, our intellectual property position, the potential safety, efficacy, reimbursement, convenience 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, 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., our results of operations, cash needs, spending of the proceeds from this offering, 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.

- Three broad technology platforms generating multiple product candidates
- Roxadustat – a novel oral treatment for anemia in Phase 3
  - Targeting the multi-billion dollar global anemia market
  - IP protection expected through 2033 and potentially beyond
  - >1400 subjects evaluated in P1 + P2; P3 to enroll ~ 7500 to 8500 subjects globally
  - Global collaborations: Astellas and AstraZeneca
    - \$2.5 billion in potential payments (\$683 million received through 9/30/14)
    - Plus royalties, transfer prices, and clinical development support
    - Regulatory filings anticipated 2016 (China), 2018 (US)
    - Funded through expected global commercialization
- FG-3019 – a novel anti-CTGF Ab for treating fibrotic disease
  - Phase 2 proof of concept established in IPF and pancreatic cancer
  - DMD clinical trial design reviewed by expert body of TREAT-NMD and pre-IND activities underway
- FG-5200 – collagen type III replacement cornea & scaffold for corneal blindness
- \$343 M - \$348 M cash, cash equivalents, investments, receivables as of 12/31/14 (unaudited)

IPF: idiopathic pulmonary fibrosis

DMD: Duchenne Muscular Dystrophy

TREAT-NMD is an EU-based network aiming to advance treatments and care for patients with neuromuscular disease; TACT, the TREAT-NMD Advisory Committee for Therapeutics, is an expert multidisciplinary body that provides the neuromuscular community with guidance on advancing new therapies for neuromuscular diseases

# Management Team

**FIBROGEN**

<b>THOMAS NEFF</b> Chief Executive Officer	  <sup>1</sup>  
<b>PAT COTRONEO</b> Chief Financial Officer	   
<b>FRANK VALONE, MD</b> Chief Medical Officer	  
<b>K. PEONY YU, MD</b> VP, Clinical Development	   
<b>CHRIS CHUNG</b> Exec Director & China Project Leader	 
<b>LEANNE PRICE, JD</b> VP, Intellectual Property & Corp Strategy	 
<b>R. WAYNE FROST, PHARM D</b> VP, Regulatory Affairs	   
<b>ELIAS KOUCHAKJI, MD</b> VP, Drug Safety	   
<b>MICHAEL LOWENSTEIN, JD</b> VP, Legal Affairs	
<b>ANATOLE BESARAB, MD</b> Exec Director, Clinical Research	
<b>LYNDA SZCZECH, MD</b> Exec Director, Clinical Development	  
<b>SETH PORTER, PHD</b> Exec Director & FG-3019 Project Leader	  
<b>GREG MANN</b> Exec Director, IR	  

<sup>1</sup> Predecessor entities.



# Our Platforms and Product Portfolio

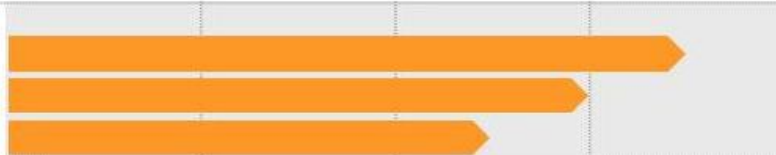
**FIBROGEN**

## HIF PLATFORM

PRECLINICAL PHASE 1 PHASE 2 PHASE 3

**Roxadustat** (HIF-PH Inhibitor for anemia)

- United States / Europe
- China
- Japan



**FG-6874** (HIF-PH Inhibitor; Stem Cell Mobilization)



**FG-8205** (Selective HIF-PH Inhibitor for heart failure after myocardial infarction)



## FIBROTIC DISEASE PLATFORM

PRECLINICAL PHASE 1 PHASE 2 PHASE 3

**FG-3019** (Anti-CTGF Antibody)

- Pancreatic Cancer
- IPF
- Liver Fibrosis
- Duchenne Muscular Dystrophy

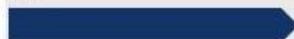


## rhCOLLAGEN III SCAFFOLD

PILOT

PIVOTAL

**FG-5200** (Corneal Blindness)<sup>1</sup>



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

Partnered

Wholly-Owned

# FIBROGEN

Roxadustat

## THE CONDITION



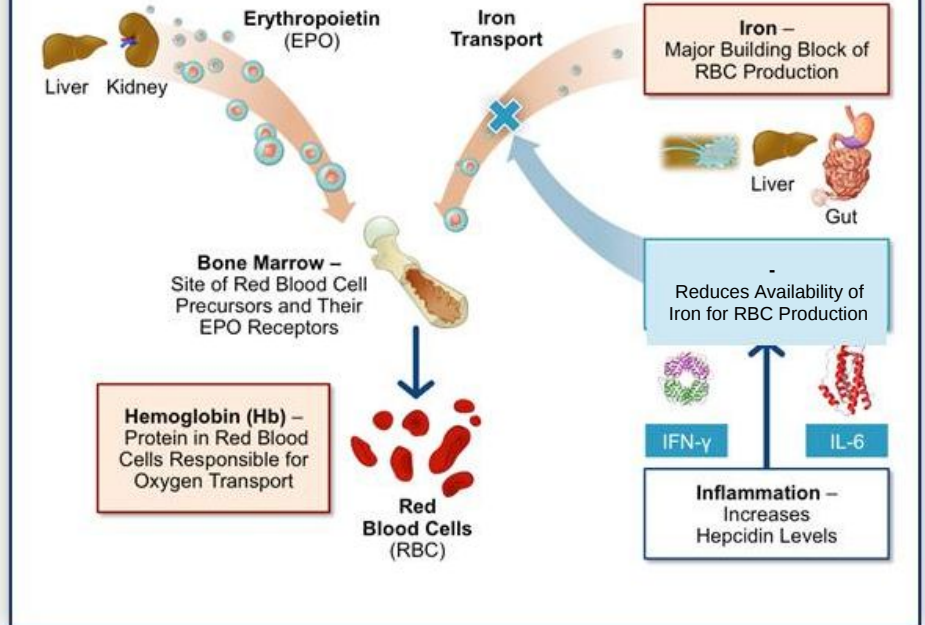
Reduced Oxygen-Carrying Capacity of Blood

ANEMIA IN CKD  
Dialysis & Pre-Dialysis



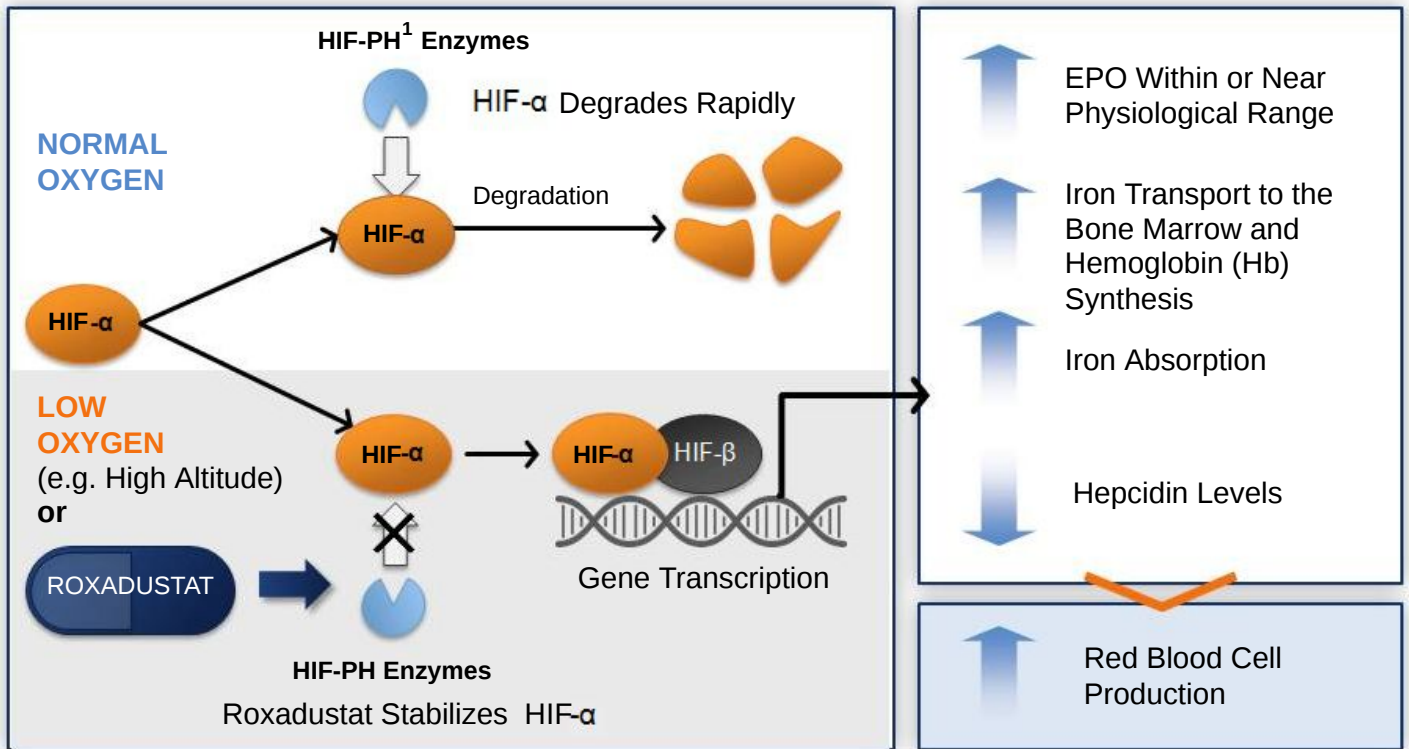
INCREASED MORTALITY

## RED BLOOD CELL CREATION (ERYTHROPOIESIS)



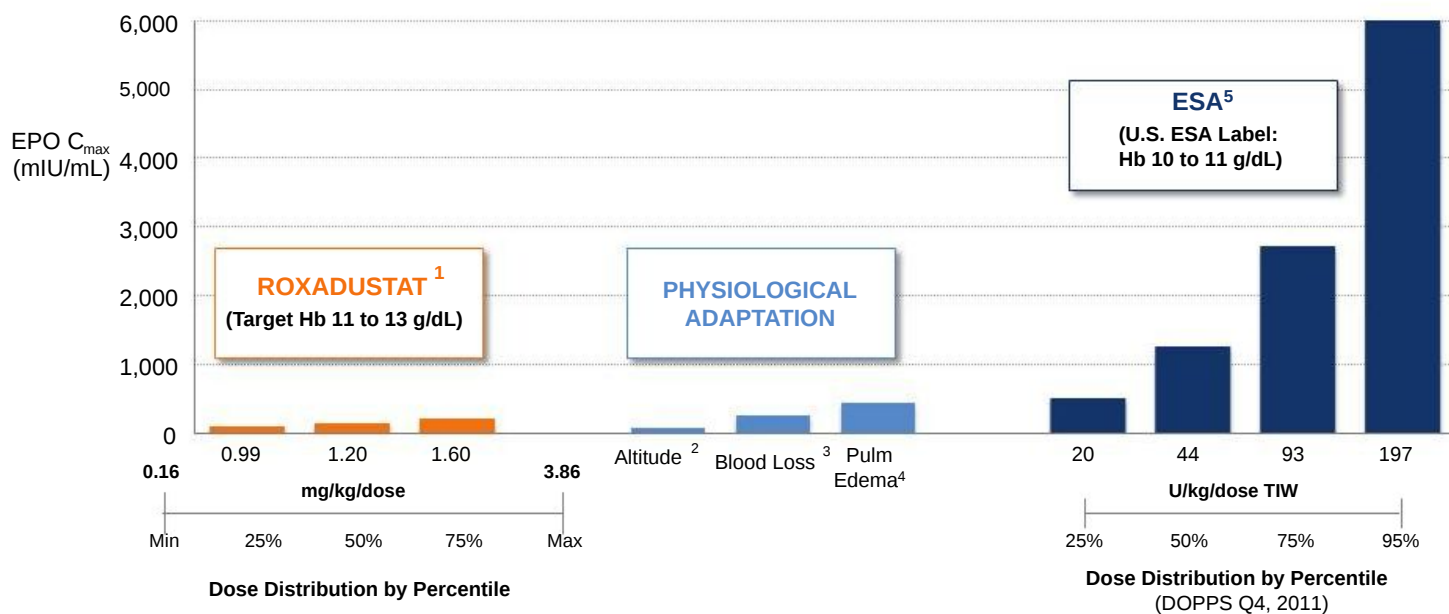
# Roxadustat Activates a Natural Pathway to Increase Red Blood Cell Production

FIBROGEN



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

# Roxadustat Achieves Target Hb with Physiologic EPO C<sub>max</sub> Levels



<sup>1</sup> C<sub>max</sub> data for roxadustat estimated for a subset of 243 patients who achieved Hb response and were dosed at expected therapeutic doses.

<sup>2</sup> Milledge & Cotes (1985) J Appl Physiol 59:360.

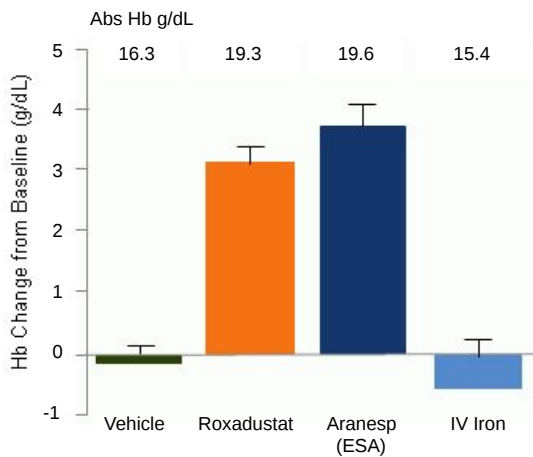
<sup>3</sup> Goldberg et al. (1993), Clin Biochem 26:183, Maeda et al. (1992) Int J Hematol 55:111.

<sup>4</sup> Kato et al. (1994) Ren Fail 16:645.

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

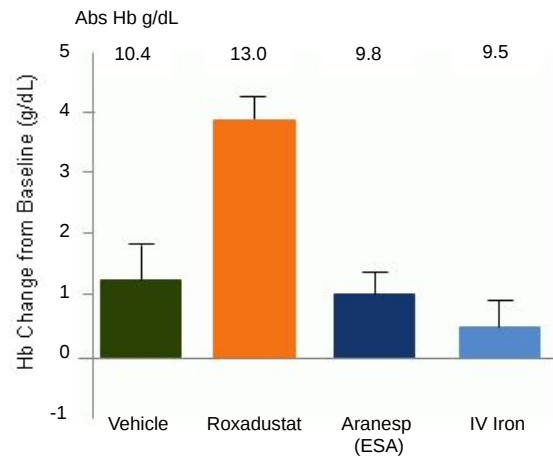
## Normal Animals

- Roxadustat Increased Hb
- Aranesp® Increased Hb but Reduced Mean Cell Volume (Depletes Iron)
- IV Iron Ineffective



## Anemia of Inflammation

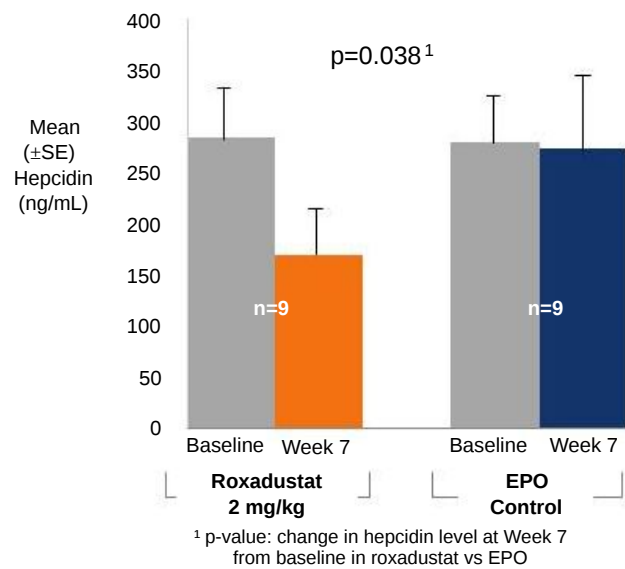
- Roxadustat Increased Hb
- Aranesp® or IV Iron Ineffective for Anemia of Inflammation



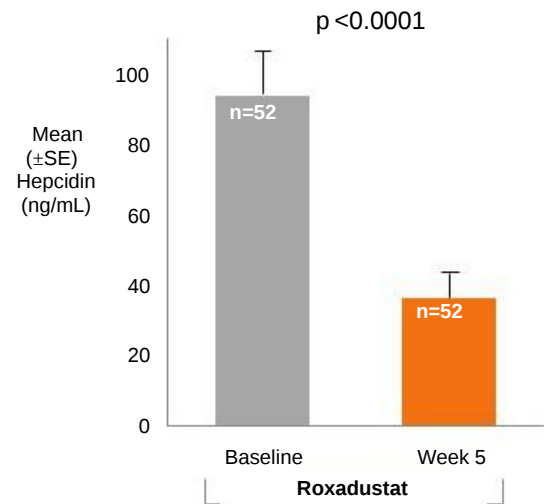
Model of inflammation using rats challenged with PG-PS, ACD; Klaus, S, et al, Induction of Erythropoiesis and Iron Utilization by FG-4592, Poster Presentation, ASN 2005.

## Decreased Hepcidin Improves Iron Availability and Reduces ESA Resistance

**CKD-DD Patients Previously Treated with EPO and Randomized (Study 040a) (Conversion, ESA Hyporesponders)**

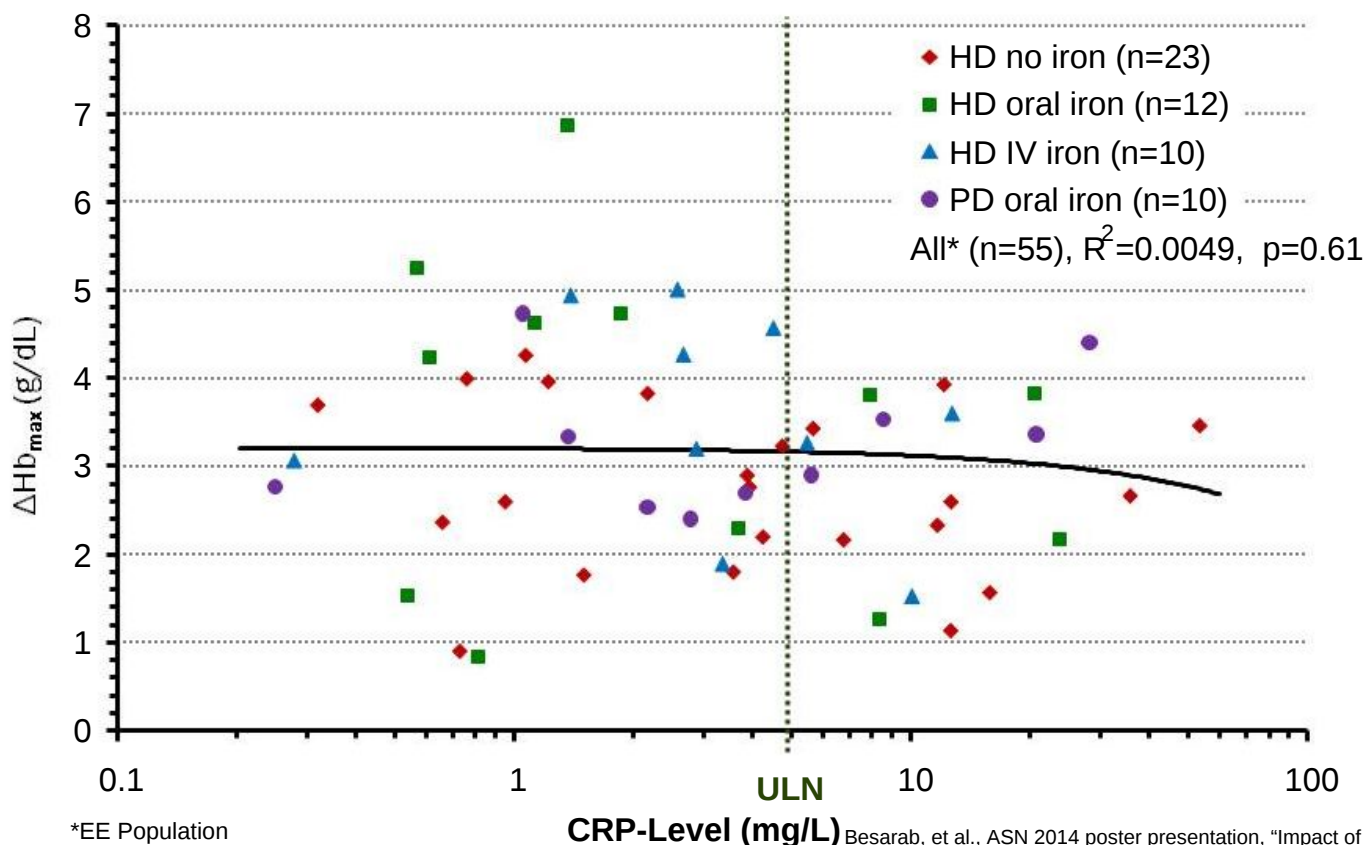


**CKD-DD Newly Initiated Dialysis (Study 053)**



# Hb Correction by Roxadustat is Independent of Inflammatory State (Study 053)

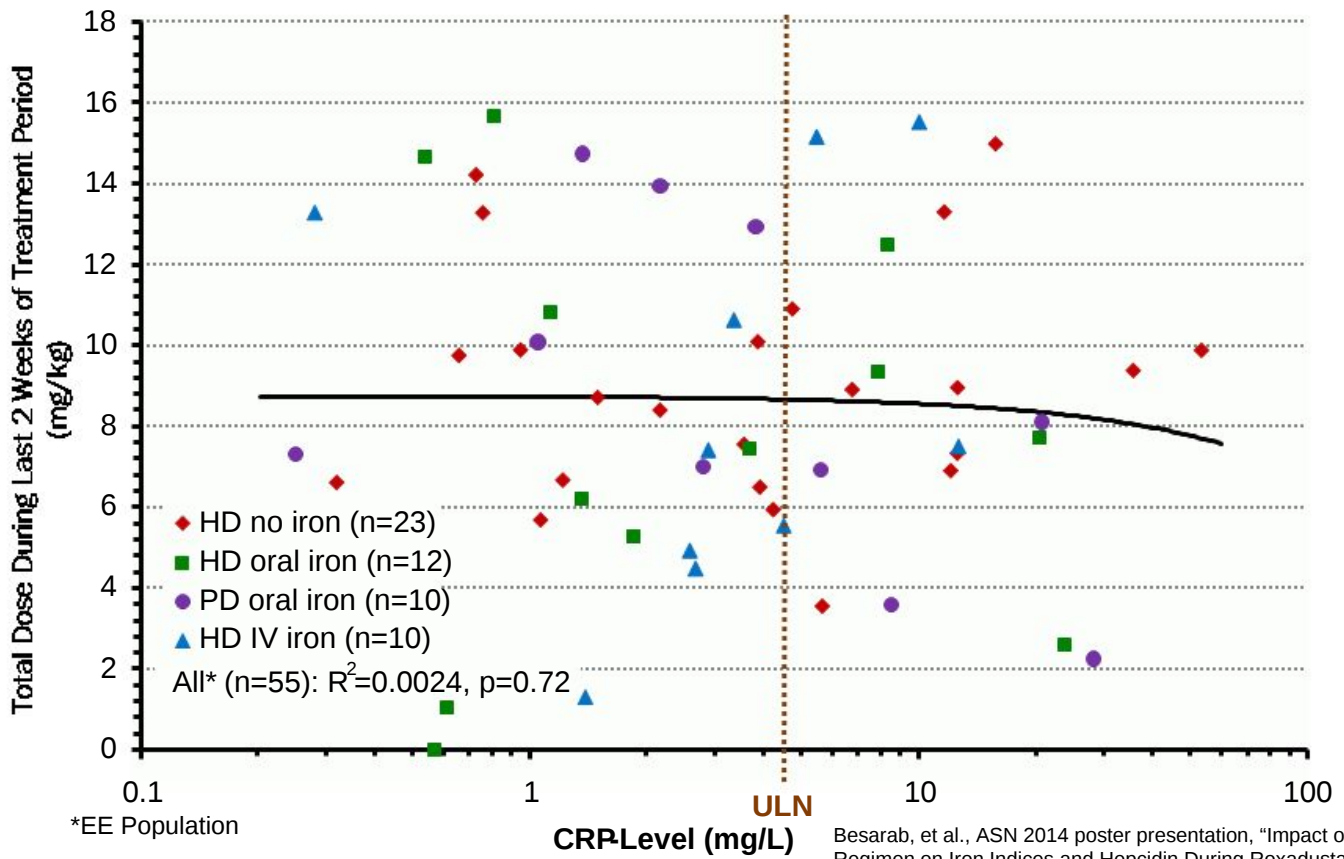
FIBROGEN



Besarab, et al., ASN 2014 poster presentation, "Impact of Iron Regimen on Iron Indices and Hepcidin During Roxadustat (FG-4592) Anemia Correction in Incident Dialysis Patients".



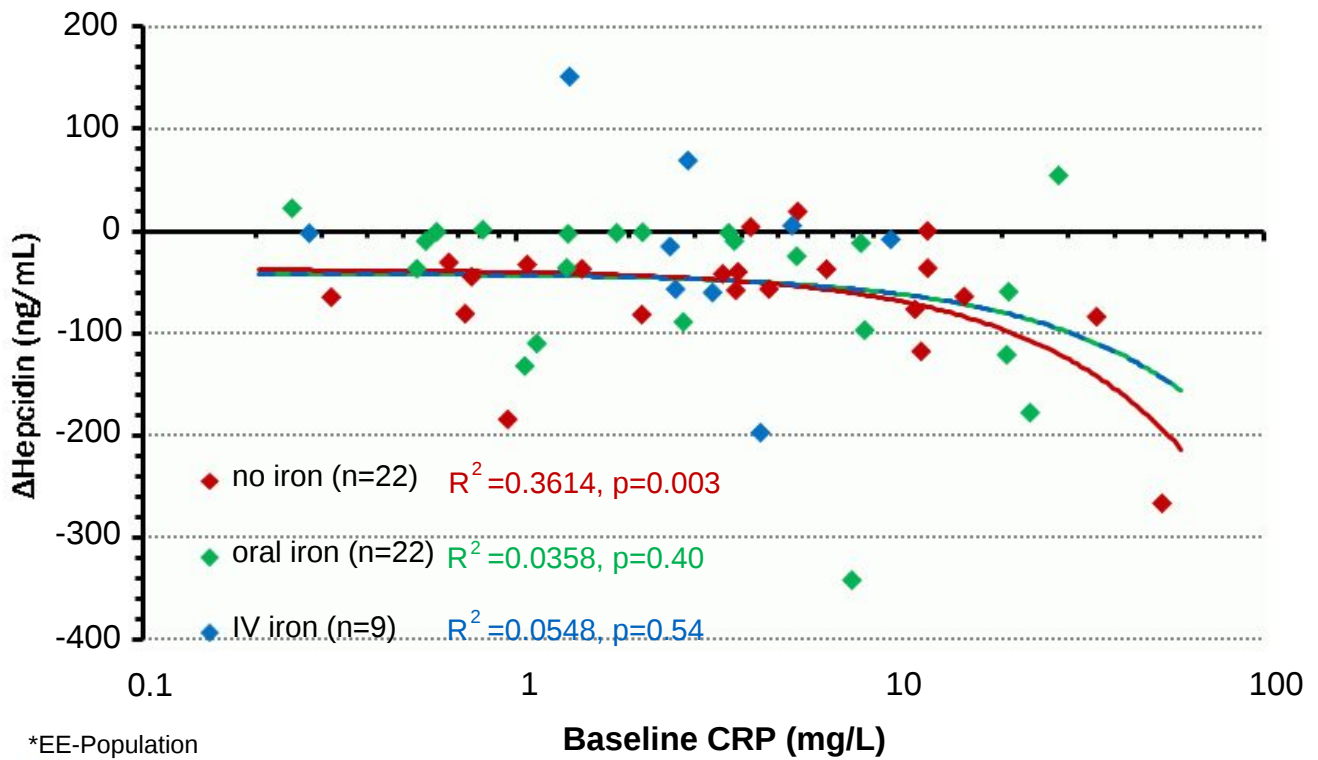
# Roxadustat Dose Required for Hb Maintenance is Independent of Inflammatory State (Study 053)



Besarab, et al., ASN 2014 poster presentation, "Impact of Iron Regimen on Iron Indices and Hepcidin During Roxadustat (FG-4592) Anemia Correction in Incident Dialysis Patients".

# Larger Hepcidin Reduction in Patients with Higher BL CRP (Study 053)

FIBROGEN



Besarab, et al., ASN 2014 poster presentation, "Impact of Iron Regimen on Iron Indices and Hepcidin During Roxadustat (FG-4592) Anemia Correction in Incident Dialysis Patients".

# Phase 2 Program Conducted Across Different CKD Populations

STUDY		PATIENTS	WEEKS	DOSE LEVELS	TIER WEIGHTS	CONTROL	KEY RESULTS
<b>Placebo-Controlled Pre-Dialysis</b>							
017	Dose Range Finding, NDD	116	4	4	No	Placebo	<ul style="list-style-type: none"> <li>Reduction in Hepcidin</li> <li>Dose-dependent Increase in Hb</li> </ul>
047	Pre-dialysis	91	8	2	3	Placebo	<ul style="list-style-type: none"> <li>Encouraging Safety Data</li> <li>Validation of Tier Weight-based Dosing</li> </ul>
<b>ESA-Controlled Dialysis Conversion</b>							
048	Dialysis (Converted)	96	6	3	3	ESA	<ul style="list-style-type: none"> <li>Encouraging Safety Data</li> <li>Successful Conversion from ESA IV &amp; SQ</li> </ul>
040a	Dialysis	60	6	3	No	ESA	<ul style="list-style-type: none"> <li>Successful Conversion, Includes ESA Hyporesponsive Patients</li> <li>Dose Dependent Decrease in Hepcidin</li> </ul>
<b>Phase 2b Key Proof of Concept Studies</b>							
041	Pre-dialysis (Six Correction and Maintenance Dose Cohorts)	145	16 and 24	6	3		<ul style="list-style-type: none"> <li>Both tier weight and fixed starting doses can initiate Hb correction</li> <li>Maintained Hb with TIW, BIW, QW</li> <li>Decrease in Blood Pressure Observed (Subgroup)</li> <li>Reduced Total Cholesterol Levels</li> </ul>
040b	Dialysis* (Conversion)	101	19	5	3	ESA	<ul style="list-style-type: none"> <li>Maintenance</li> <li>Reduced Total Cholesterol Levels</li> </ul>
053	Dialysis (Newly Initiated)	60	12	1	3		<ul style="list-style-type: none"> <li>Oral Iron <math>\approx</math> IV Iron</li> <li>Oral Iron HD <math>\approx</math> oral Iron PD</li> </ul>

\* Many patients were ESA hyporesponsive. Higher doses of ESA are generally needed to treat such patients.

# Study 017: Placebo-Controlled Proof of Concept Study in Pre-Dialysis

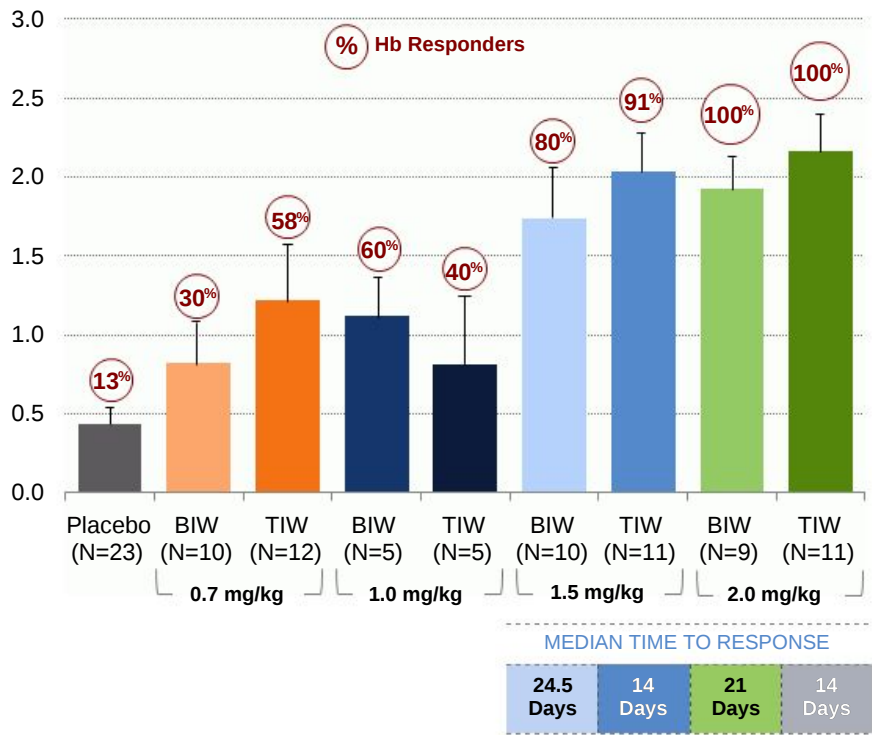
## DESIGN

- Anemic Pre-dialysis Patients not Receiving ESA
- Randomized to Placebo or Roxadustat, BIW or TIW
  - 4-week Dose Ranging Study Evaluating 4 Weight-based Doses
  - Responder = Hb rise  $\geq 1$  g/dL

## OBSERVATIONS

- Statistically significant, dose-dependent Hb increase for all 4 doses and for all assessments from Day 8 ( $p=0.025$ ) to end of treatment (Day 22  $p=0.0001$ ; Day 26-29  $p<0.0001$ )
- 100% Response Rate at Highest Dose
- Hepcidin reduction in 1.5 mg/kg cohort ( $p=0.048$ ) and in 2.0 mg/kg cohort ( $p=0.001$ )

Mean ( $\pm$  SE)  $\Delta$  hb<sub>max</sub> (g/dL)



# Study 047: Placebo-Controlled Study in Pre-dialysis

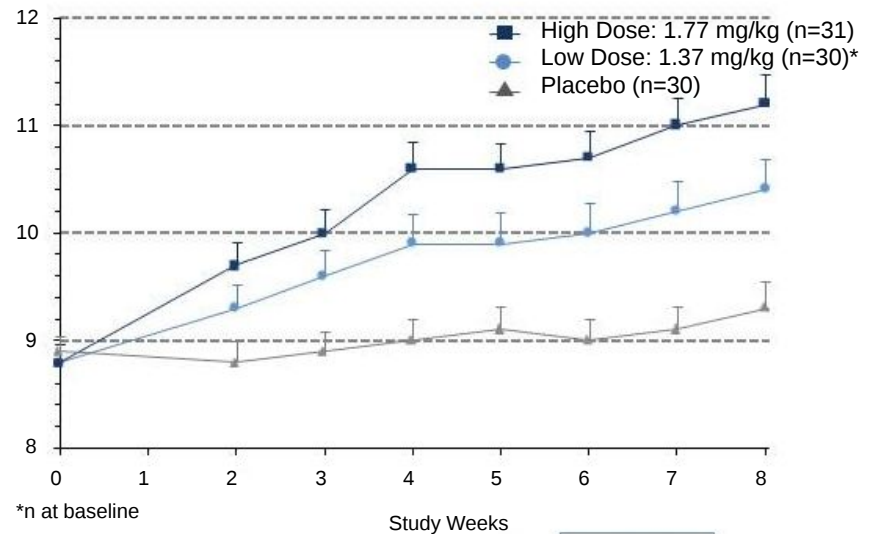
## DESIGN

- Anemic Pre-dialysis Patients not Receiving ESA
- Randomized to Placebo or Roxadustat TIW
  - Two Tier Weight-based Doses
  - 8 Weeks Dosing

## OBSERVATIONS

- Statistically Significant, Dose-dependent Hb Increase for Both Cohorts
- 93.1% Hb response rate at highest dose

Mean ( $\pm$ SE) Hb Change from BL (g/dL)



TREATMENT	N	BASELINE HB	MAX CHANGE IN HB	P-VALUE VS PLACEBO	PATIENTS WITH HB INCREASE $\geq$ 1 G/DL	P-VALUE VS PLACEBO
High Dose	31	8.9	2.4	<0.0001	93.1%	<0.0001
Low Dose	30	8.8	1.6	<0.0001	88.5%	<0.0001
Placebo	30	9.0	0.4		25.9%	

\* Hb increase  $\geq$  1 g/dL and Hb  $\geq$ 11.0 g/dL at end of treatment

# Studies 048 and 040a: ESA Comparator Study in Stable Dialysis Patients when Switched from Epoetin $\alpha$ (Conversion)

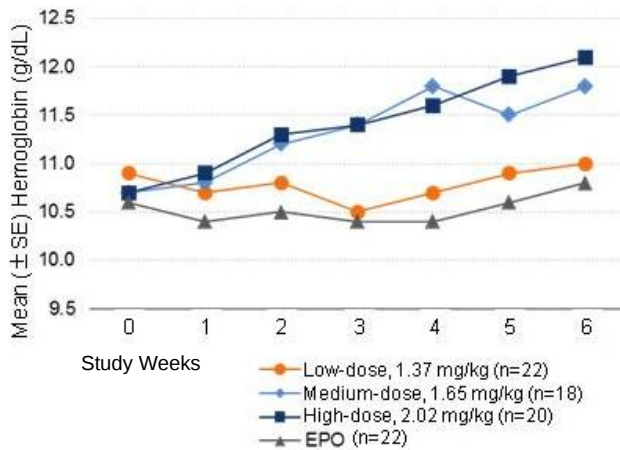


## DESIGN Studies 048 and 040

- Hemodialysis Patients with Hb Corrected on Stable Doses of ESA
- For Study 048, approximately 50:50 split between SC and IV
- Randomized to Roxadustat TIW or Continuation of EPO for 6 Weeks of Treatment

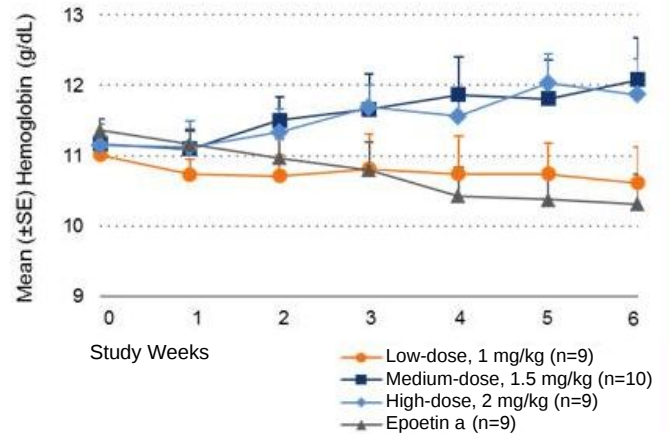
### OBSERVATIONS – Study 048

- Roxadustat Maintained Hb in All Cohorts
- Hb Response Rates\*
  - Low Dose (59.1%), Mid Dose (88.9%), High Dose (100%)
  - EPO (50%), p=0.005 (Mid Dose), p=0.0002 (High Dose)



### OBSERVATIONS – Study 040a (6 wks)

- Successful in Wide Range of Patients, Includes EPO Hyporesponsive Patients



\* % of Patients Maintaining Hb Level No Lower than 0.5 g/dL below Baseline at Both Week 6 and Week 7

# Phase 2B Program

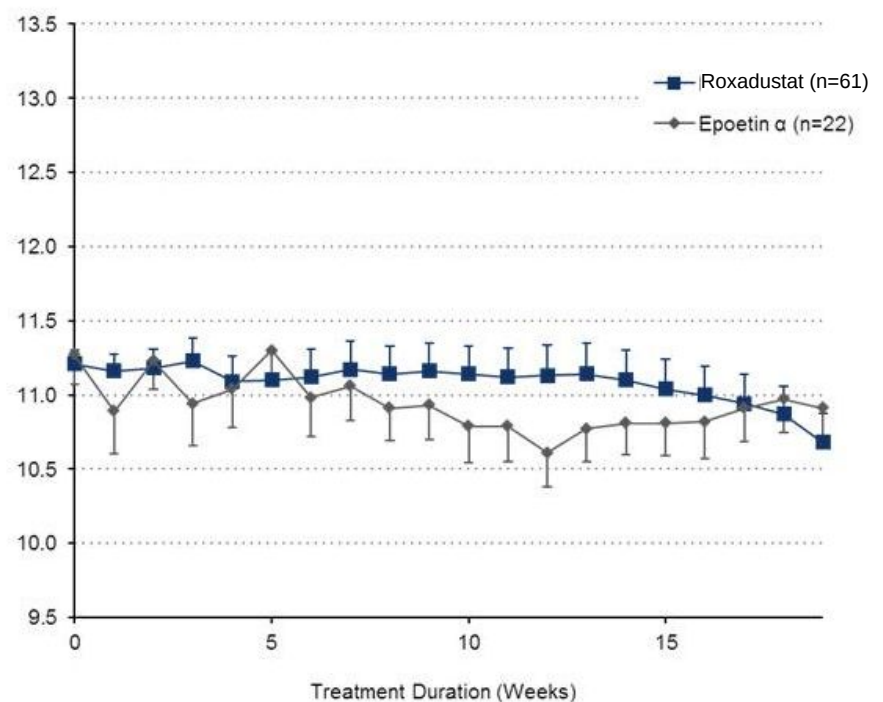
## DESIGN – Stable Dialysis Conversion from ESA

- Hemodialysis Patients with Hb Corrected on Stable Doses of ESA
- Randomized to Roxadustat TIW or Continuation of EPO
- 19-week Treatment Duration

## OBSERVATIONS

- Mean Baseline EPO Doses: 168 U/kg/wk IV (Dosed TIW)
- Low and High EPO Users
- Roxadustat Maintains Hb Levels Without IV Iron
- Roxadustat Maintains Hb Levels with Lower Cmax EPO Levels than IV Epoetin

Mean ( $\pm$ SE) Hemoglobin (g/dL)





# Study 041: Dose Finding in Pre-dialysis

Different Targets, Different Correction Rates, Single Maintenance Algorithm

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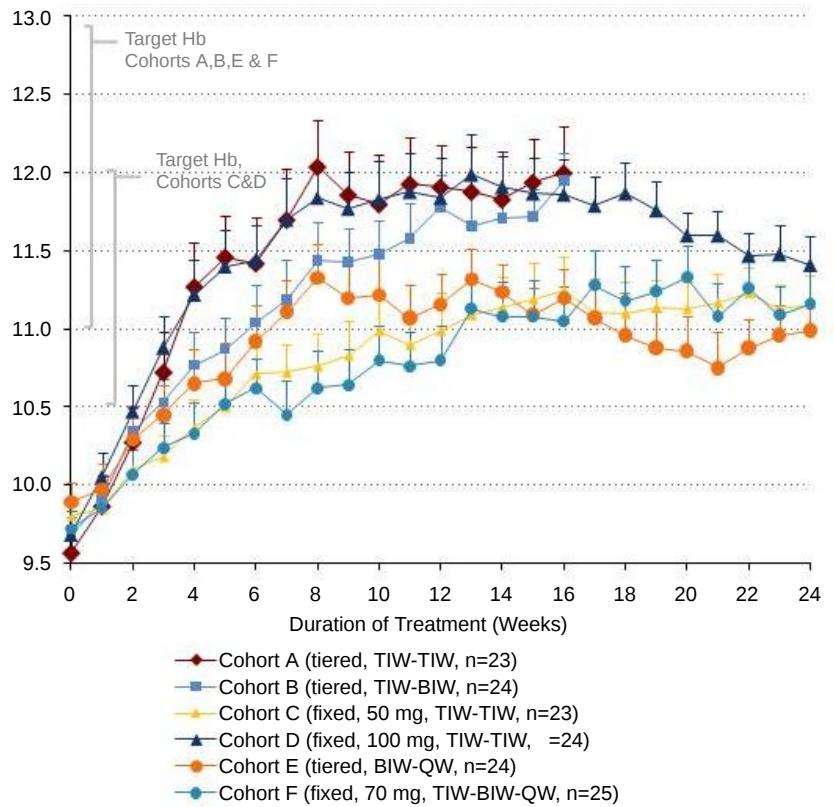
## DESIGN

- CKD Patients not on Dialysis
- Roxadustat Starting Doses
  - TIW or BIW
  - Tier Weight Dosing: 3 Sizes
- Dose Titration to Achieve Hb
  - Dose Adjustment Every 4 Wks
- Maintenance Dosing Upon Achieving Hb 11 g/dL
  - TIW, BIW or QW
- Dual Endpoint  $\Delta\text{Hb} \geq 1$  and Achieved  $\text{Hb} \geq 11$  g/dL
- 16 or 24 Week Treatment

## OBSERVATIONS

- 92% Response Rate
- Correction Achieved and Maintained to Ends of Treatment, Regardless of Starting and Maintenance Dose
- Reduction in Serum Hepcidin at Week 9 vs Baseline,  $p=0.0003$

Mean ( $\pm$ SD) Hemoglobin (g/dL)



Source: Besarab et al. 2011, J Am Soc Nephrol 22:196A

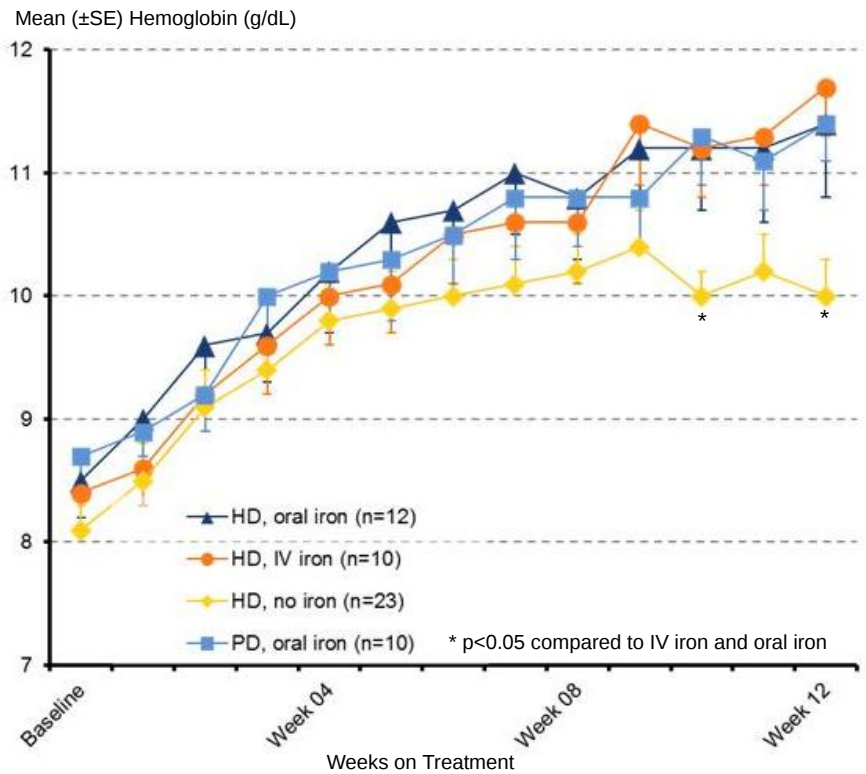
# Study 053: Roxadustat Corrects Anemia in Newly Initiated Dialysis Patients without IV Iron

## DESIGN

- Incident Dialysis (Newly Initiated Dialysis) Patients with Low Hb Levels and not on ESAs
- All Received Roxadustat
- Comparison of Treatment Response Under Different Iron Supplementation Conditions
- HD (Hemodialysis) Randomized to
  - No Iron
  - IV Iron
  - Oral Iron
- PD (Peritoneal) Received Oral Iron

## OBSERVATIONS

- Roxadustat Raised Hb as Efficiently with Oral Iron as with IV Iron
- Oral and IV Iron Arms Had Similar Hb Responses in PD and HD
- $\geq 1$  g/dL Hb correction in >90% patients at Week 12



Besarab, et al., J Am Soc Nephrol 23:428A and 24:91A.

- Evaluated Broad Range of CKD Patient Population: Stable Dialysis, Incident Dialysis and Nondialysis; ESA Hyporesponders
- In Dialysis and Nondialysis: Consistent, Dose-Dependent Hb Response with Roxadustat
- In Nondialysis: Both Tiered and Fixed Dosing Regimens Produced 90% Response Rates and Maintained Stable Hb
- In Nondialysis and Dialysis: Substantial Reduction of Hepcidin Observed in All Cohorts
- In Incident Dialysis: No Increased Level of Roxadustat Dosing Required (Study 053)
- In Dialysis: Oral Iron is Comparable to IV Iron in Achieving and Maintaining Hb Correction with Roxadustat in Patients on Dialysis

## **SAFETY OBSERVATIONS IN COMPLETED PHASE 1 & 2 STUDIES**

Roxadustat Exposure  
~1,100 Subjects  
16 patients > 1 year  
9 patients > 3 years

- No Overall Safety Signal
  - An independent data monitoring committee reviewed data
  - Frequency and type of AEs expected in CKD patients
- No Cardiovascular Signal
- Lowers Cholesterol Levels
- No Increase in Blood Pressure
- Reduction in Blood Pressure at End of TIW Dosing
- Platelet Reduction in Patients with High Platelet Count
- No Cardiac Conduction Effect (TQT Study Negative)
- No Drug Related Renal Toxicity
- No Liver Safety Signal, No Special Liver Monitoring Requirement in Phase 3

## **EXTENSIVE PRECLINICAL EVALUATION OF CANCER RISK**

- Carcinogenicity Studies Complete
- No Clinical Evidence of Tumor Risk to Date

## Placebo-Controlled Phase 2 Trials (Anemia correction in non-dialysis patients)

	Protocol 017 4 Weeks		Protocol 047 8 Weeks	
	Roxadustat	Placebo	Roxadustat	Placebo
Number of subjects	88	28	61	30
SAEs	4 (4.5%)*	1 (3.6%)	8 (13.1%)*	4 (13.3%)
Cardiovascular SAEs	0	1 (3.6%)	0	1 (3.3%)
CSE**	0	0	0	1 (3.3%)

## EPO-Controlled Phase 2 Trials (Conversion study in dialysis patients)

	Protocol 048 6 Weeks		Protocol 040b 19 Weeks	
	Roxadustat	EPO	Roxadustat	EPO
Number of subjects	74	22	66	23
SAEs	0	0	15 (22.7%)*	4 (17.4%)
Cardiovascular SAEs	0	0	1 (1.5%)	2 (8.7%)
CSE**	0	0	8 (12.1%)	4 (17.4%)

\*No SAEs were attributed to roxadustat in completed trials. No statistically significant differences from comparators.

\*\*CSE=death, myocardial infarction, congestive heart failure, subendocardial ischaemia, cerebrovascular accident, thrombosis (fistula), arteriovenous fistula occlusion, angina pectoris, and vascular graft thrombosis.

# Roxadustat Submissions for Marketing Approvals: US, Europe, and China

- **Indication**
  - Treatment of Anemia Associated with Chronic Kidney Disease (CKD) in Patients on Dialysis and Not on Dialysis
- **Primary Efficacy Endpoints - Based on Hemoglobin (Hb) Measurements**
  - Change in Hb from Baseline, or % Hb responders
  - US & EU: pre-specify primary endpoint by region
- **Safety Assessment Focused on Cardiovascular Events, Large Phase 3 Program for CKD Anemia**
  - Dialysis (DD) - in addition to stable dialysis, include incident dialysis, a high-risk population
  - Nondialysis (NDD) – first placebo-controlled pivotal study for this population
- **~ 8,000 Subjects in 10 Studies\*** (8 ex-China, 2 China)




REGULATORY AUTHORITIES	US 	EUROPE 	CHINA 
# of P3 Studies to Support Regulatory Approval	7**	6**	2
# of P3 Patients to Support Regulatory Approval	~7,500**	Up to 4,000**	450
Minimum Duration	52+ weeks	36+ weeks	26-52 weeks (100 for 1 yr)
Average Duration	1.3 to 1.5 years	1 year	6-12 months
Estimated Patient Years	~10,000	~4,000	~275
Mandatory Post-Approval Safety Study (China)	None at this time	None at this time	~2,000 patients
Pharma Partners	AstraZeneca	Astellas	AstraZeneca

\* Excludes Japan where Phase 2 studies are being completed and Phase 3 plans will be finalized in 2015.

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

# Roxadustat Phase 3 Program

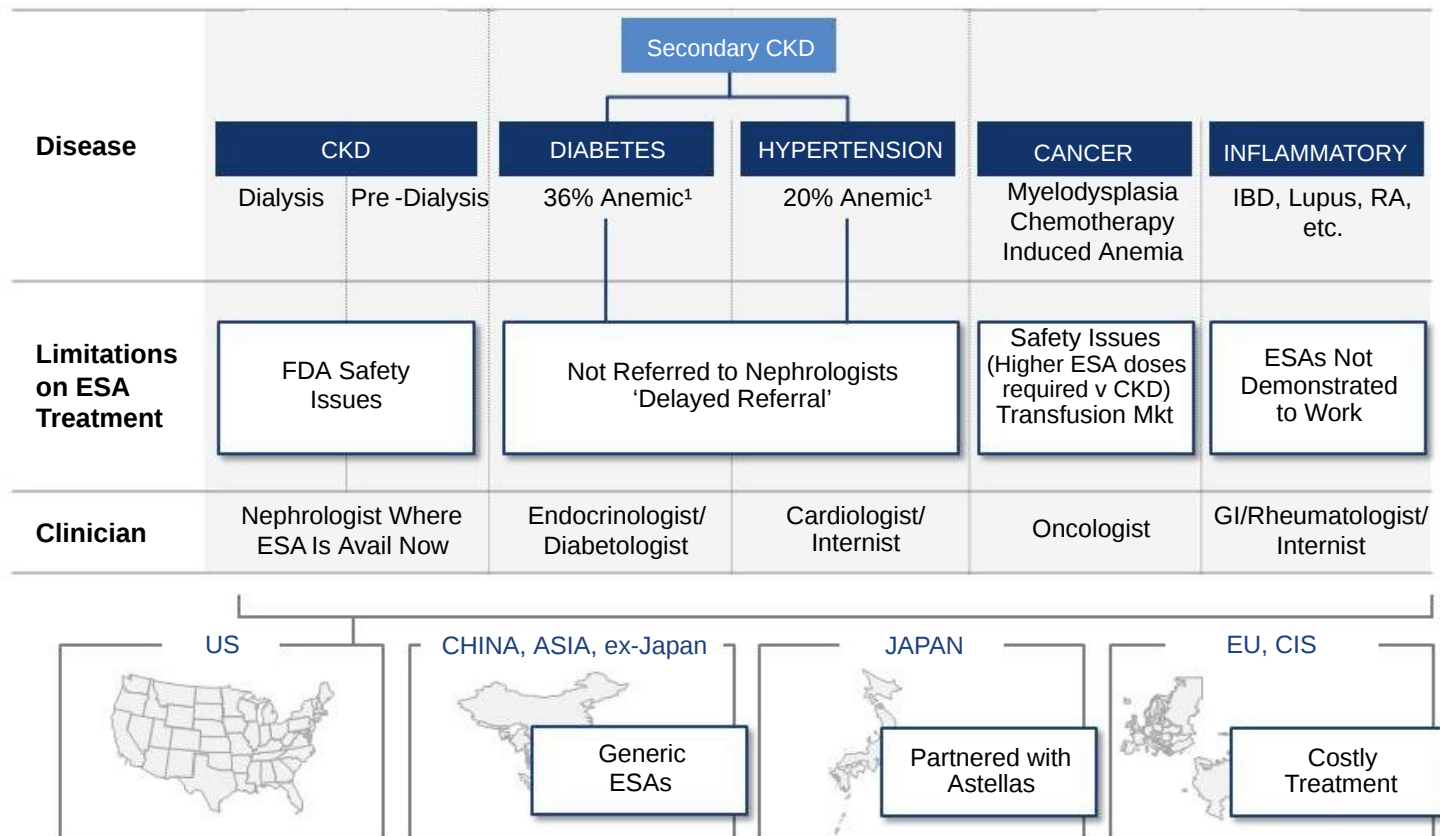
FIBROGEN

STUDY NUMBER	COMPARATOR	RANDOMIZATION	N	STUDY LOCATIONS	 CHINA	 EUROPE	 US	STUDY SPONSOR
<b>PHASE 3 STUDIES TO SUPPORT REGULATORY APPROVAL</b>								
<b>Stable Dialysis</b>								
CL-613 <sup>1</sup>	Epoetin $\alpha$ /Darbe	376/200/174	750	EU, MEA <sup>3</sup>			36+ wks 52+wks	Astellas
FG-064 <sup>1</sup>	Epoetin $\alpha$	1:1	Up to 750	US+/-Global			36+ wks 52+wks	FibroGen
FG-806	Epoetin $\alpha$	2:1	300	China	26-52 wks			FibroGen
<b>Incident Dialysis</b>								
FG-063 <sup>1</sup>	Epoetin $\alpha$	1:1	Up to 750	Global			36+wks 52+ wks	FibroGen
<b>Incident and Stable Dialysis</b>								
AZ-002	Epoetin $\alpha$	1:1	1425	Global			52+ wks	AstraZeneca
<b>Non-Dialysis</b>								
FG-060*	Placebo	2:1	Up to 600	US, LA <sup>2</sup> , APAC <sup>3</sup>			36+ wks 52+ wks	FibroGen
CL-0608*	Placebo	2:1	450-600	EU, MEA <sup>4</sup>			36+ wks 52+ wks	Astellas
FG-808	Placebo	2:1	150	China	26-52 wks			FibroGen
AZ-001	Placebo	1:1	~2,600	Global			52+ wks	AstraZeneca
<b>EUROPEAN REIMBURSEMENT STUDY</b>								
CL-0610	Darbepoetin	2:1	570	EU, MEA			36+ wks N/A	Astellas

<sup>1</sup>Plan 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)

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

# Roxadustat Has Potential to Address Unmet Need in Multiple Markets



<sup>1</sup> FibroGen estimate



# Potential Multiple Global, Multi-Billion Dollar Markets for Anemia

	Secondary CKD					
<b>Disease</b>	<b>CKD</b> Dialysis    Pre-Dialysis		<b>DIABETES</b> 36% Anemic <sup>†</sup>	<b>HYPERTENSION</b> 20% Anemic <sup>†</sup>	<b>CANCER</b> Myelodysplasia Chemotherapy Induced Anemia	<b>INFLAMMATORY</b> IBD, Lupus, RA, etc.
<b>Roxadustat Market Opportunity</b>	<b>1</b> <b>Existing Market:</b> Superiority to ESAs		<b>2</b> <b>New Market:</b> First-in-Class Oral Therapy in Secondary CKD		<b>3</b> <b>Re-Establish Market:</b> Safer Option	<b>4</b> <b>New Market:</b> Treat in Presence of Inflammation
<b>Clinician</b>	Nephrologist Where ESA Is Avail Now		Endocrinologist/ Diabetologist	Cardiologist/ Internist	Oncologist	GI/Rheumatologist/ Internist



<sup>†</sup> FibroGen estimate

- Most advanced HIF-PHI in development: Global Phase 3 program underway
- Extensive clinical experience: >1,100 patient exposures in Phase 1 & 2
- 3 year maximum exposure duration
- Intermittent dosing
- Phase 3 dosing regimen based on extensive testing in Phase 1 and Phase 2
- Completed End of Phase 2 meetings with regulators
  - Phase 3 MACE-based safety endpoints based on end of Phase 2 discussions with FDA
  - Planned US NDA submission for both dialysis and pre-dialysis

Roxadustat Study 041 (pre-dialysis)	
Sample size	145
Completion Rate	92%
Definition of Hb response	Achievement of Hb 11 g/dL <u>and</u> Hb increase $\geq$ 1 g/dL
Renal SAEs and/or dialysis initiation	5.5% (8)
Dialysis initiation while on study	3.4% (5=4 SAEs + 1 non-SAE)
With no dialysis	2.1% (3)
SAEs – probably or possibly related	0
Deaths – probably or possibly related	0
SAEs – related (angioedema, severe allergic reaction)	0
SAEs – related (liver abnormality)	0

# Phase 3 Dosing Regimen Optimized for Hb Effect and Convenience

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## Starting dose: non-dialysis (1 study)

Roxadustat dose	70 mg
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## Starting doses: non-dialysis and incident dialysis (3 studies and 1 study, resp.)

Body weight (kg)	<70 kg	≥70 kg
Roxadustat dose	70 mg	100 mg

## Starting dose: stable dialysis (3 studies)

Conversion from baseline EPO dose to roxadustat dose, based on conversion factor data from two Phase 2 studies

## 3x per week (TIW) dose frequency

- *Except a subset of 2 non-dialysis studies*
  - BIW 2x/ week n~ 60 in study FG-060, n=20+ in CL-608, also testing in CL-610
  - QW 1X/ week n~ 60 in study FG-060, n= 20+ in CL-608, also testing in CL-610

## Dose adjustments every 4 weeks, tested in five Phase 2 studies

## Experience from Phase 1 and Phase 2 supports Phase 3 dosing regimen

### Phase 2

- Several hundred patients dosed at doses being utilized in Phase 3

### Phase 1:

- > 300 subjects dosed between 0.4 to 3 mg/kg
- Dose-limiting toxicity not reached at highest dose of 5 mg/kg

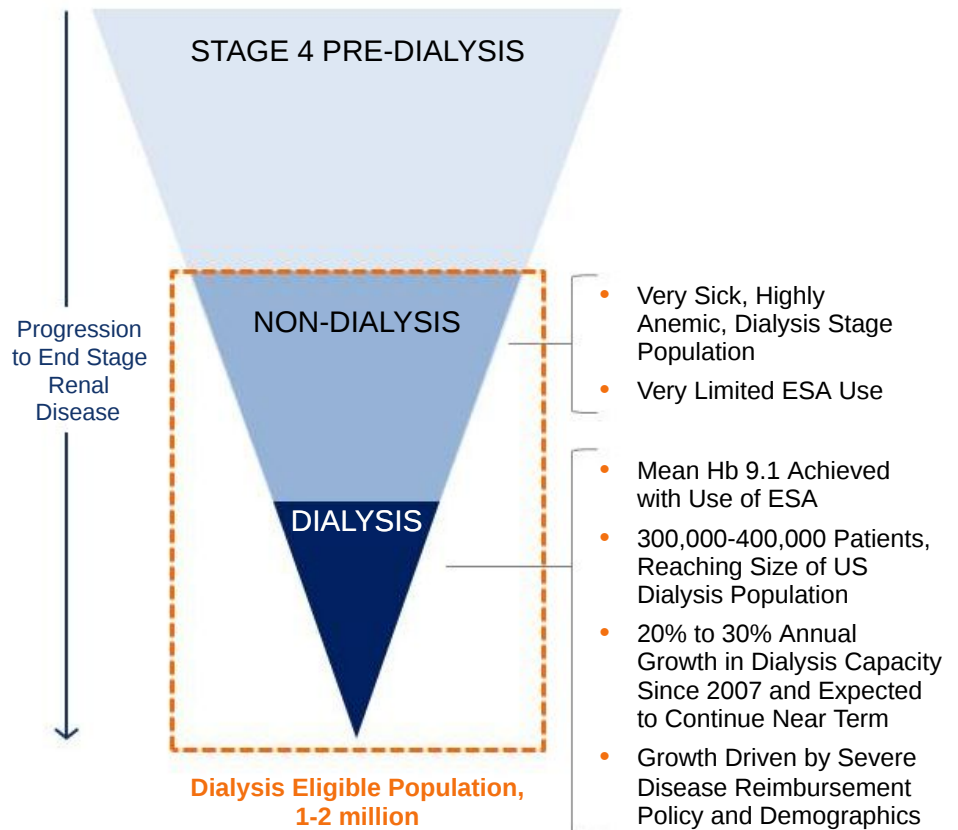
**FIBROGEN CHINA**

法博进(中国)医药技术开发有限公司



**AstraZeneca**

- Unique Positioning as a Domestic Chinese Company
- CFDA Green Pass Status
- AZ, Our Commercial Partner, 2nd Largest Multinational Pharmaceutical Company by Sales in China
- 1st Phase 3 Results with Roxadustat – Potential 1st Launch Country
- Potential Entry into #2 Pharma Market in the World
- Platform for Rapid Entry into China – Corneal Implants



Graphic not to scale



## Proprietary Recombinant Human Type III Collagen

- Integration of Implants with Host Tissue
- Encourages Nerve Regeneration
- Allows for Clearer Vision and No Rejection

### URGENT, SEVERE UNMET MEDICAL NEED

- Approximately 4 to 5 Million Patients with Corneal Blindness in China
- 100,000 New Cases per Year, Approx. 3,000 Corneal Implant Surgeries
- Cadaver Transplants Very Limited by Cultural Restriction

### PLATFORM TO FOCUS ON CHINA FIRST

- FG-5200 Targets Patients Treatable with Partial Thickness Implants
- 60-month Proof of Concept Data with Prototype in 10 Patients in Sweden
- Possibility to Address Major Unmet Need – *Science Translational Medicine*
- Opportunity to Expand Outside China
- Plan to Meet with CFDA on Clinical Program



	\$ Millions	JAPAN, EU, ETC.	U.S., CHINA, ROW	CASH RECEIVED TO DATE*
PAYMENTS TO FIBROGEN	Equity Investment in FibroGen	\$81	\$20	\$101
	Upfront, Non-Contingent	\$360	\$402	\$360 + \$220
	Development & Reg. Milestones	\$543	\$571	\$103+ \$0
	Commercial Milestones	\$15	\$653	\$0
	<b>POTENTIAL TOTAL</b>	<b>\$918 M</b>	<b>\$1,626 M</b>	<b>\$683 M of \$2,543 M</b>

**China Partnership:**  
50% Profit Sharing and 50% Development and Launch Cost Responsibility

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

DEVELOPMENT FUNDING	FibroGen ex-China Costs Capped at \$116.5 M (Cost-Share < 50% of Planned CKD Anemia Development Costs)
LAUNCH FUNDING	Commercialization Costs Are Covered by Partners in All Territories Ex-China

\* As of November 2014

# FG-3019

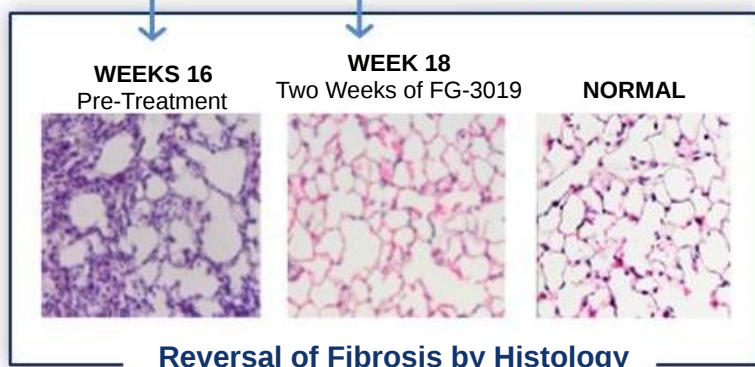
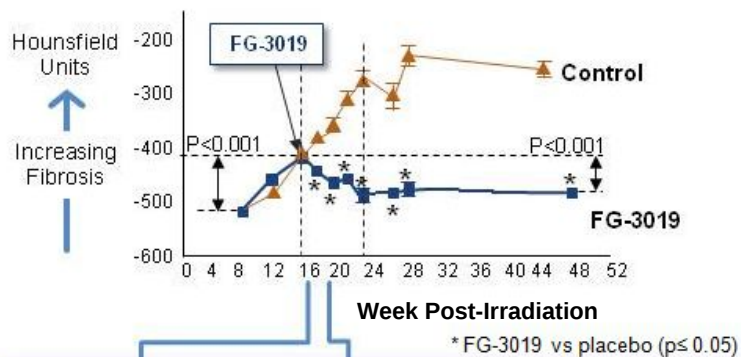
Monoclonal Antibody to Connective Tissue Growth Factor (CTGF)



# FG-3019 Improved Fibrosis in Mouse Model and in Human Disease

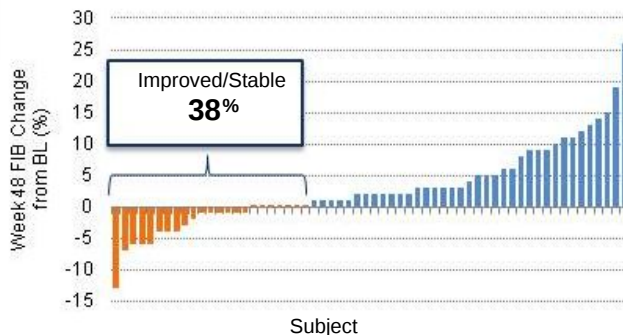
## Radiation-Induced Mouse Lung Fibrosis

### Reversal of Fibrosis by Micro-CT Imaging

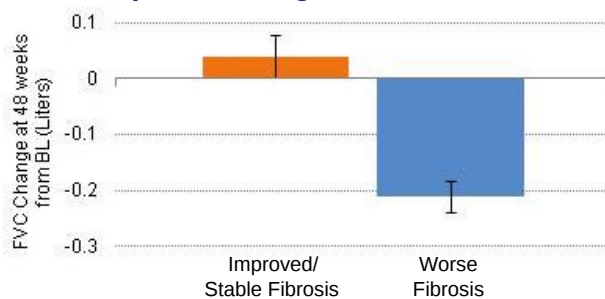


## Phase 2A IPF Clinical Trial

### Reversal of Lung Fibrosis by High Resolution CT at Week 48



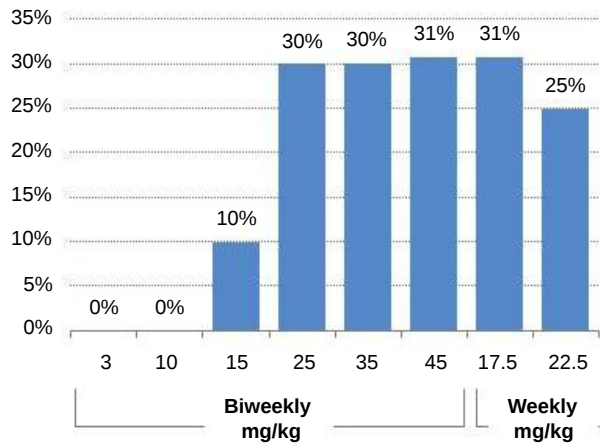
### Improved / Stable Fibrosis Correlates with Improved Lung Function



## FG-3019 Combined with Gemcitabine and Erlotinib (n=75)

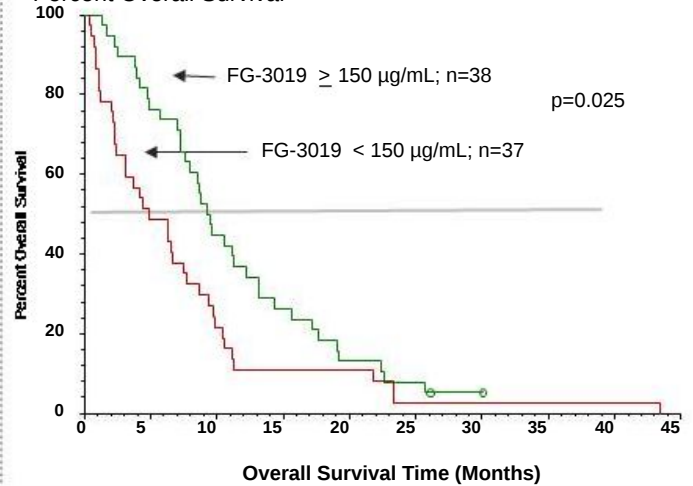
### Relationship of 1-Year Survival to Dose

Percent 1 Year Survival Rate



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

Percent Overall Survival



### KEY FINDINGS

- Dose-Related Increase in Survival
- Day-15 Minimum FG-3019 Plasma Level  $\geq 150 \mu\text{g/mL}$ 
  - 2x Median Survival (9.4 vs. 4.8 Months) ( $p=0.025$ )
  - 3x One-Year Survival (37% v 11%) ( $p=0.01$ )

# Phase 2 Trials in IPF and Pancreatic Cancer

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## IPF

- Randomized placebo-controlled clinical trial
- 136 patients
- Naïve; previously treated; pirfenidone / nintedanib failures
- Key endpoints
  - Pulmonary function: change in FVC from baseline
  - Fibrosis by HRCT
- Currently enrolling

## LOCALLY ADVANCED INOPERABLE PANCREATIC CANCER

- Main goal: convert to operable state
- 40 patients to be enrolled, with potential to expand
- Randomization 1:1 up to 6 months of
  - FG-3019, gemcitabine, nab-paclitaxel
  - Gemcitabine and nab-paclitaxel
- Endpoint: complete tumor removal
- Currently enrolling

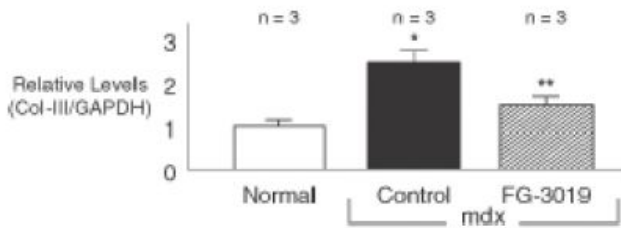
## METASTATIC PANCREATIC CANCER NOT PREVIOUSLY TREATED

- Combination of FG-3019 and Chemotherapy
- ~240 patients
- Randomization 1:1 , treat to progression
  - FG-3019, gemcitabine, nab-paclitaxel
  - Gemcitabine and nab-paclitaxel
- Endpoints: CA19.9, tumor response (PET & CT scans), disease control
- Study design under development

- DMD – rare hereditary disease: ~1 in 3,500 boys in the US
  - No FDA/EU approved treatment to date
  - Progressive muscle weakness and respiratory failure (age 5-18)
  - DMD leads to muscle fibrosis and loss of muscle function: muscles replaced by fibrotic tissue in advanced disease
- CTGF: Directly impacts not just fibrosis but muscle cell phenotype <sup>1</sup>
  - Strongly associated with fibrosis in skeletal muscle of human muscular dystrophy (MD)
  - Strongly associated with fibrosis in heart of mouse (mdx) MD
  - Induces de-differentiation of skeletal muscle cells
  - Over-expression in normal mice transiently induces features of skeletal MD
  - Reducing CTGF reduces mdx mouse MD

<sup>1</sup> Au (2011); Morales (2011); Morales (2013); Pessina (2014); Vial et al (2008)

## FG-3019 significantly reduced collagen content/fibrosis in muscle (mdx mouse)

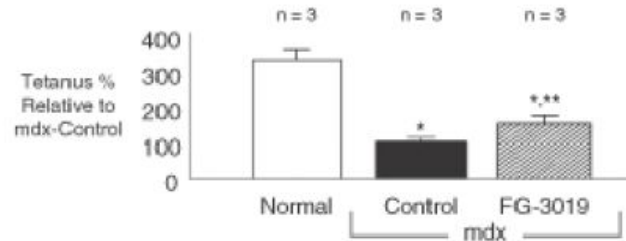


\* p < 0.05 vs Normal

\*\* p < 0.05 vs mdx control

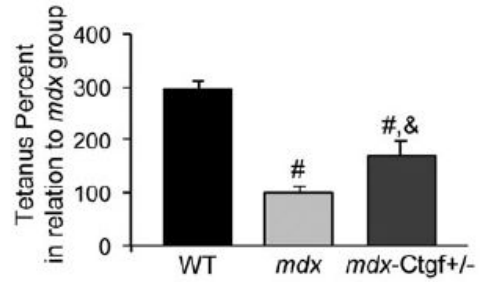
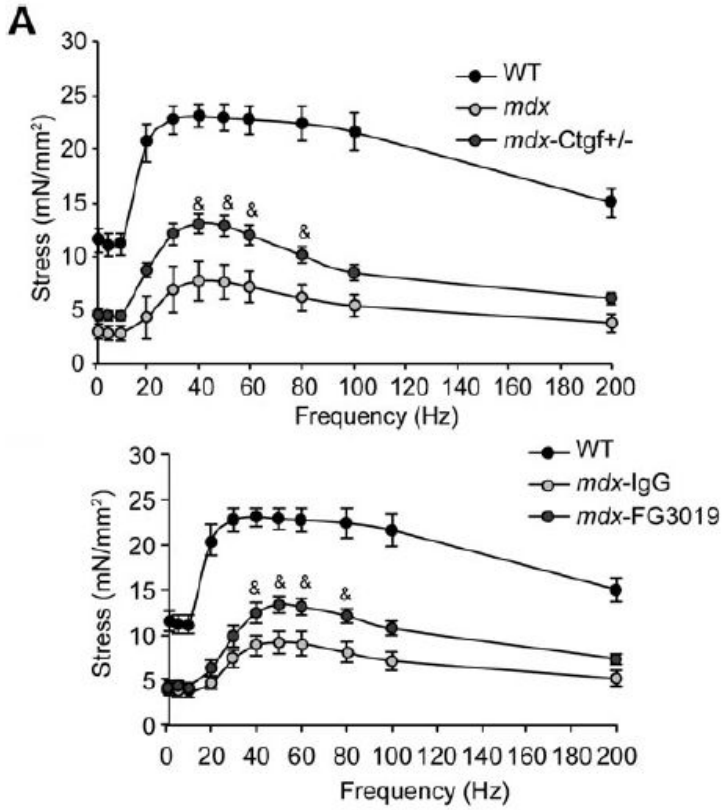
Morales et al. Human Molecular Genetics, 2013, Vol. 22, No. 24

## FG-3019 increased Isometric Force by 50% (mdx mouse)

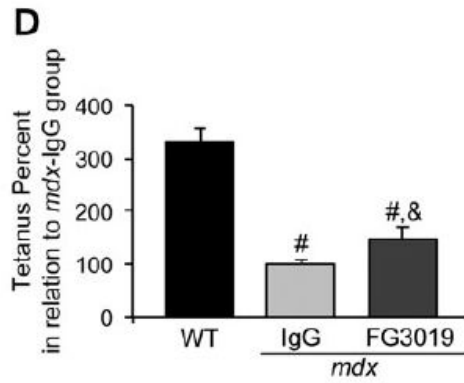


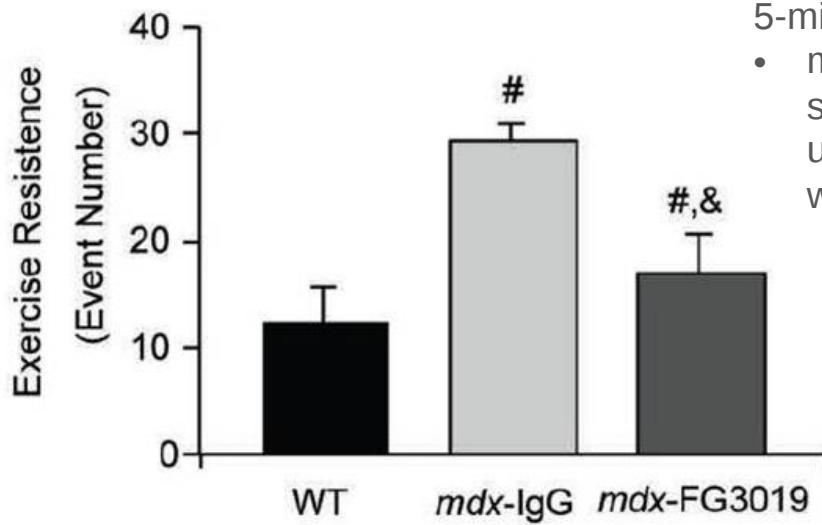
# Decreased CTGF Increased Skeletal Muscle Function in mdx Mice

CTGF hemi-zygous or FG-3019-treated mdx mice exhibited increased isometric force



WT- wild type, normal mice;  
mdx - disease model





5-min treadmill exercise tolerance test:

- mdx mice treated with FG-3019 stopped fewer times to rest than untreated mice (mdx-control) and were more similar to normal mice

- Three broad technology platforms generating multiple product candidates
- Roxadustat – a novel oral treatment for anemia in Phase 3
  - Targeting the multi-billion dollar global anemia market
  - IP protection expected through 2033 and potentially beyond
  - >1400 subjects evaluated in P1 + P2; P3 to enroll ~ 7500 to 8500 subjects globally
  - Global collaborations: Astellas and AstraZeneca
    - \$2.5 billion in potential payments (\$683 million received through 9/30/14)
    - Plus royalties, transfer prices, and clinical development support
    - Regulatory filings anticipated 2016 (China), 2018 (US)
    - Funded through expected global commercialization
- FG-3019 – a novel anti-CTGF Ab for treating fibrotic disease
  - Phase 2 proof of concept established in IPF and pancreatic cancer
  - DMD clinical trial design reviewed by expert body of TREAT-NMD and pre-IND activities underway
- FG-5200 – collagen type III replacement cornea & scaffold for corneal blindness
- \$343 M - \$348 M cash, cash equivalents, investments, receivables as of 12/31/14 (unaudited)

IPF: idiopathic pulmonary fibrosis

DMD: Duchenne Muscular Dystrophy

TREAT-NMD is an EU-based network aiming to advance treatments and care for patients with neuromuscular disease; TACT, the TREAT-NMD Advisory Committee for Therapeutics, is an expert multidisciplinary body that provides the neuromuscular community with guidance on advancing new therapies for neuromuscular diseases



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## Discussion Materials

February 2015