FibroGen, Inc. Corporate Presentation

May 2021



Forward-Looking Statements

This presentation contains "forward-looking" statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, business strategy, and plans, and objectives of management for future operations, are forward looking statements. These forward-looking statements can generally be identified 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 and include statements regarding our intentions, beliefs, projections, outlook, analyses, or current expectations concerning, among other things, our ongoing and planned development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for roxadustat, pamrevlumab, and our other product candidates, the potential safety, efficacy, reimbursement, convenience, or clinical and pharmaco-economic benefits of our product candidates, including in China, the potential markets for any of our product candidates, our ability to develop commercial functions, results of commercial operations, or our ability to operate in China, expectations regarding clinical trial data, our results of operations, cash needs, spending of proceeds from our public offerings, 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, including the other risks and uncertainties that are described in the Risk Factors section of our most recent annual report on Form 10-K or quarterly report on Form 10-Q filed with the Securities and Exchange Commission. Forward-looking statements represent our management's beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.



Company Overview

Company Mission

Developing innovative, first-in-class medicines for the treatment of chronic and life-threatening or debilitating conditions

Employees

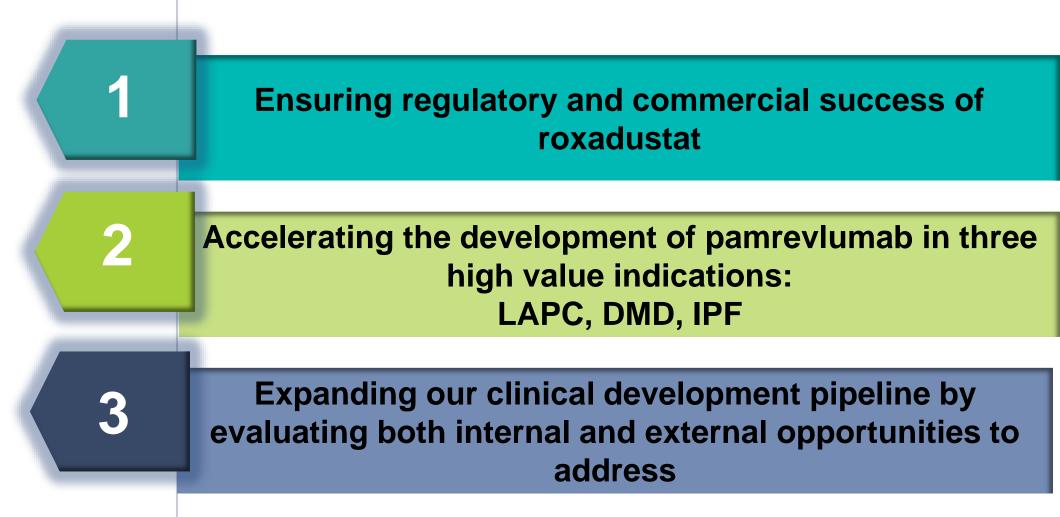


Cash as of March 31, 2021 \$682.6 million

- \$245 million in expected roxadustat milestones in 2021
- Related to approvals in the U.S. and EU and first commercial sale in U.S.
- Estimated 2021 ending cash to be in the range of \$660-\$670 million



Strategic Objectives: Three Areas of Focus





First-in-Class Product Programs Addressing Significant Unmet Medical Needs

ROXADUSTAT

Anemia Associated with Chronic Kidney Disease (CKD)

- Launched in China and Japan for both NDD-CKD and DD-CKD
- NDA submitted in U.S. for both NDD-CKD and DD-CKD
 - FDA will hold AdCom on July 15, 2021
- EU MAA for both NDD-CKD and DD-CKD submitted 2Q 2020
 - Decision anticipated mid-2021
- ROW submissions to date include, Canada, Mexico, Australia, South Korea, and several other countries

Chemotherapy-Induced Anemia (CIA)

 WHITNEY Phase 2 study enrollment completed

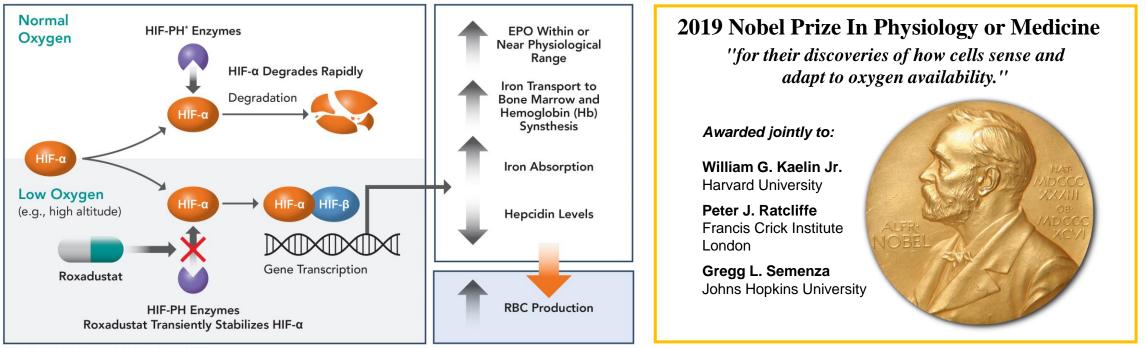
Anemia Associated with Myelodysplastic Syndromes (MDS)

 MATTERHORN Phase 3 study enrolling



Roxadustat: Novel, First-in-Class Treatment for CKD Anemia

- ROXADUSTAT Oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor Based on 2019 Nobel Prize-winning science
 - Increases hemoglobin (Hb) by mimicking the body's natural response to low oxygen
 - Studied for treatment of anemia in Stage 3-5 CKD patients, both on and not on dialysis



*Hypoxia-inducible factor prolyl hydroxylase (HIF-PH)

First-in-Class Product Programs Addressing Significant Unmet Medical and Patient Needs

PAMREVLUMAB

Locally Advanced Unresectable Pancreatic Cancer

• LAPIS Phase 3 study enrolling

Duchenne Muscular Dystrophy

- LELANTOS (non-ambulatory) Phase 3 study enrolling
- LELANTOS-2 (ambulatory) Phase 3 study enrolling

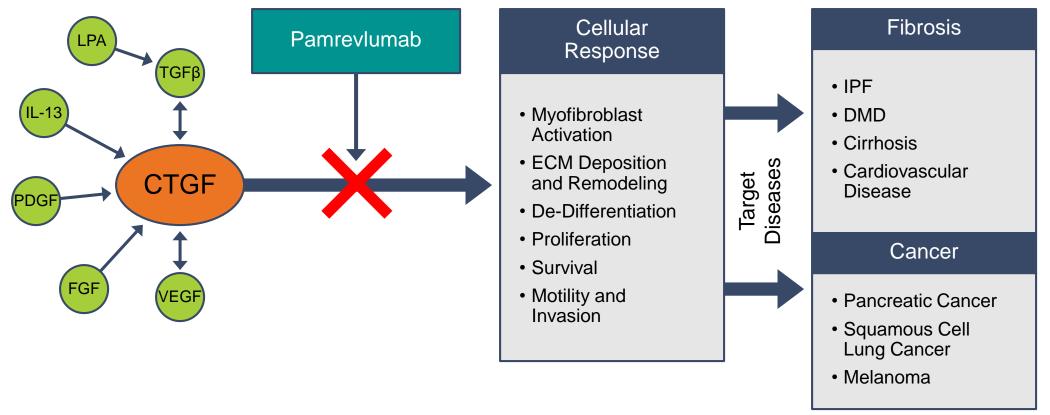
Idiopathic Pulmonary Fibrosis

- ZEPHYRUS Phase 3 study enrolling
- ZEPHYRUS-2 Phase 3 study enrolling

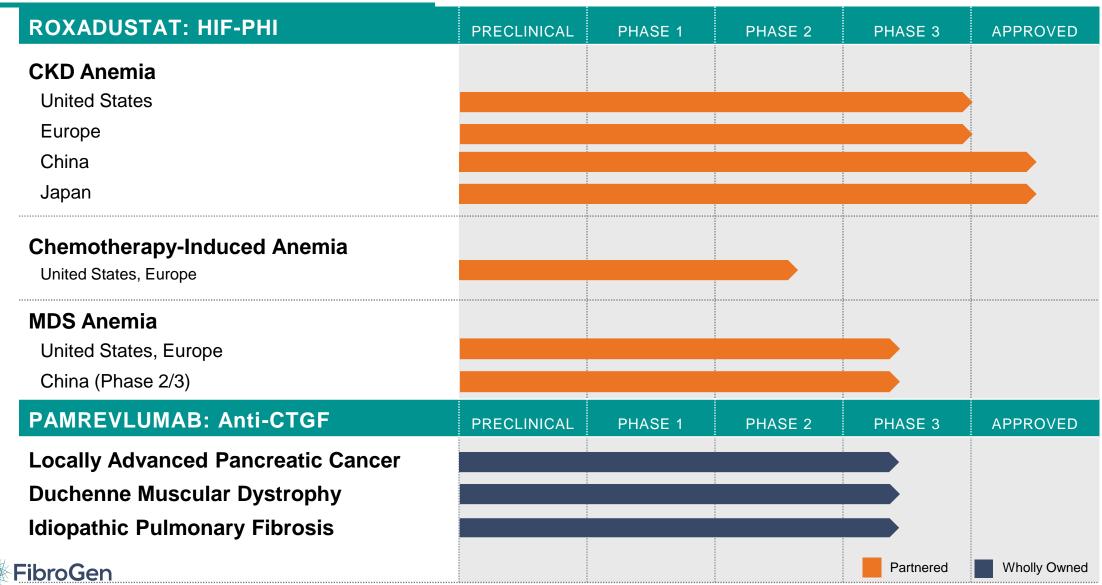


Pamrevlumab: Innovative Treatment for Fibrosis and Fibroproliferative Disease

 PAMREVLUMAB – Fully humanized monoclonal antibody targeting activity of connective tissue growth factor, a central factor in fibrosis and fibroproliferative diseases



FibroGen Marketed and Late-Stage Portfolio



Partnerships: Astellas: Japan, Europe, Turkey, Russia and the Commonwealth of Independent States, the Middle East and South Africa; AstraZeneca: U.S., China, other markets in the Americas and in Australia/New Zealand as well as Southeast Asia

Clinical Trial Timelines

Study Phase	Indication	Study Name	Enrollment Target	Topline Data				
	ROXADUSTAT							
2	CIA	WHITNEY	100 (completed)	2H 2021				
3	MDS	MATTERHORN	160	1H 2022				
	PAMREVLUMAB							
3	LAPC	LAPIS	280	2H 2022				
3	DMD	LELANTOS	90	2H 2022				
3	DMD	LELANTOS-2	70	TBD				
3	IPF	ZEPHYRUS	340	TBD				
3	IPF	ZEPHYRUS-2	340	TBD				



Roxadustat

Anemia

Roxadustat Efficacy

Roxadustat Efficacy Demonstrated in Phase 3 studies

Met primary efficacy endpoint (change in Hb) in individual studies and pooled analyses

- NDD: Roxadustat was superior to placebo and efficacious regardless of iron-repletion
- **DD:** Roxadustat achieved larger mean Hb increase than epoetin alfa, including in patients with inflammation

Lower RBC transfusion risk

- NDD: In roxadustat patients compared with placebo
- DD: In roxadustat patients compared with epoetin alfa

Other benefits

- **DD/NDD:** effective in both iron replete and non-replete patients
- DD: less IV iron required in patients on roxadustat versus epoetin alfa
- DD: effective in patients with higher levels of systemic inflammation as evidenced by elevated Creactive protein (CRP)



Roxadustat Cardiovascular Safety

CV Safety Demonstrated in Phase 3 studies

Non-Dialysis

• Risk of MACE, MACE+, and all-cause mortality in roxadustat patients comparable to placebo patients in the NDD population

Dialysis and Incident Dialysis Subgroup

 Risk of MACE, MACE+, and all-cause mortality in roxadustat patients comparable to epoetin-alfa patients in the DD and ID



Roxadustat Phase 3 Manuscripts on the Treatment of Anemia Published in Peer-Review Medical Journals

Title	Study	Journal
Roxadustat for the Treatment of Anemia in Chronic Kidney Disease (CKD) Patients Not on Dialysis: A Phase 3, Randomized, Double- Blind, Placebo-Controlled Study (ALPS).	ALPS	<u>Nephrology Dialysis</u> <u>Transplantation</u>
Roxadustat for Treating Anemia in Patients with CKD Not on Dialysis: Results from a Randomized Phase 3 Study.	ANDES	Journal of the American Society of <u>Nephrology</u>
Roxadustat for Chronic Kidney Disease-related Anemia in Non-dialysis Patients.	OLYMPUS	Kidney International Reports
Roxadustat for Anemia in Patients with End- Stage Renal Disease Incident to Dialysis.	HIMALAYAS	<u>Nephrology Dialysis</u> <u>Transplantation</u>
A Randomized Trial of Roxadustat in Anemia of Kidney Failure: SIERRAS Study	SIERRAS	Kidney International Reports



Roxadustat: An Innovative Approach to Addressing Anemia

Transformational Oral Anemia Therapy Leveraging Body's Natural Response to Hypoxia

- Superiority to ESAs in hemoglobin change from baseline and reduction in risk of blood cell transfusion
- CV safety demonstrated in pooled analyses
- Overcomes suppressive effects of inflammation on erythropoiesis
- Coordinated erythropoiesis, encompasses iron mobilization, and hepcidin reduction

Advanced by FibroGen from Discovery Through Approval

- Dialysis-dependent and non-dialysis-dependent CKD patients Registration and Approval
- Anemia associated with myelodysplastic syndromes (MDS) Phase 3
- Anemia associated with chemotherapy induced anemia (CIA) Phase 2

Partnered with Astellas and AstraZeneca

- Astellas: Japan, Europe, Turkey, Russia and the Commonwealth of Independent States, the Middle East and South Africa
- AstraZeneca: U.S., China, other markets in the Americas and in Australia/New Zealand as well as Southeast Asia



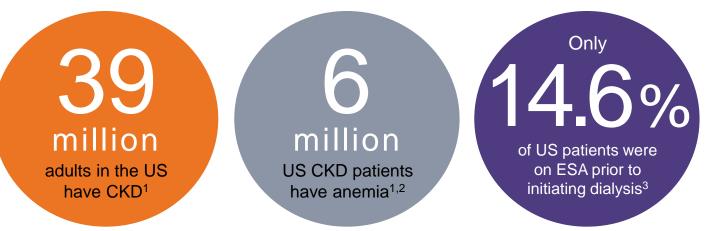




CKD Anemia Patients Not On Dialysis are Undertreated



Despite Associated Health Risks, Anemia is Often Left Untreated in CKD Non-Dialysis-Dependent (NDD) Patients



Contributing Factors of Undertreatment

- Delayed referral to nephrologists
- Inability to treat to a Hb >10 with ESA
- Inconvenience of ESA administration
 - Injectable
 - Frequent office visits to receive therapy
 - Buy and Bill requirement
 - Patients not comfortable with ESA self-injections



Sources: ¹ Bikbov B et al. Global, regional, and national burden of chronic kidney disease, 1990–2017: A systematic analysis for the Global Burden of Disease Study 2017. The Lancet 2020; 395(10225):709–33 ²Stauffer ME, Fan T. Prevalence of anemia in chronic kidney disease in the United States. *PLoS ONE*. 2014;9(1):e84943. ³United States Renal Data System (USRDS) Annual Data Report 2019 estimate as of Year End 2017

Opportunity for Therapies which Overcome the Limitations of Current SOC in Dialysis-Dependent Patients

DD-CKD Population Continues to Grow Globally

- In the US as of Dec 2017 over 520K patients are on dialysis vs. 370K in Dec 2007 (CAGR 3.4%)¹
- In China, over 600K patients are currently on dialysis. Double digit growth Y/Y due to rapid increase of diabetes and hypertension, the two leading causes of CKD.
- Over 90% DD-CKD patients require anemia therapy

Limitations of Current Anemia Standard of Care

- Most patients start receiving anemia therapy when the dialysis therapy is initiated
- Limitations of ESA include:
 - Majority of patients require supplemental iron
 - Patients with inflammation are often hyporesponsive to ESA
 - Safety concerns about high ESA dosage



Roxadustat Opportunity in Treatment of CKD Anemia

Roxadustat, A Potential First-in-Class, Orally Administered, Small Molecule HIF-PH Inhibitor, Has The Opportunity To Revolutionize The CKD Treatment Paradigm

Past

Only Option was Transfusion

 Transfusion was the only option when iron alone was not enough

Present

Treated as EPO Deficiency¹

 With supplemental EPO combined with extra iron supplements for red blood cell production

O Future

Treat CKD Anemia by Enabling the Body to Stimulate Coordinated Erythropoiesis

 Activating HIF pathway has the potential to stimulate endogenous production of red blood cells

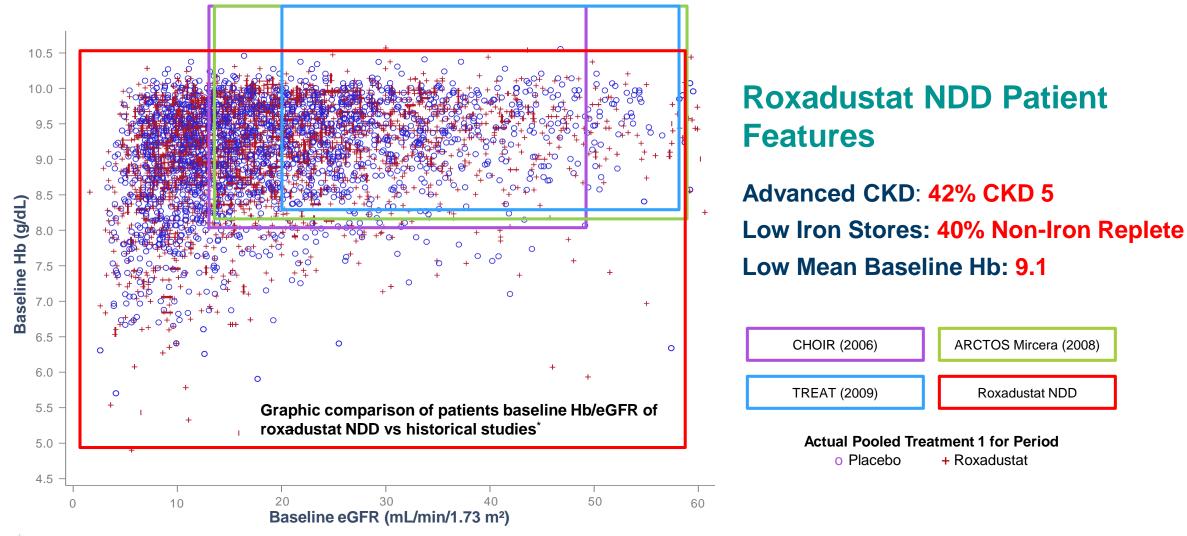
FibroGen Source: 1. Nephrologist survey conducted by Company. EPO: erythropoietin

Roxadustat NDD and DD Program: One of the Largest CKD Anemia Clinical Development Programs

Phase 3 CKD Non-Dialysis-Dependent (NDD) Pool					
D5740C00001	FGCL-4592-060	1517-CL-0608	NDD Pooled		Number of Patients:
OLYMPUS	ANDES	ALPS			
AstraZeneca	FibroGen	Astellas	Roxa	Placebo	4,277 Patient Exposure Years: 6,194
N=2761	N=922	N=594	N=2391	N=1886	
R 1:1	R 2:1	R 2:1	1.62 Avg PEY	1.23 Avg PEY	

Phase 3 CKD Dialysis-Dependent (DD) Pool					
D5740C00002	FGCL-4592-064	FGCL-4592-063	DD Pooled		
ROCKIES	SIERRAS	HIMALAYAS			Number of Patients:
AstraZeneca	FibroGen	FibroGen	Roxa	EPO	3,880
N=2106	N=741	N=1043	N=1943	N=1947	
R 1:1	R 1:1	R 1:1			Patient Exposure Years: 7,059
Correction & maintenance Early & Stable DD	Maintenance Early & Stable DD	Correction Study Entry w/in 4 mos of dialysis initiation (Early)	1.71 Avg PEY	1.92 Avg PEY	7,033

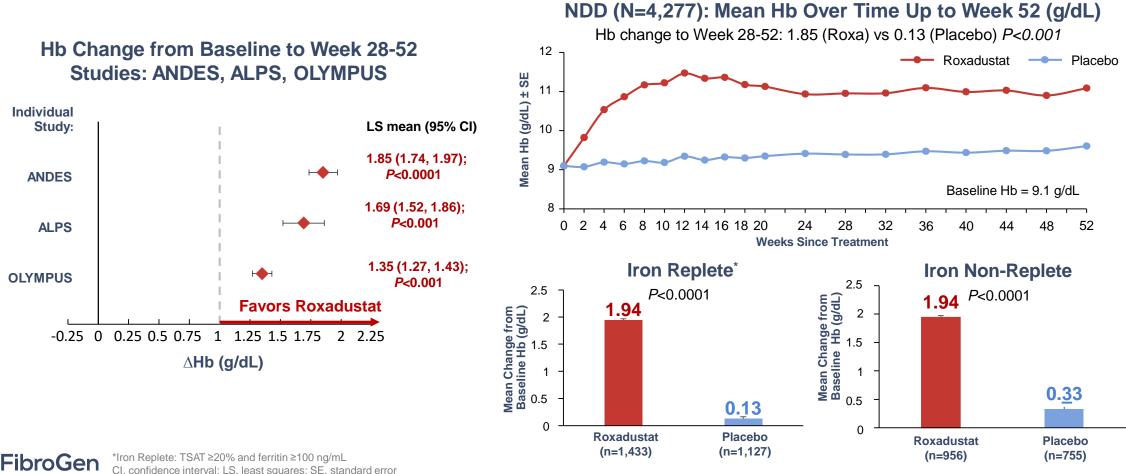
NDD Roxadustat Program: Evaluation of Anemia Therapy in a Broad Range of Patients Not Included in Prior CKD Anemia Trials





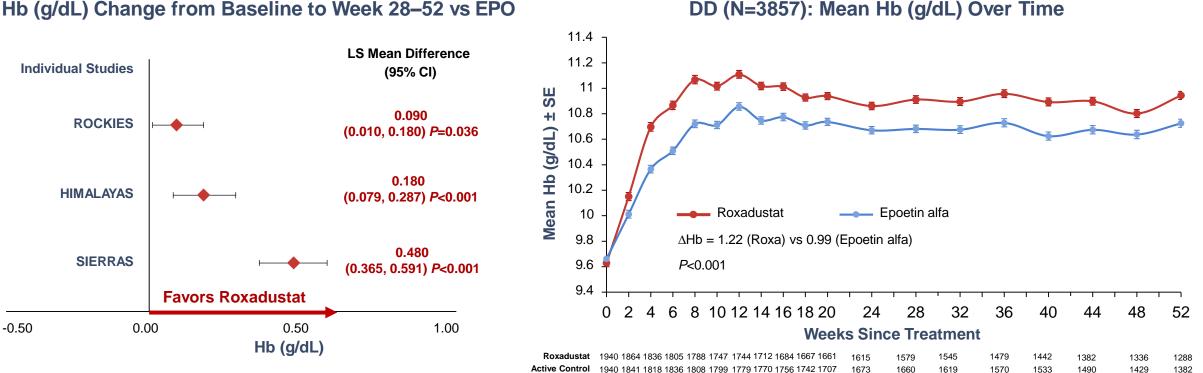
NDD: Roxadustat is Superior to Placebo, Regardless of Baseline Iron Status

Primary Efficacy Endpoint (Change in Hb from Baseline to Hb Averaged Over Weeks 28-52) was Met in Individual Studies and Pooled Analyses



DD: Roxadustat Achieved Larger Hb Increase than EPO in **Individual Studies and Pooled Analyses**

Primary Efficacy Endpoint (Change in Hb from Baseline to Hb Averaged **Over Weeks 28-52) was Met**

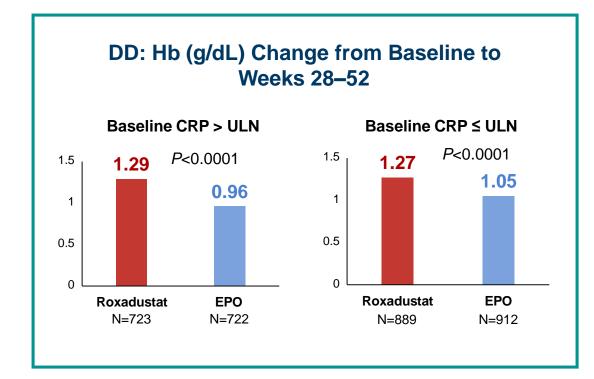


Hb (g/dL) Change from Baseline to Week 28–52 vs EPO

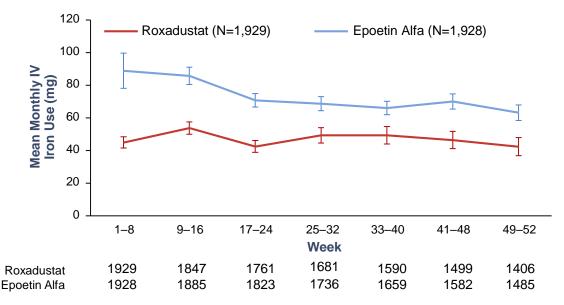
proGen CRP, C-reactive protein; EPO, epoetin alfa

DD: Roxadustat Efficacious Regardless of Inflammation and Requires Less IV Iron than Epoetin Alfa

- Roxadustat achieved higher Hb increase in patients with inflammation (CRP > ULN) and in patients without inflammation (CRP ≤ ULN), compared to epoetin alfa
- Less IV iron was required in roxadustat patients than in patients on epoetin alfa

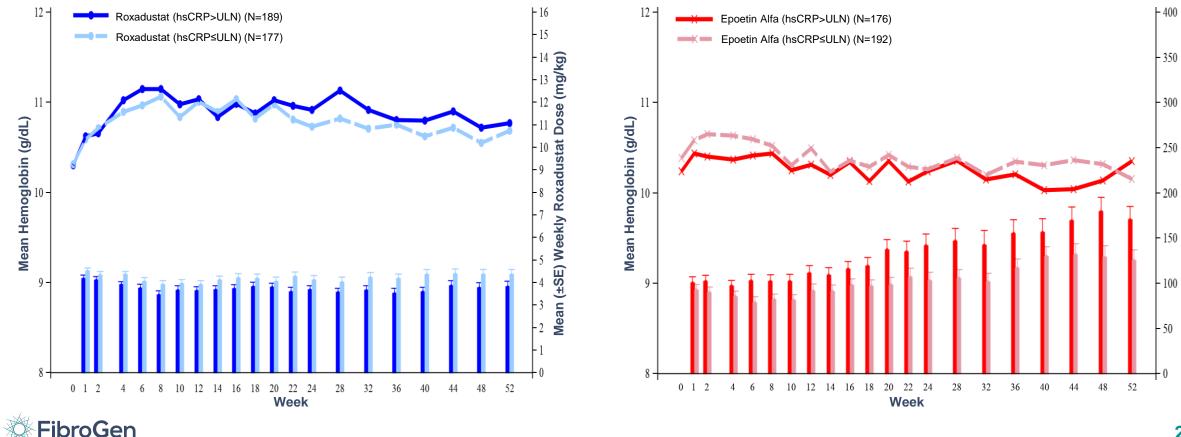






SIERRAS (064) US-Only Study in Stable Dialysis Patients: Roxadustat Efficacy Unaffected by Inflammation and Durable Over Time

Roxadustat Patients With or Without Inflammation Achieved Comparable Hb Levels with Comparable Average Doses, and Stable Over 52 Weeks EPO Patients with Inflammation (CRP>ULN) Required Higher Doses than Patients Without Inflammation (Low CRP), and Avg Dose Increased by ~50% Over 52 Weeks



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EPO

Mean (±SE) Weekly

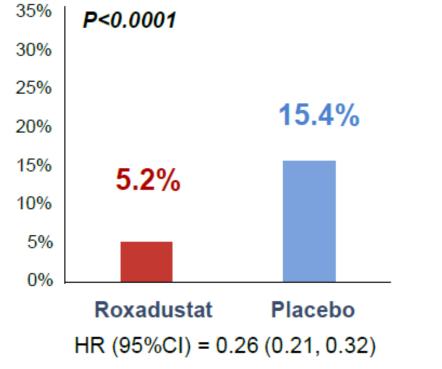
Roxadustat Lowers Use of Rescue^{*} Therapies in NDD; Reduction in RBC Transfusion in NDD (vs Placebo) and in DD (vs Epoetin Alfa)

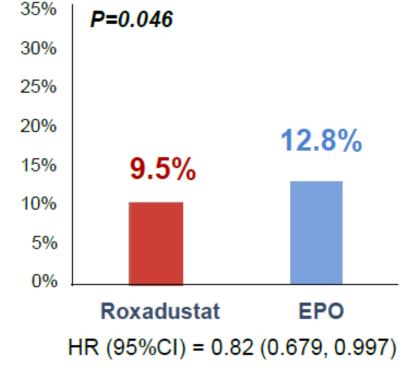
NDD: RBC Transfusion

Percent Patients with RBC Transfusion in First 52 Weeks



Percent Patients with RBC Transfusion During Treatment

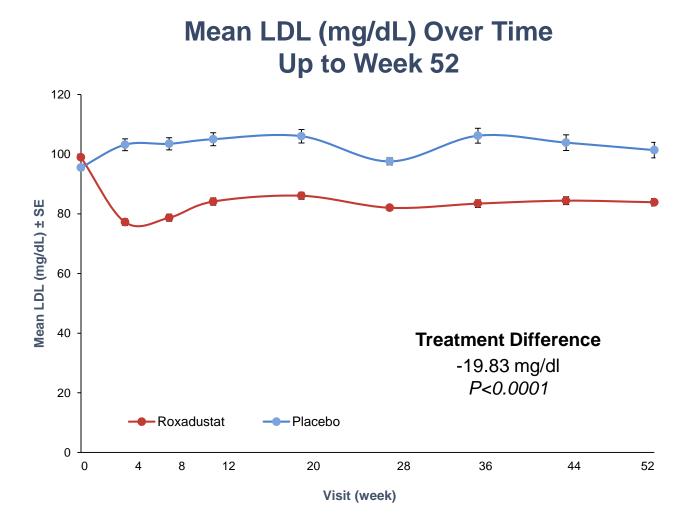






*Rescue = RBC transfusion, ESA, or IV iron HR, hazard ratio; RBC, red blood cell

Roxadustat: Potential Additional Benefits in NDD



FibroGen LDL, low-density lipoprotein

Cardiovascular Safety Pooled Analyses

• Cardiovascular (CV) safety endpoints analyzed in NDD pool and in DD pool

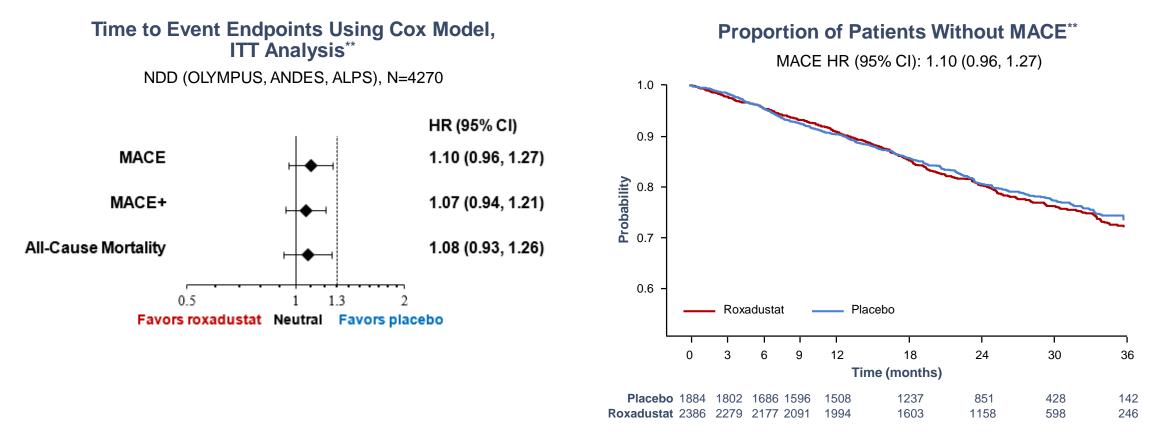
Key safety endpoints:

- Time to first MACE
 - MACE (Major Adverse Cardiovascular Events) include: all-cause mortality, myocardial infarction, and stroke
- Time to first MACE+
 - MACE+ includes MACE, unstable angina requiring hospitalization, and congestive heart failure requiring hospitalization
- Time to all-cause mortality
- CV events were **centrally adjudicated** by independent experts blinded to treatment assignment



NDD: Pooled Cardiovascular Safety Endpoints

Risks of MACE, MACE+, or All-Cause Mortality in Roxadustat Patients were Comparable to Placebo in NDD Patients^{*}





*"comparable" based on hazard ratio (HR) upper bound of 95% confidence interval (95%CI) below reference non-inferiority margin of 1.3 **ITT analysis = Intent to treat analysis evaluation period to include on-treatment and off-treatment long term follow-up, until end of study

Dolomites Phase 3 NDD Study



Primary Efficacy Endpoint

Hemoglobin Response^a During the First 24 Weeks of Treatment (Per Protocol Set)

	Roxadustat (n=286)	Darbepoetin (n=273)
% Patients achieving a response ^a	89.5%	78.0%
Difference of proportions (roxadustat – darbepoetin alfa), % (95% CI) ^b	11.51 (5.66, 17.36)	
Sensitivity analysis (FAS) of primary endpoint difference of proportions % (95% CI) (roxadustat - darbepoetin alfa)		

Time to First MACEHazard Ratio (95% CI)MACE^c0.81 (0.52, 1.25)

aResponse defined as Hb \geq 11.0 g/dL and Hb change \geq 1.0 g/dL if baseline Hb >8.0 g/dL; or change \geq 2.0 g/dL if baseline Hb \leq 8.0 g/dL at two consecutive visits separated by \geq 5 days, without rescue therapy. bEstimated using a generalized linear model as an approximation for the Miettinen and Nurminen method adjusted for stratification factors.

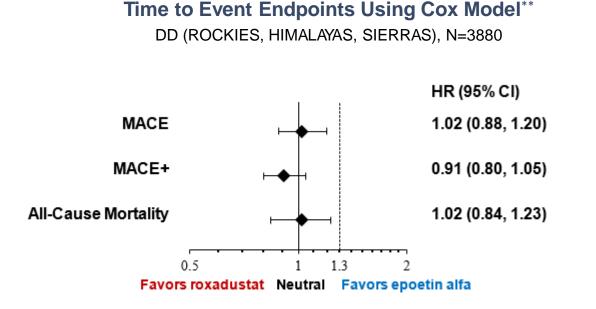
bEstimated using a generalized linear model as an approximation for the Miettinen and Nurminen method adjusted for

cMACE is defined as death, non-fatal myocardial infarction, and/or stroke.



DD: Pooled Cardiovascular Safety Endpoints

 Risk of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to epoetin alfa in DD patients^{*}

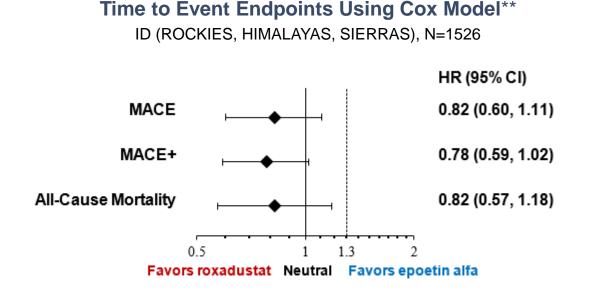


Proportions MACE+ Components Rates, N (%)				
Events	Roxadustat	Epoetin Alfa		
n	1940	1940		
Death (all-cause mortality)	207 (10.7%)	232 (12.0%)		
Myocardial Infarction	103 (5.3%)	109 (5.6%)		
Stroke	45 (2.3%)	50 (2.6%)		
Unstable Angina	18 (0.9%)	22 (1.1%)		
Congestive Heart Failure	120 (6.2%)	166 (8.6%)		

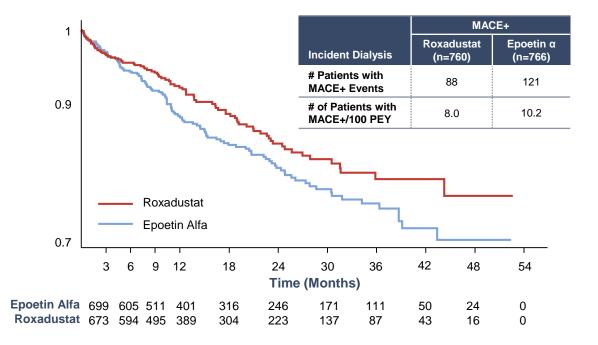


Incident Dialysis Pool: Cardiovascular Safety Analyses

 Risk of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to epoetin alfa in incident dialysis patients^{*}



Proportion of Patients Without MACE+ Over Time



Oncology Anemia Market Opportunities

Addressing Under-Served Patient Populations

Chemotherapy-Induced Anemia (CIA)



patients undergo chemotherapy each year in the US¹

- 30%-90% cancer patients receiving chemotherapy develop anemia.²
- Anemia rate varies by tumor type and increases with each successive chemotherapy round.

80-90% reduction in ESA oncology use since 2006

 Publication of RCTs in cancer populations led to Box warning by the U.S. FDA in 2007 and a subsequent decline in ESA oncology sales.

Myelodysplastic Syndromes (MDS) Anemia

60-170K US prevalence³

- Annual incidence rate: 4.9/100K adults in U.S.⁴; 1.51/100K adult in China.
- Anemia is the most common clinical presentation in MDS, leading to frequent red blood cell transfusions and related risks such as iron overload, impairment of QOL, and shorter lifespan.



- ESA response rate as low as 20%-32% in low risk MDS.
- Majority of patients (low and high risk) are transfusion dependent and face associated risks of transfusions.



WHITNEY Roxadustat Chemotherapy-Induced Anemia (CIA) Phase 2 Study

Patient Population

 Anemic Patients Receiving Chemotherapy Treatment for Non-Myeloid Malignancies

Primary Endpoint

 Maximum change in hemoglobin from baseline without RBC transfusion

Secondary Endpoints

- Mean change in hemoglobin level from baseline to week 16 (without RBC transfusion)
- Change in hemoglobin from baseline at Week 8, 12, 16 (without RBC transfusion)
- Number (%) of patients who had a RBC transfusion from beginning of Week 5

Study Design

- Open label
- Completed enrollment ~100 subjects at 25 sites globally

Topline data expected 2H 2021





MATTERHORN Roxadustat Anemia Associated with Myelodysplastic Syndromes (MDS) Phase 3 Study

Patient Population

 Anemic Patients with Lower Risk Myelodysplastic Syndrome (MDS)

Primary Endpoint

- Transfusion independence ≥ 56 consecutive days
- Hemoglobin correction/maintenance and reduction of RBC transfusion

Secondary Endpoints

- Safety
- Quality of life parameters
- Transfusion independence

Study Design

- Randomized Double-Blind Placebo-Controlled Study
- Enroll ~160 subjects at ~72 sites globally

Topline data expected 1H 2022

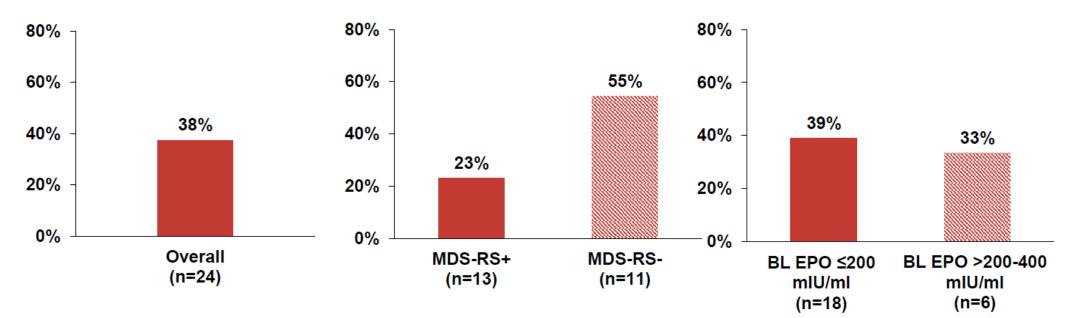


NCT03263091



Anemia Associated with Myelodysplastic Syndromes (MDS) Phase 3 – Open label data reported at ASH '20

Primary & Exploratory Endpoints: Transfusion Independence (TI) for ≥8 weeks (During Both 28 & 52 Weeks)



- 78% (7 of 9) patients were on 2.5 mg/kg dose at the time of transfusion independence
- During the first 8 weeks FIXED DOSE, transfusion independence was achieved in a small proportion of patients in cohorts 1 (25%) and 3 (50%).

Exploratory endpoint of patients with/without ring sideroblasts (RS) during weeks 1-28 and 1-52

Exploratory endpoint of patients in baseline erythropoietin (BL EPO) categories during weeks 1-28 and 1-52

Roxadustat Collaboration Economics

- Royalty/Transfer Price in low 20% range in U.S./EU and ROW
 - China 50/50 profit split
- Development Costs and commercialization paid by partners
- Total Milestones of \$2.5 Billion
- \$245 million on U.S. and EU approval and first U.S. commercial sale

\$ Millions	→astellas Japan, EU, etc.	AstraZeneca US, China, ROW	Payments Received/Billed through March 31, 2021
Equity Investment in FibroGen	\$81	\$20	\$101
Upfront, Non-Contingent	\$360	\$402	\$762
Development and Reg. Milestones	\$543	\$571	\$399
Commercial Milestones	\$15	\$653	\$0
POTENTIAL TOTAL	\$918 M	\$1,626 M	\$1,161M of \$2,544M

- All roxadustat R&D costs reimbursed, ex-China
- All roxadustat commercial costs covered by partners, ex-China

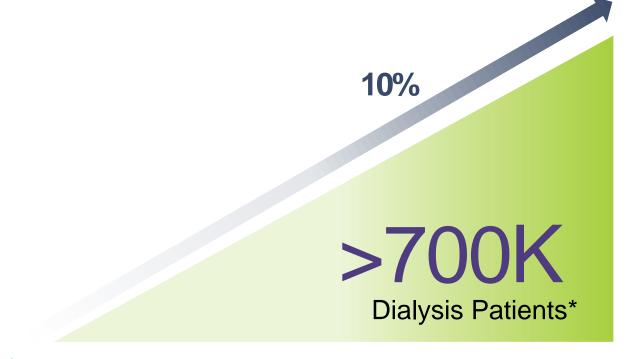


FibroGen China

China: Transforming the Treatment of CKD Anemia

Largest Dialysis Market in the World

~90% of Dialysis patients treated for Anemia of CKD ~40% reach the Ministry of Health target of Hb 11



Non-Dialysis

NDD-CKD

- CKD patients in stage 3 and stage 4, as well as stage 5 who are not eligible for dialysis
- Largely untreated with ESAs

Dialysis-Eligible NDD Population

- China has a large population of dialysis-eligible
 NDD-CKD patients
- These patient qualify for dialysis under treatment guidelines but are not dialyzed
- Estimated at 1-2 million patients
- At risk for severe anemia

ibroGen *source Chinese Renal Data System (CNRDS)

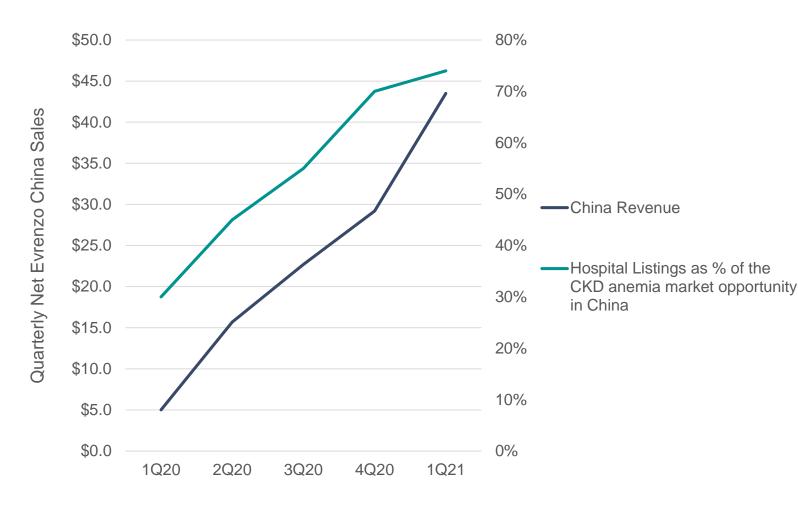
China: Roxadustat Commercialization Underway

FibroGen-AZ Roxadustat China Partnership





China First Quarter 2021 Roxadustat Results

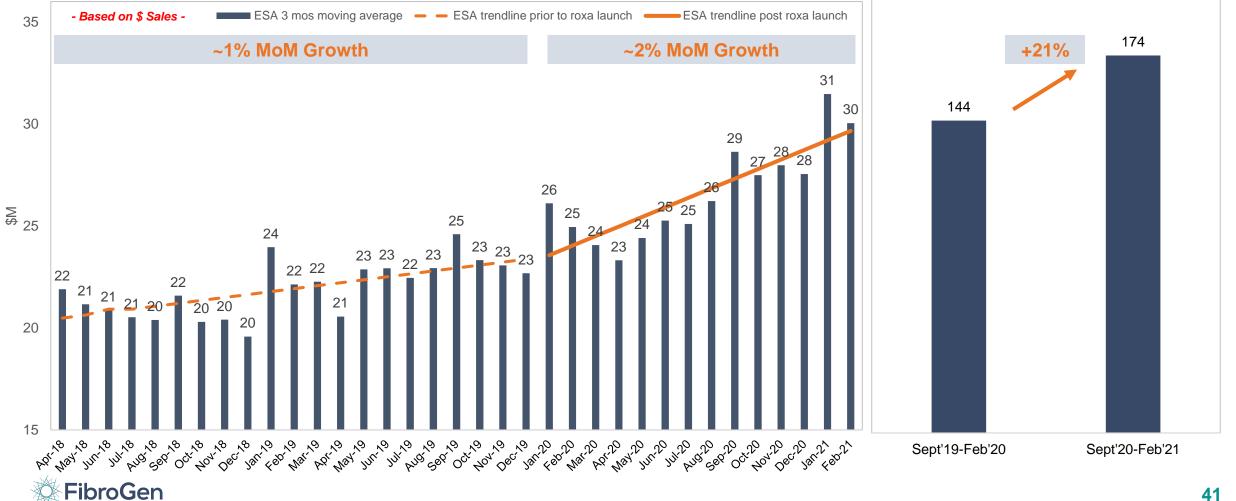


- Roxadustat net sales to distributors in China of \$43.5 million in first quarter 2021
- FibroGen net product revenue under U.S.
 GAAP of \$15.4 million
- Broad utilization across all types of CKD anemia patients including:
 - Non-dialysis dependent
 - Incident dialysis
 - Hemodialysis
 - Peritoneal dialysis
- Hospital Listings now represents ~74% of the CKD anemia market opportunity

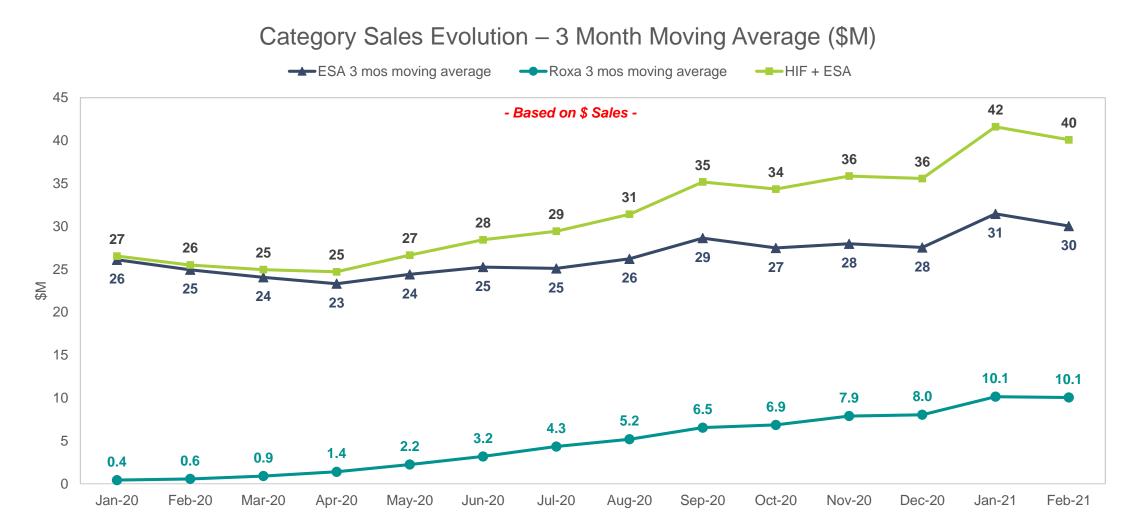


CHINA: Since Roxadustat Launch, ESA Market Growth has Accelerated

ESA \$ Sales Evolution -3 Month Moving Average (\$M) ESA \$ Sales in Last 6 Months vs Same Period in Prior Year (\$M)

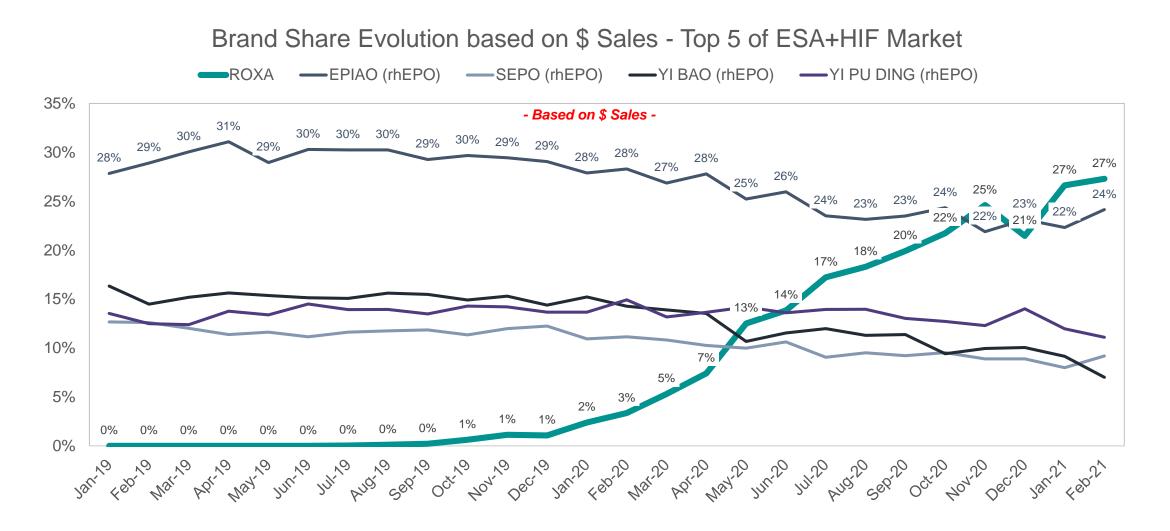


CHINA: Roxadustat has Expanded the Anemia of CKD Category Since Inclusion on the NRDL in January 2020



FibroGen

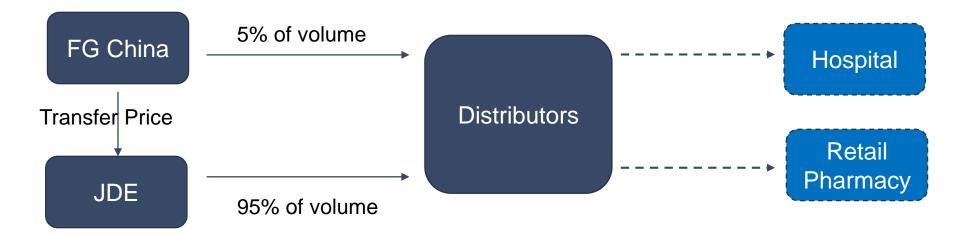
CHINA: Roxadustat is the #1 brand in the Anemia of CKD Market Based on \$ Sales for the last Two Months





China Revenue

- Joint Distribution Entity (JDE) performs ~95% of Roxa volumes, reported by AZ starting 1Q 2021
- FG China delivers Roxa to JDE for a transfer price
 - 30-45% of JDE's net sales
 - JDE pays both AZ's commercialization expenses and AZ's portion of profit share (previously our responsibility)



- FG China Revenue:
 - Direct Distributor Sales
 - approx. 5% of volumes; plus
 - JDE Transfer Price
 - 30-45% of JDE's net sales

FibroGen

Pamrevlumab

Fibrosis

Pamrevlumab: Targeting High Need Medical Indications

Pancreatic Cancer (LAPC)

- FDA Fast Track and Orphan Drug Designation
- LAPIS Phase 3 study enrolling

Duchenne Muscular Dystrophy (DMD)

- FDA Orphan Drug, Fast Track and Rare Pediatric Disease Designation
- EMA Orphan Medicinal Product Designation
- LELANTOS Phase 3 study enrolling
- LELANTOS-2 Phase 3 study enrolling

Idiopathic Pulmonary Fibrosis (IPF)

- FDA Fast Track and Orphan Drug Designation
- ZEPHYRUS Phase 3 study enrolling
- ZEPHYRUS-2 Phase 3 study enrolling
- Primary endpoint of change in forced vital capacity (FVC) from baseline



LAPC Patient Population Lacks Treatment Options

Addressing Under-Served and Growing Patient Population



- ~45,000 (70-80%) of PDAC are metastatic²
- ~12,000 (20-30%) are locally advanced of which
- ~4,000 (1/3) are unresectable²

Clinical Significance of Resection

Locally Advanced Unresectable Disease

- 50% survive 8-12 months
 - ~8% survive 5 years
 - Survival rate similar to metastatic disease

Borderline and Resectable Disease

- 50% survive 17-27 months
- ~20% survive 5 years



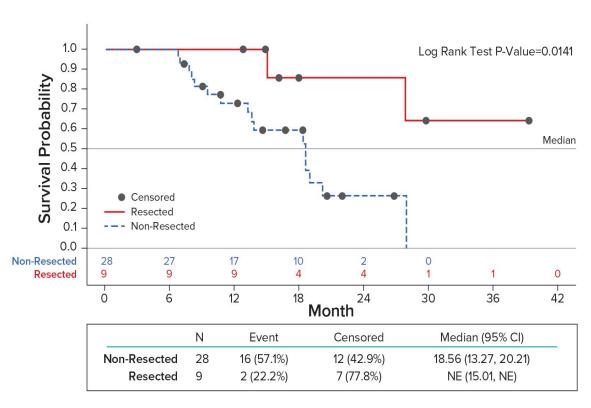
1. American Cancer Society "https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf.

2. Epidemiology of Pancreatic Cancer: Global Trends, Etiology and Risk Factors World J Oncol. 2019;10(1):10-27

Phase 2 LAPC: Surgical Resection Increases Survival*

- 37 LAPC patients randomized to pamrevlumab (n=24) vs placebo (n=13), as neoadjuvant agent added to (gemcitabine+ paclitaxel); evaluation after 6 cycle of chemotherapy at ~6 months:
- Increased surgical eligibility rate:
 - 70.8% (pamrevlumab) vs 15.4% (placebo)
- Higher achieved surgical resection rate:
 - 33.3% (pamrevlumab) vs 7.7% (placebo)
- Resection increases survival
 - Statistically significance in median survival p-value=0.0141
 - Median survival >40 months (resected) vs 18.6 months (non-resected)

Resection Increases Survival



Overall Survival (OS) by Resection

LAPIS Pamrevlumab LAPC Phase 3 Study

Patient Population

- Locally advanced, unresectable pancreatic cancer
- ECOG 0-1 (health status of patient)
- No prior therapy

Primary Endpoint

• Overall Survival (OS)

Secondary Endpoints

- Progression-free survival
- Patient-reported outcomes

Study Design

- Double-blind, placebo-controlled
- Enroll ~280 subjects at 60-80 sites globally
- Randomization 1:1 to pamrevlumab + gemcitabine/nab-paclitaxel or to placebo + gemcitabine/nab-paclitaxel
- Six cycles of neoadjuvant treatment followed by evaluation for surgical eligibility and possible resection
- Assessment six months postcompletion of enrollment for resection and resectability
- Long-term overall survival follow-up for all subjects



NCT03941093



DMD Background

- Affects ~1 in every 5,000 newborn boys
- About 20,000 children are diagnosed with DMD globally each year
- A fatal disease caused by genetic mutations leading to the absence or defect of dystrophin, a protein necessary for normal muscle function:
 - The absence of dystrophin results in muscle weakness, muscle loss, fibrosis, and inflammation
- Patients with DMD are often non-ambulatory before the age of 12, and their progressive muscle weakness can lead to serious medical problems relating to diminished function of respiratory and cardiac muscles



LELANTOS Pamrevlumab DMD Phase 3 Study

Patient Population

 Males 12 years and older with nonambulatory DMD

Primary Endpoint

 Change in the total score of performance of upper limb (PUL) assessment, from baseline to Week 52

Secondary Endpoints

- Pulmonary function tests
- Cardiac function tests

Study Design

- Double-blind, placebo-controlled
- Enroll ~90 subjects at 60-80 sites globally
- Randomized 1:1 to receive pamrevlumab plus systemic corticosteroids, or placebo plus systemic corticosteroids, for up to 52 weeks



NCT04371666



LELANTOS-2 Pamrevlumab DMD Phase 3 Study

Patient Population

 Males 6-12 years old with ambulatory DMD

Primary Endpoint

 Ambulatory function assessment, measured by the change in North Star Ambulatory Assessment (NSAA) from baseline to Week 52

Secondary Endpoints

 Additional functional secondary endpoints will be assessed in the study

Study Design

- Double-blind, placebo-controlled
- Enroll ~70 subjects at 60-80 sites globally
- Randomized 1:1 to receive pamrevlumab plus systemic corticosteroids, or placebo plus systemic corticosteroids, for up to 52 weeks
- Subjects who complete the 52week study will be eligible for rollover into an open-label extension study





NCT04632940



IPF Patients Need New Therapeutic Options



- U.S. prevalence of ~44,000 to 135,000¹
- U.S. incidence of ~21,000 to 52,000¹ cases per year
- Incident and mortality are on the rise, and prevalence is expected to increase with the aging population²



- Leads to irreversible loss of lung function with high morbidity and mortality rates
- Median survival of 3-5 years following diagnosis

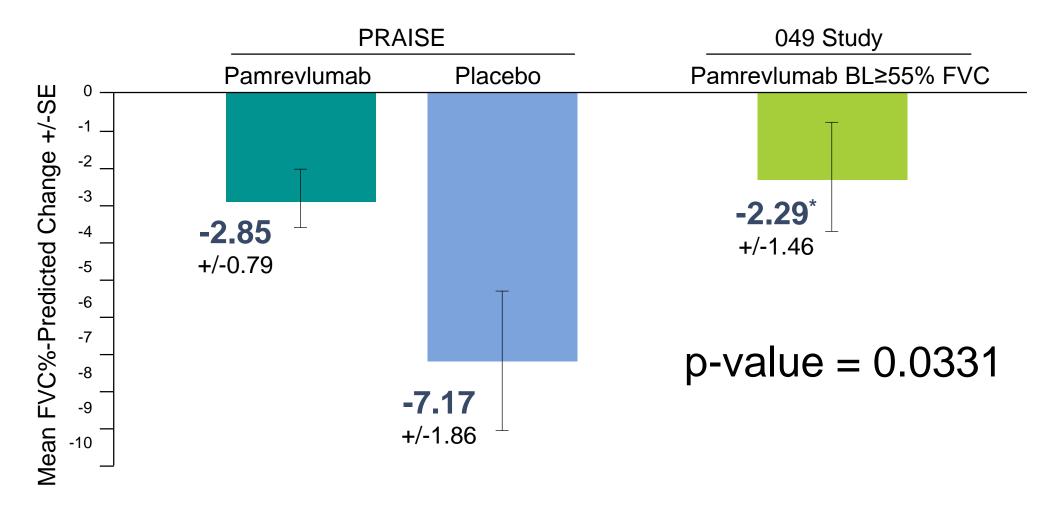


- Slow pulmonary function loss
- Modest effect on slowing disease progression
- No demonstration of reversal
- Require side effect management
- Esbriet and Ofev combined 2020 sales >\$3B

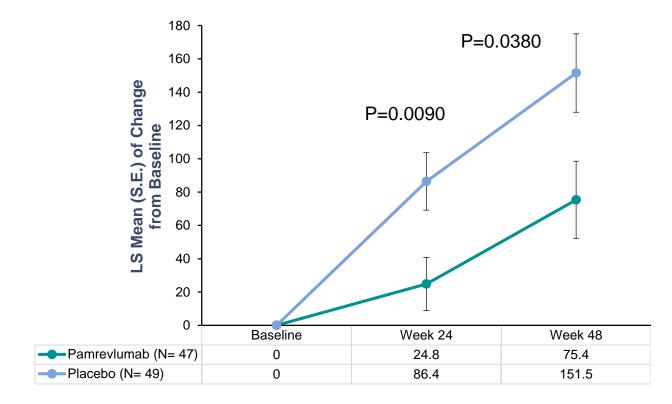


Phase 2 PRAISE Study met Primary Efficacy Endpoint by Slowing Decline in FVC Percent Predicted

FVC%-Predicted



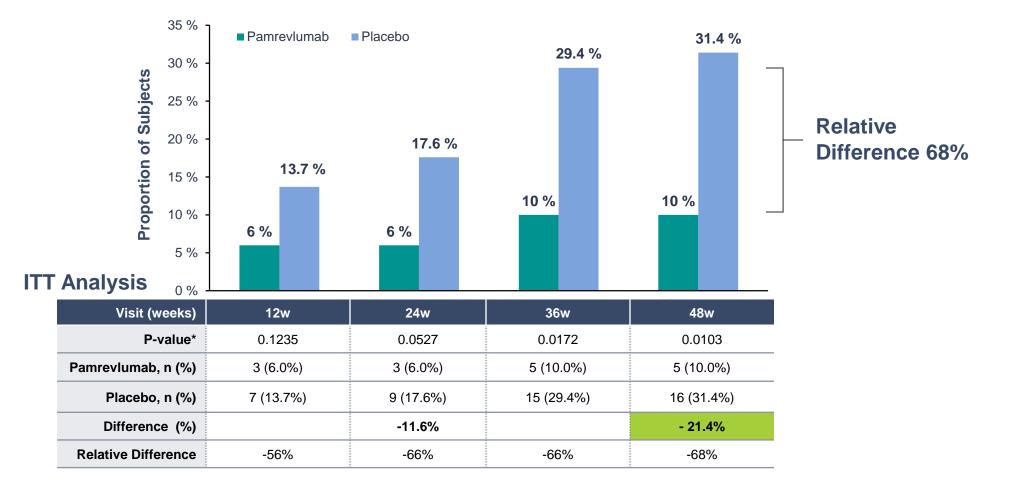
Pamrevlumab Attenuated Progression of Fibrosis



- Absolute differences in QLF changes from baseline to Weeks 24-48 between pamrevlumab arm and placebo arm were 61.6 ml and 76.2 ml, respectively
- First reported statistically significant results for attenuation of fibrosis by qHRCT
- Change in fibrosis (lung structure) correlates with change in FVC% predicted (lung function), primary endpoint of study (Spearman's correlation coefficient of -0.64, p=0.0001)

Attenuation of IPF Disease Progression

IPF Disease Progression (FVC% Predicted Decline ≥10% or Death) vs. Placebo





Pamrevlumab IPF Phase 3 Program: ZEPHYRUS and ZEPHYRUS-2

Patient Population

- IPF diagnosis according to ATS/ERS/JRS/ALAT guidelines^{*}
 - ZEPHYRUS
 - IPF patients who have declined approved therapies
 - IPF patients previously but not now currently being treated with approved therapies
 - ZEPHYRUS-2
 - IPF patients previously but not now currently being treated with approved therapies

Study Design

- Placebo-controlled, double-blind
- Enroll ~340 patients in each study
- Randomization 1:1 pamrevlumab
 or placebo

Primary Endpoint

- Change in forced vital capacity (FVC) from baseline for U.S
- Disease progression defined as FVC % predicted decline of 10% or death for EU/UK

Secondary Endpoints

- Quantitative changes in lung fibrosis volume from baseline
- Patient-reported outcomes





NCT04419558



Upcoming Milestones

ROXADUSTAT

Anemia of Chronic Kidney Disease (CKD)

- Potential U.S. approval 2021
- Potential EU approval mid-2021

Chemotherapy-Induced Anemia

• WHITNEY Phase 2 topline data 2H 2021

Anemia Associated with MDS

MATTERHORN Phase 3 topline data 1H 2022

PAMREVLUMAB

Locally Advanced Unresectable Pancreatic Cancer (LAPC)

• LAPIS Phase 3 study enrolling, topline resection data 2H 2022

Duchenne Muscular Dystrophy (DMD)

• LELANTOS (non-ambulatory) Phase 3 study enrolling, topline data 2H 2022



Thank You

For more information contact ir@fibrogen.com