



# FibroGen, Inc. Corporate Presentation

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September 2020

# 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 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.

# Company Overview

## Company Mission

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

## Employees

**500+**  
worldwide

- 300+ US
- 200+ ex-US

## Year End 2020 Cash Guidance

**\$720-\$730**  
million

- \$245 million in expected roxadustat milestones between now and mid-year 2021
  - Related to approvals in the US and EU and first commercial sale in US
- No debt

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

## ROXADUSTAT

### Anemia Associated with Chronic Kidney Disease (CKD)

- Launched in China for NDD-CKD and DD-CKD
- Launched in Japan for DD-CKD
  - NDD sNDA submitted Jan 2020
- U.S. NDA submitted 4Q 2019
  - PDUFA date December 20, 2020
- EU MAA submitted 2Q 2020
- ROW submissions to date include Canada, Mexico, Australia, South Korea, and several other countries

### Anemia Associated with Myelodysplastic Syndromes (MDS)

- Phase 3 study enrolling

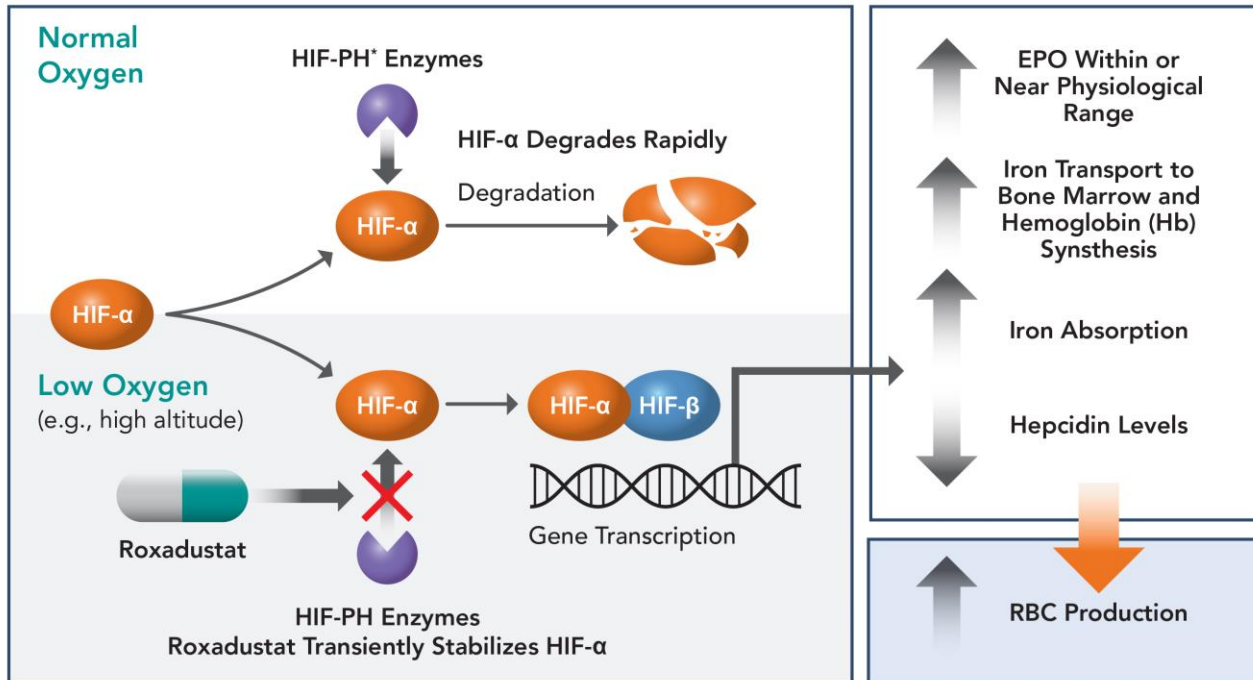
### Chemotherapy-Induced Anemia (CIA)

- Phase 2 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



### 2019 Nobel Prize In Physiology or Medicine

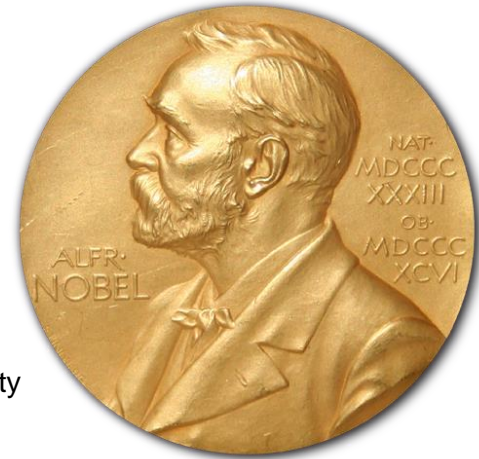
*"for their discoveries of how cells sense and adapt to oxygen availability."*

**Awarded jointly to:**

**William G. Kaelin Jr.**  
Harvard University

**Peter J. Ratcliffe**  
Francis Crick Institute  
London

**Gregg L. Semenza**  
Johns Hopkins University



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

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

## PAMREVLUMAB

### Idiopathic Pulmonary Fibrosis

- ZEPHYRUS Phase 3 study enrolling
- Plan to initiate ZEPHYRUS-2 Phase 3 study in 2020

### Locally Advanced Unresectable Pancreatic Cancer

- LAPIS Phase 3 study enrolling

### Duchenne Muscular Dystrophy

- LELANTOS Phase 3 study enrolling

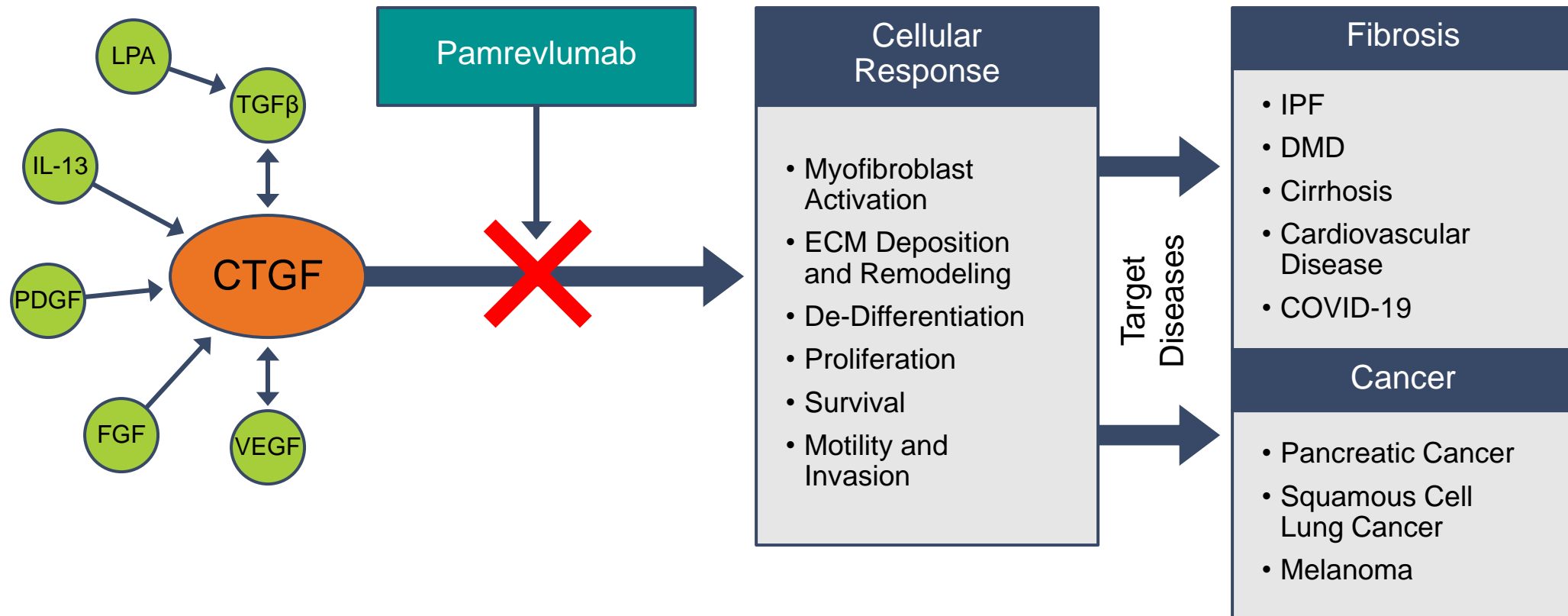
### COVID-19

- Italian BOREA Phase 2/3 study enrolling
- U.S. Phase 2 Acute study IND enrolling
- U.S. Phase 2 Post-acute study planned

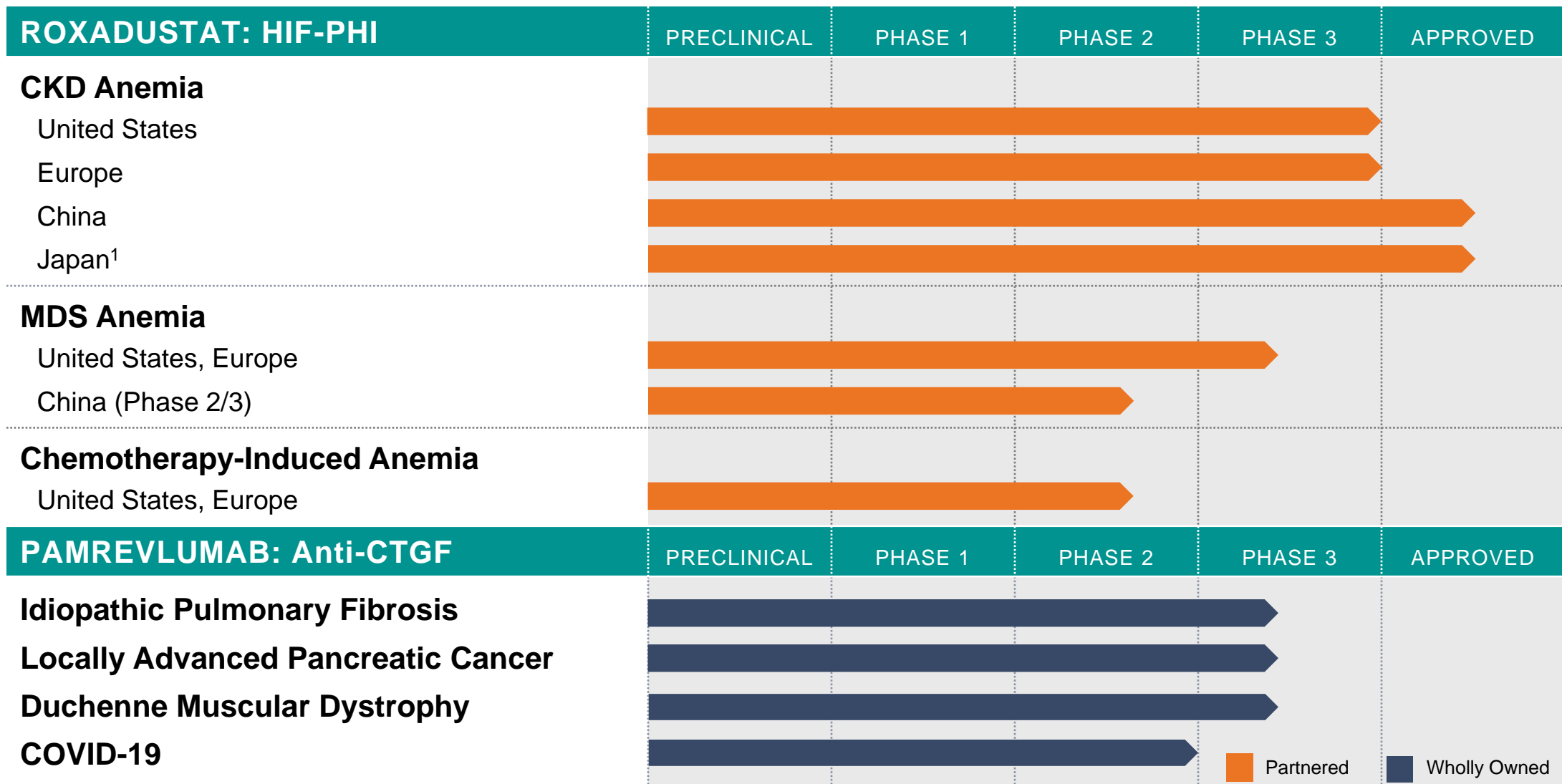
# Pamrevlumab:

## 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





# Roxadustat



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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 potential benefits

- **NDD:** Reduced LDL cholesterol
- **NDD:** Less decline in eGFR
- **DD:** less IV iron was required in roxadustat arm than in epoetin alfa

# 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

### Incident Dialysis

- Roxadustat patients had 30% lower risk of MACE and 34% lower risk of MACE+ than epoetin alfa patients, with a trend towards lower all-cause mortality in the ID subpopulation

### Dialysis

- Roxadustat patients had a lower risk of MACE+ than epoetin alfa patients
- Risk of MACE and all-cause mortality in roxadustat patients not increased compared to epoetin alfa patients in DD

# 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 in Phase 3
- 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

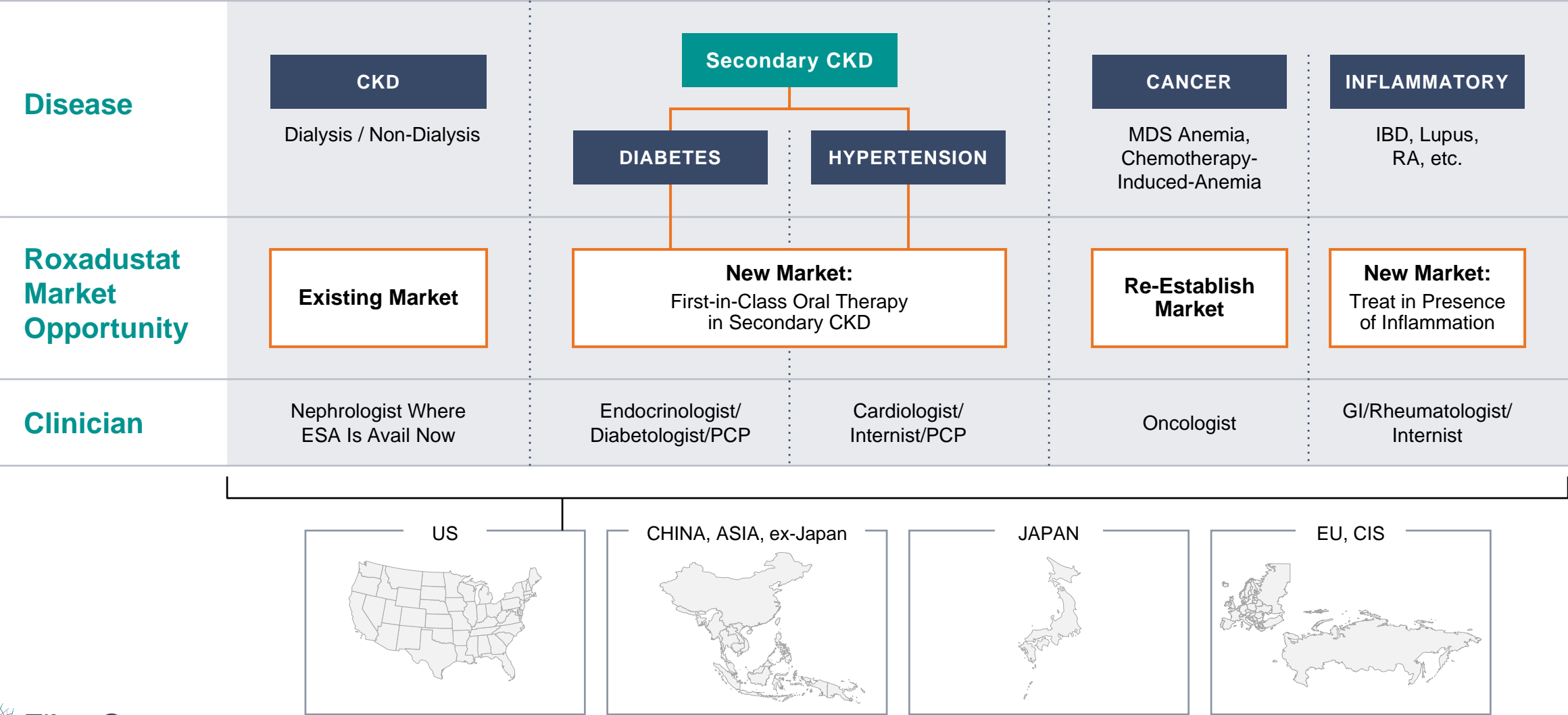
- Dialysis-dependent and non-dialysis-dependent CKD patients – Registration and Approval
- Anemia associated with myelodysplastic syndromes (MDS) – Phase 3
- Anemia associated with chemotherapy induced anemia (CIA) – Phase 2

### Partnered with Astellas and AstraZeneca

- Astellas: Europe, Middle East, CIS, South Africa, Japan
- AstraZeneca: U.S./ROW and China



# Potential Global Multi-Billion Dollar Markets for Anemia



# CKD Anemia Patients Not On Dialysis are Undertreated



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

**37**  
million  
adults in the US  
have CKD<sup>1</sup>

**4.9**  
million  
US CKD patients  
have anemia<sup>2</sup>

Only  
**13.6%**  
of US patients were  
on ESA prior to  
initiating dialysis<sup>3</sup>

### Contributing Factors of Undertreatment

- Limited use of ESAs outside of dialysis care
- Delayed referral to nephrologists
- Inconvenience of frequent visits to receive ESA therapy
- Patients not comfortable with ESA self-injections
- ESA storage and transportation requirements

# Dialysis-Dependent Patients Typically Receive ESA Anemia Therapy

## Opportunity for Therapies that Overcome the Limitations of Current SoC

### 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%)<sup>1</sup>
- 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

### Significant Mortality Risks and Turnover in Patients on Dialysis

- 20-25% of US DD-CKD patients initiate dialysis each year
- Patients face significant increased risks of death, CV events and hospitalizations during the first year on dialysis
- DD-CKD patients have high mortality rates:
  - 3 yr. survival – 57%  
\*(US hemodialysis pts)
  - 5 yr. survival – 42%  
\*(US hemodialysis pts)

### Limitations of Current Anemia SoC

- Most patients start receiving anemia therapy when the dialysis therapy is initiated
- Limitations of ESA include:
  - Often requires concomitant use of IV iron
  - Patients with inflammation are often hyporesponsive to ESA

# Roxadustat Opportunity in Treatment of CKD Anemia

Roxadustat, the Potential, First-in-Class, Orally Administered, Small Molecule HIF-PH Inhibitor, has the Potential 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 Deficiency<sup>1</sup>**

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

## 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

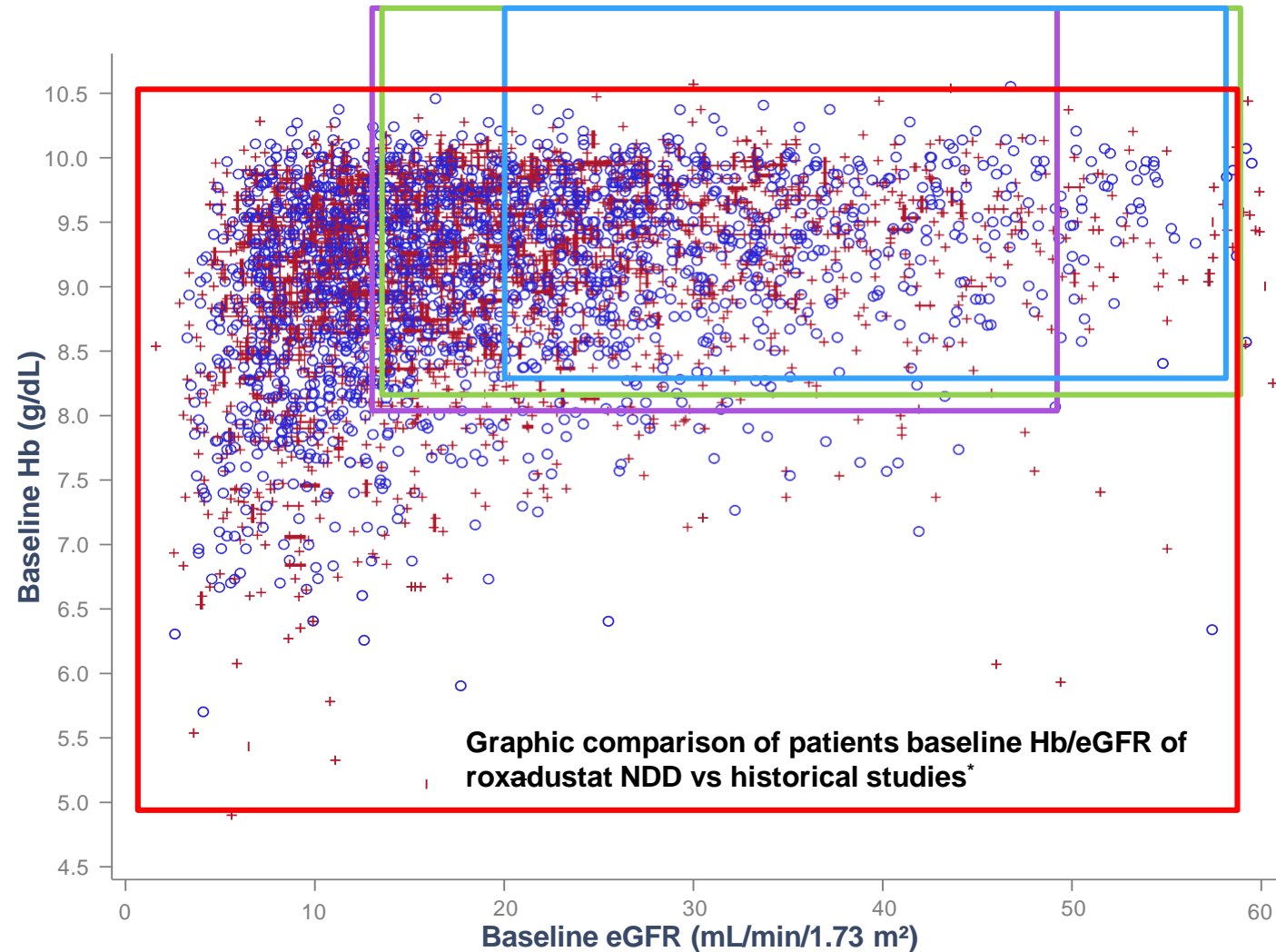


# Roxadustat NDD and DD Program:

## 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: <b>4,277</b>
<b>OLYMPUS</b>	<b>ANDES</b>	<b>ALPS</b>			
AstraZeneca	FibroGen	Astellas	<b>Roxa</b>	<b>Placebo</b>	Patient Exposure Years: <b>6,194</b>
<b>N=2761</b>	<b>N=922</b>	<b>N=594</b>	<b>N=2391</b>	<b>N=1886</b>	
R 1:1	R 2:1	R 2:1	<b>1.62 Avg PEY</b>	<b>1.23 Avg PEY</b>	
Phase 3 CKD Dialysis-Dependent (DD) Pool					
D5740C00002	FGCL-4592-064	FGCL-4592-063	DD Pooled		Number of Patients: <b>3,880</b>
<b>ROCKIES</b>	<b>SIERRAS</b>	<b>HIMALAYAS</b>			
AstraZeneca	FibroGen	FibroGen	<b>Roxa</b>	<b>EPO</b>	Patient Exposure Years: <b>7,059</b>
<b>N=2106</b>	<b>N=741</b>	<b>N=1043</b>	<b>N=1943</b>	<b>N=1947</b>	
R 1:1	R 1:1	R 1:1			
Correction & maintenance Early & Stable DD	Maintenance Early & Stable DD	Correction Study Entry w/in 4 mos of dialysis initiation (Early)	<b>1.71 Avg PEY</b>	<b>1.92 Avg PEY</b>	

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



## Roxadustat NDD Patient Features

Advanced CKD: **42% CKD 5**

Low Iron Stores: **40% Non-Iron Replete**

Low Mean Baseline Hb: **9.1**

CHOIR (2006)

ARCTOS Mircera (2008)

TREAT (2009)

Roxadustat NDD

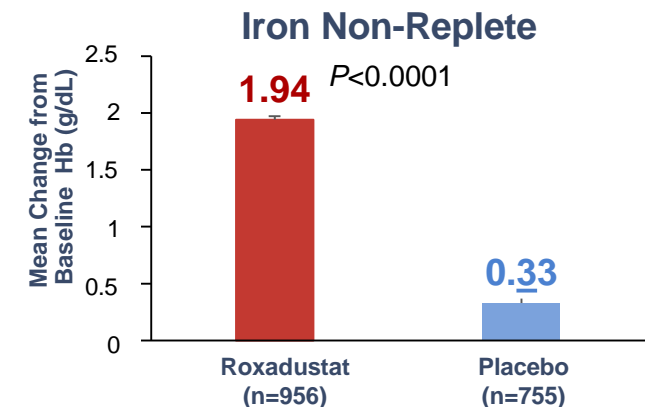
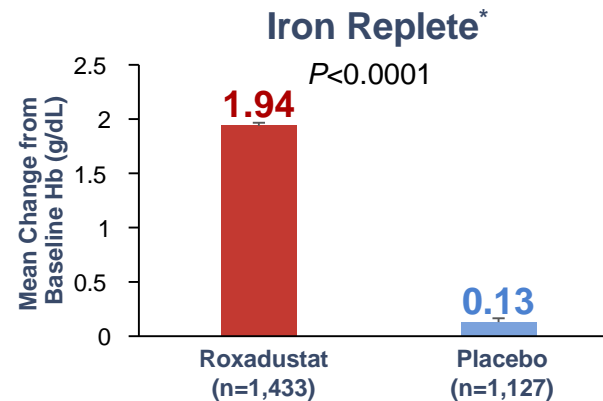
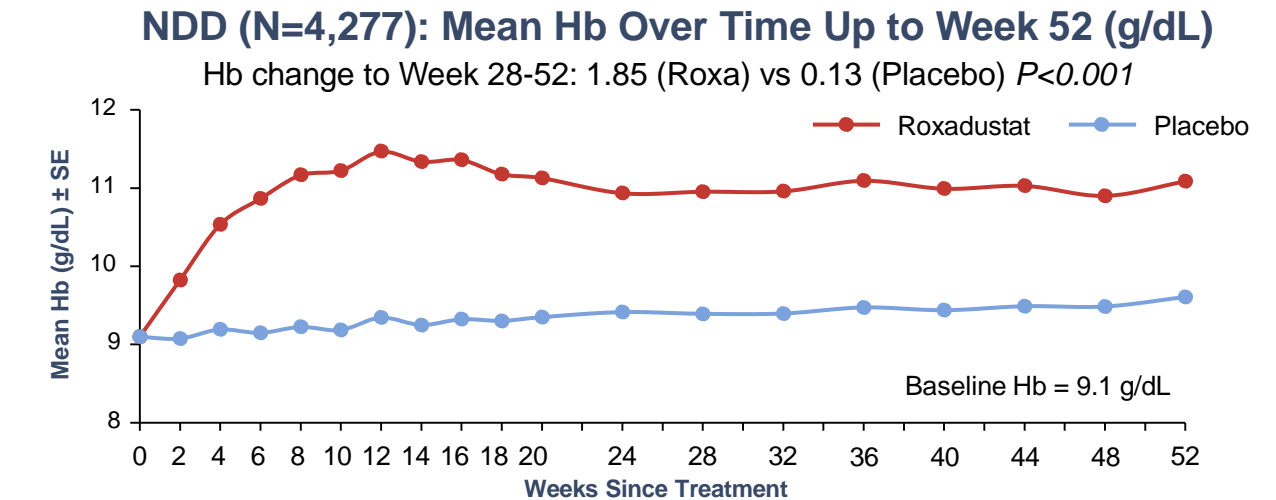
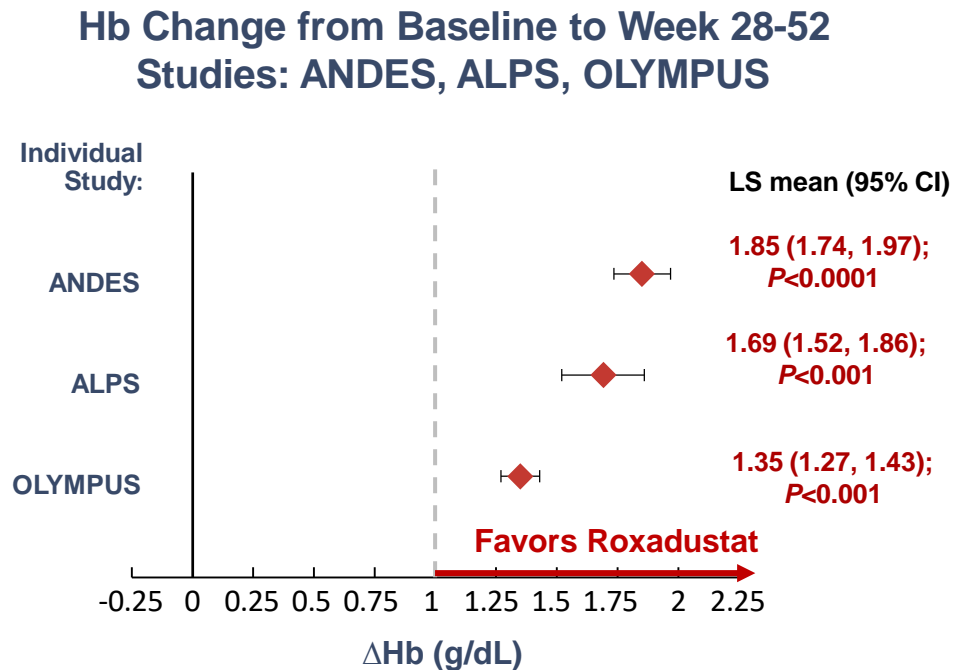
Actual Pooled Treatment 1 for Period

○ Placebo

+ Roxadustat

# NDD: Roxadustat is Superior to Placebo, Regardless of Iron Repletion

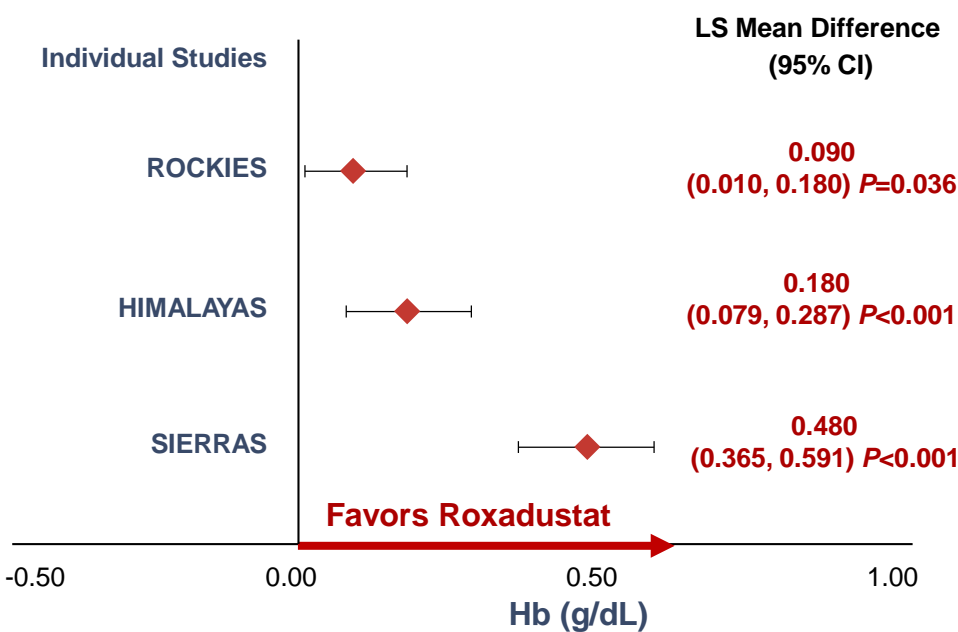
Primary Efficacy Endpoint (Change in Hb from Baseline to Hb Averaged Over Weeks 28-52) was Met in Individual Studies and Pooled Analyses



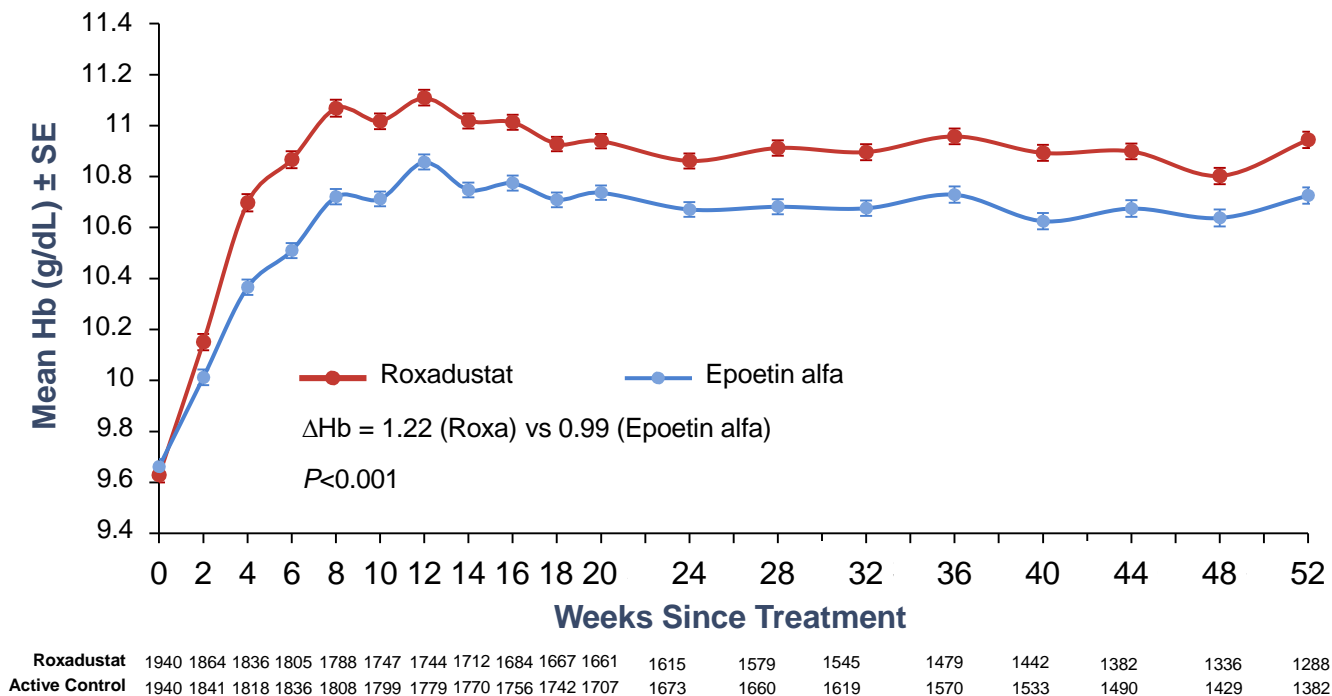
# DD: Roxadustat Achieved Larger Hb Increase than EPO in Individual Studies and Pooled Analyses

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



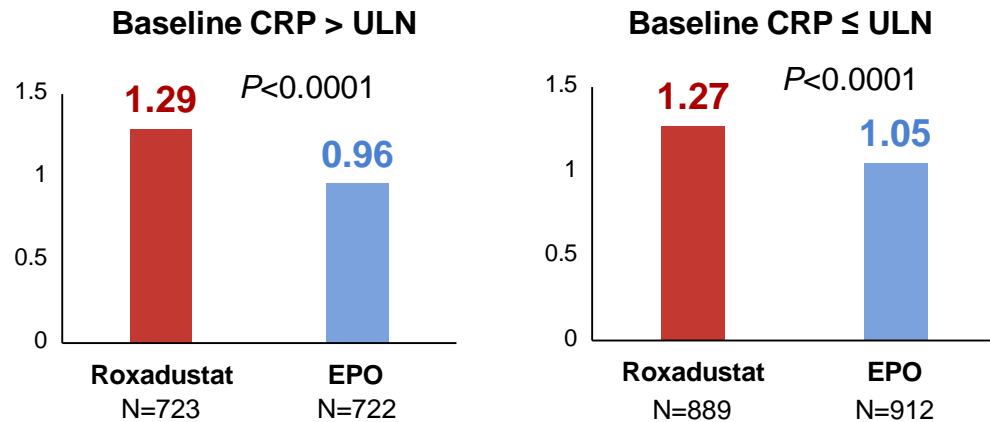
DD (N=3857): Mean Hb (g/dL) Over Time



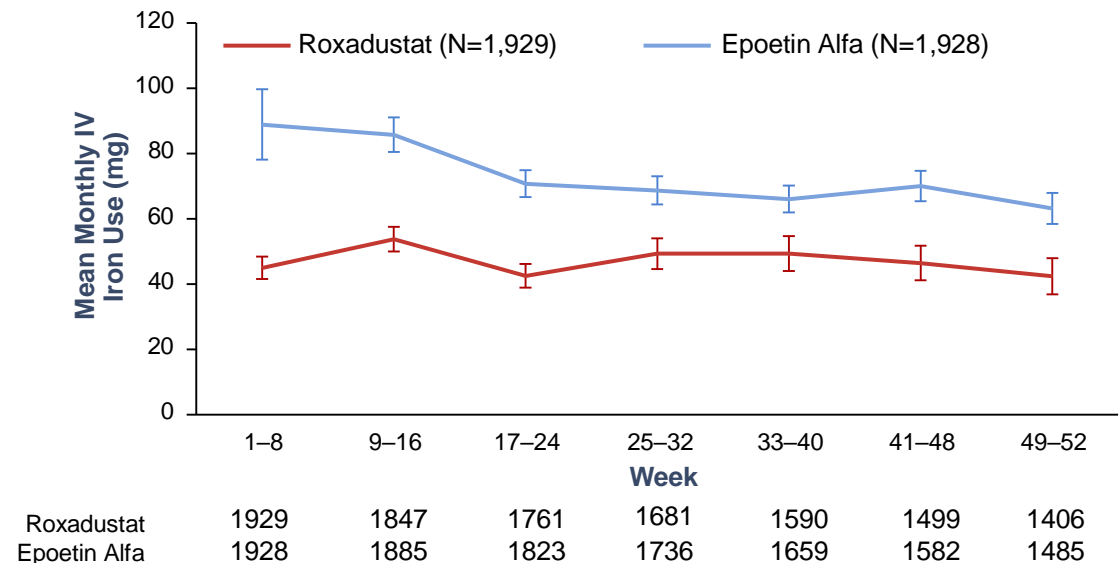
# DD: Roxadustat Efficacious Regardless of Inflammation and Requires Less IV Iron than Epoetin Alfa

- 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

DD: Hb (g/dL) Change from Baseline to Weeks 28–52

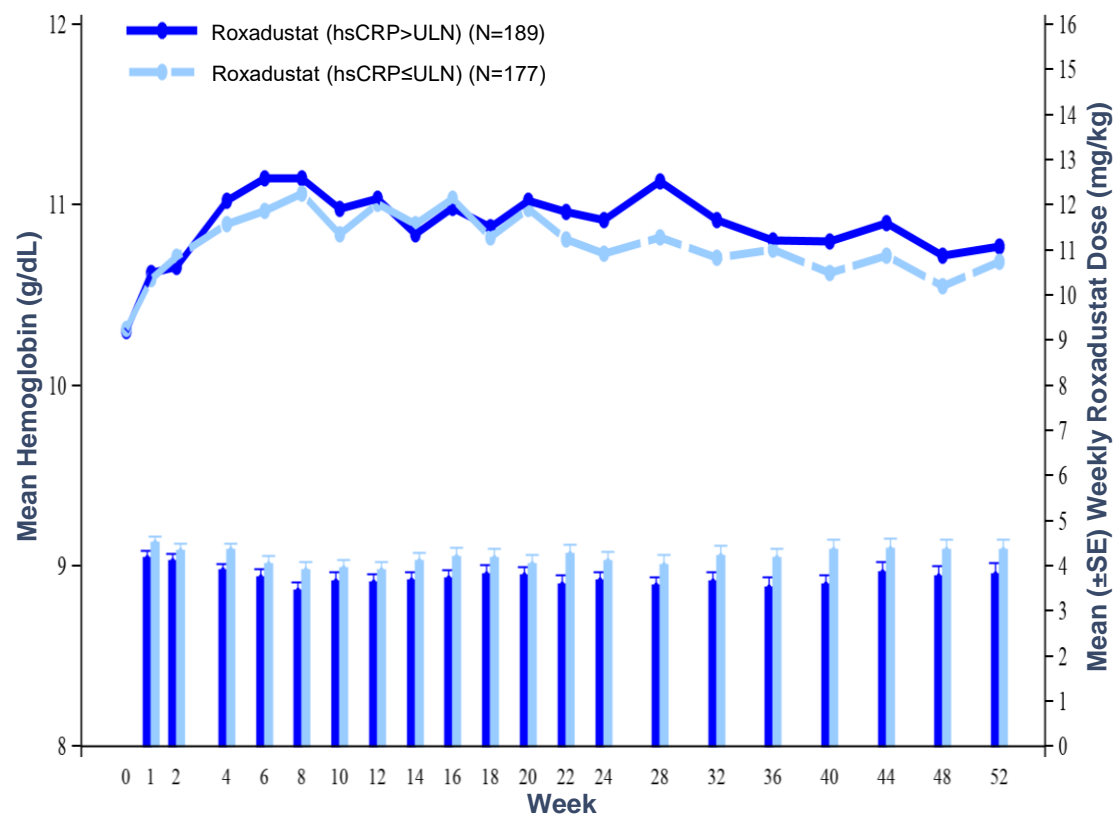


DD: Less Monthly IV Iron Use in Roxadustat Patients Than in Epoetin Alfa Patients

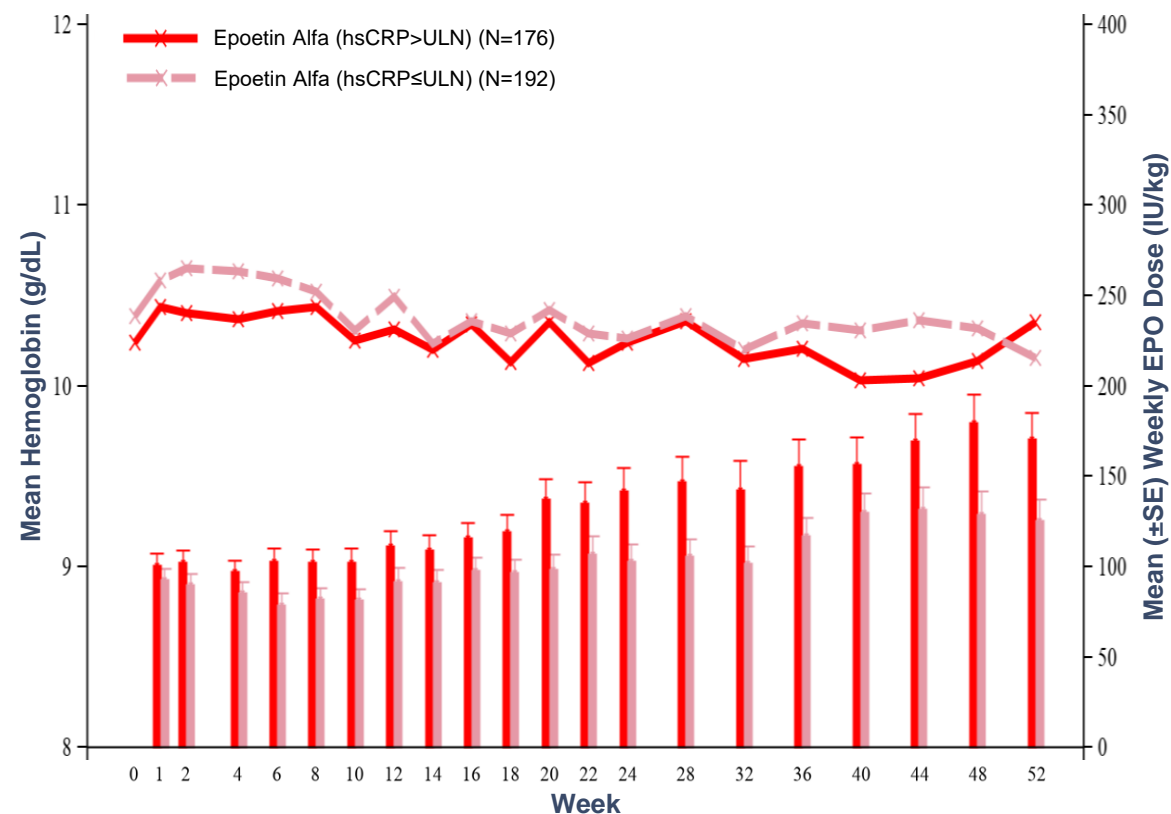


# SIERRAS (064) US-Only Study in Stable Dialysis Patients: Roxadustat Efficacy Unaffected by Inflammation and Durable Over Time

**Roxadustat Patients With or Without Inflammation Achieved Comparable Hb Levels with Comparable Average Doses, and Stable Over 52 Weeks**



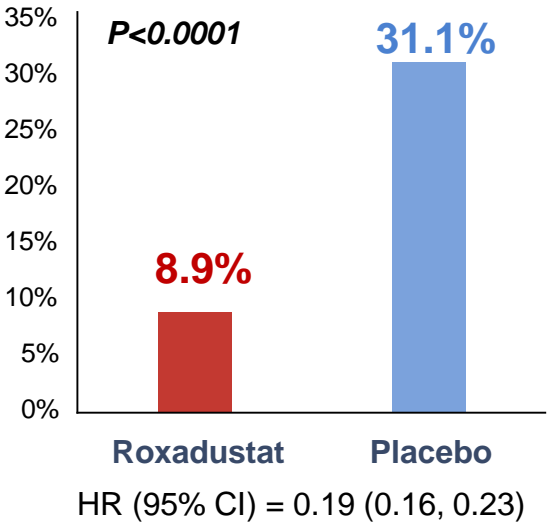
**EPO Patients with Inflammation (CRP > ULN) Required Higher Doses than Patients Without Inflammation (Low CRP), and Avg Dose Increased by ~50% Over 52 Weeks**



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

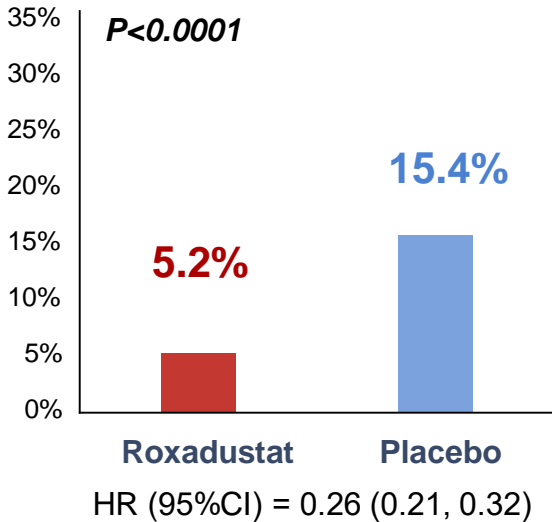
## NDD: Rescue Use

Percent Patients with Rescue Use in First 52 Weeks



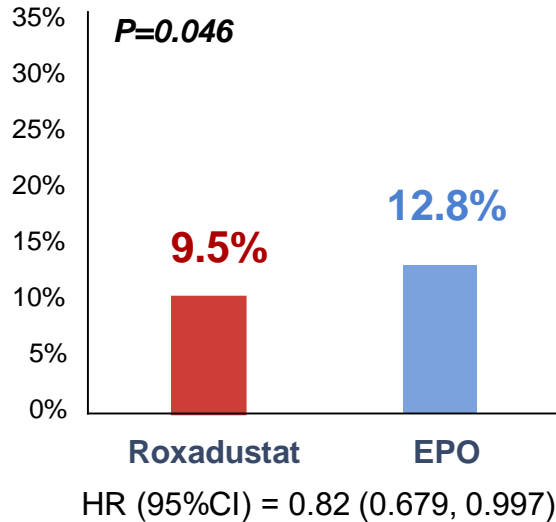
## NDD: RBC Transfusion

Percent Patients with RBC Transfusion in First 52 Weeks



## DD: RBC Transfusion

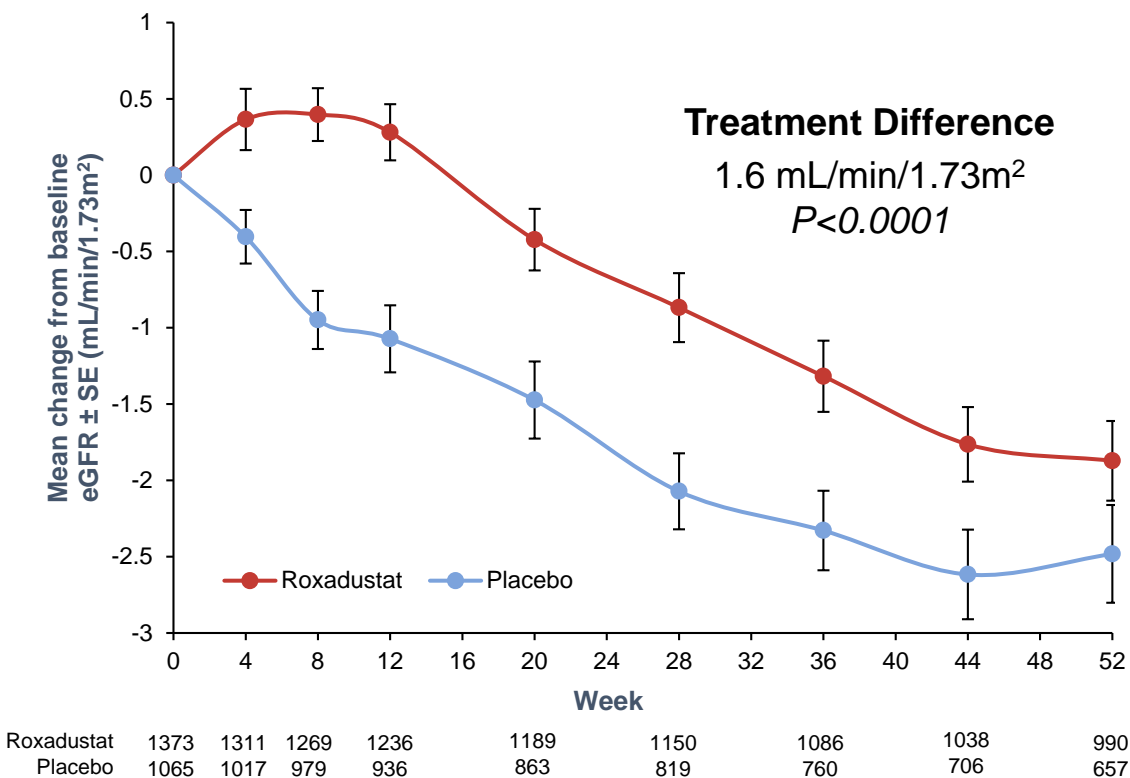
Percent Patients with RBC Transfusion During Treatment



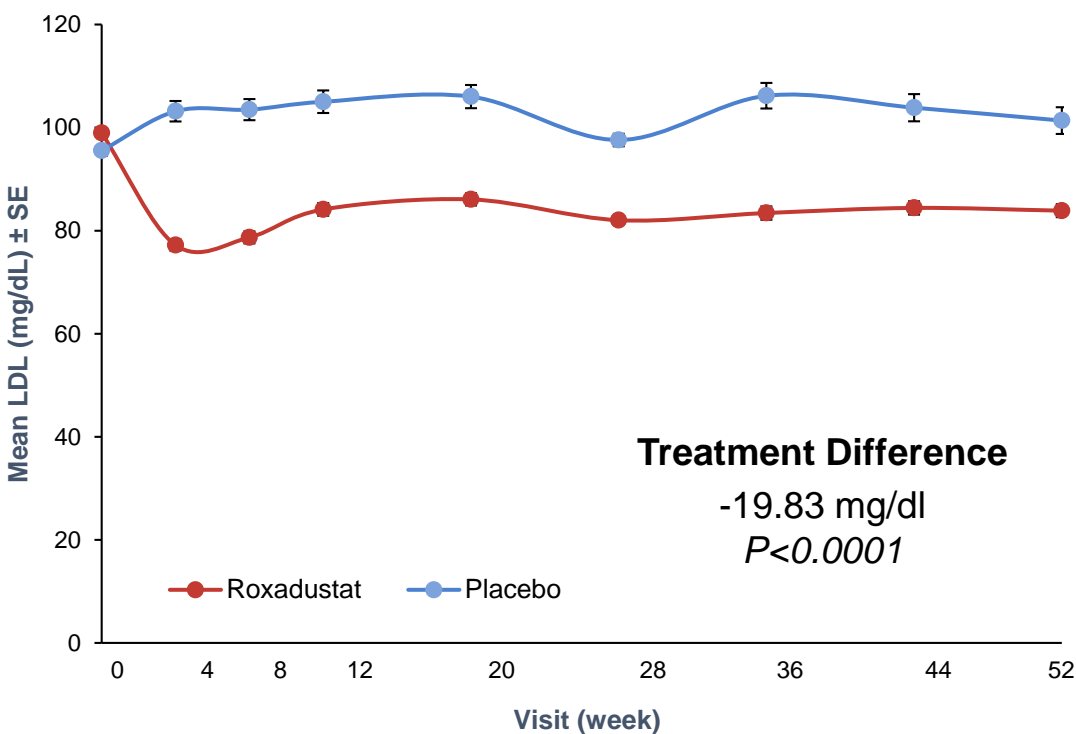
# Roxadustat: Potential Additional Benefits in NDD

## Change in eGFR from Baseline

Patients with Baseline eGFR  $\geq 15$  mL/min/1.73 m<sup>2</sup> (N=2,438)



## Mean LDL (mg/dL) Over Time Up to Week 52





# Cardiovascular Safety Pooled Analyses

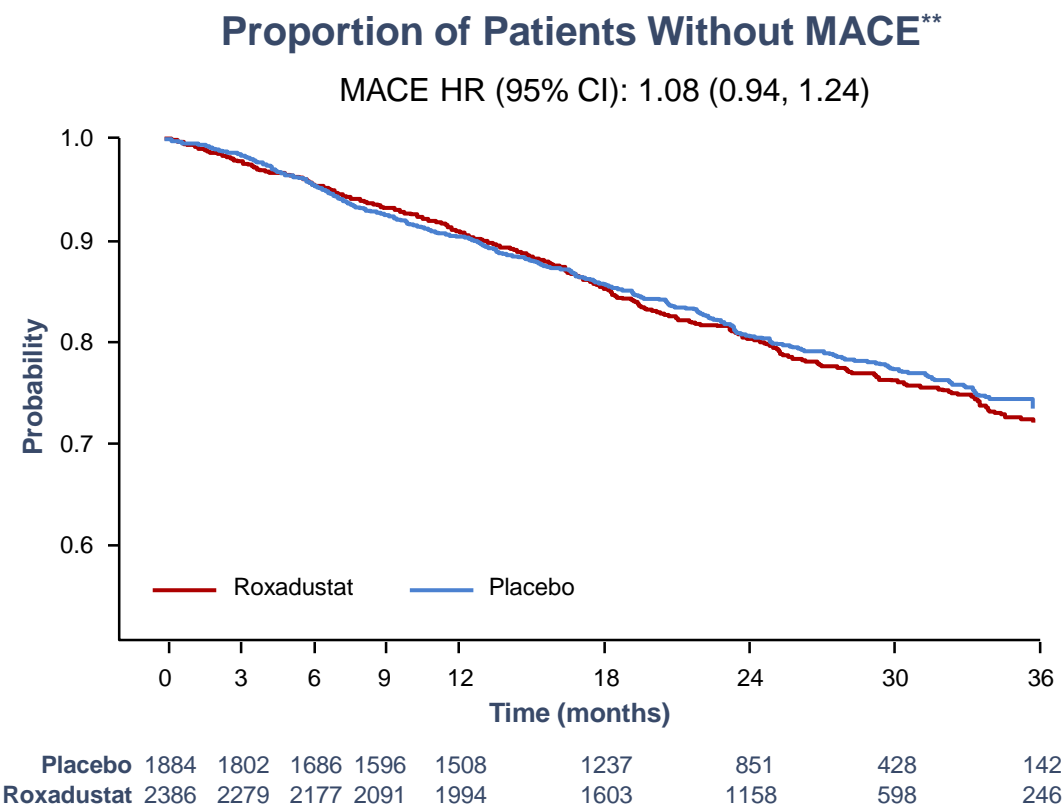
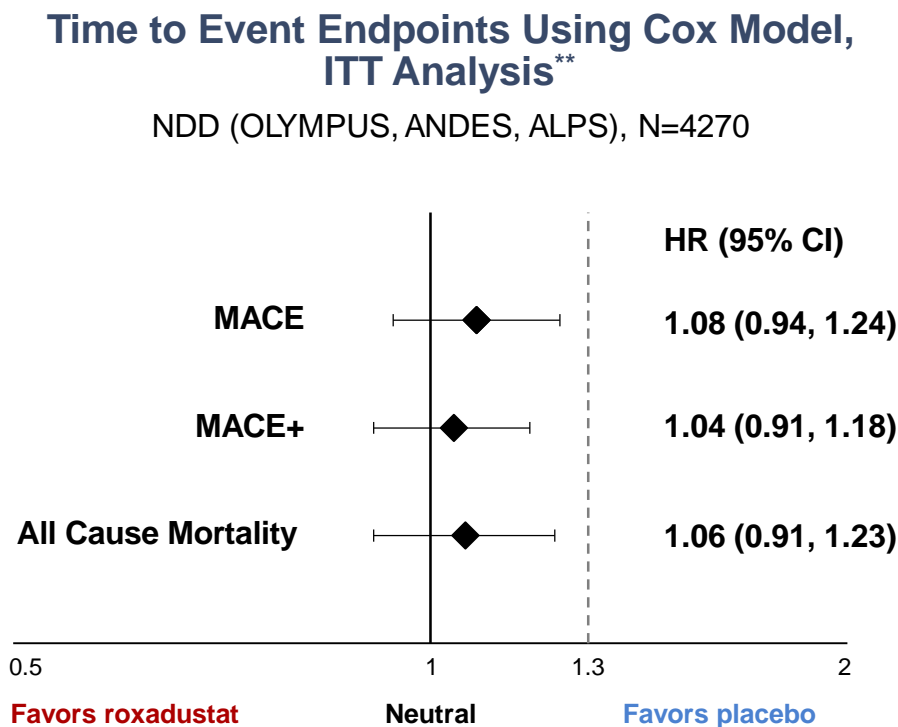
- Cardiovascular (CV) safety endpoints analyzed in **NDD pool** and in **DD pool**

## 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\*



# Dolomites Phase 3 NDD Study



## Primary Efficacy Endpoint

Hemoglobin Response<sup>a</sup> During the First 24 Weeks of Treatment (Per Protocol Set)

	Roxadustat (n=286)	Darbepoetin (n=273)
% Patients achieving a response <sup>a</sup>	89.5%	78.0%
Difference of proportions (roxadustat – darbepoetin alfa), % (95% CI) <sup>b</sup>	11.51 (5.66, 17.36)	
Sensitivity analysis (FAS) of primary endpoint difference of proportions % (95% CI) (roxadustat - darbepoetin alfa)	10.73 (4.97, 16.49)	

<sup>a</sup>Response defined as Hb ≥11.0 g/dL and Hb change ≥1.0 g/dL if baseline Hb >8.0 g/dL; or change ≥2.0 g/dL if baseline Hb ≤8.0 g/dL at two consecutive visits separated by ≥5 days, without rescue therapy.

<sup>b</sup>Estimated using a generalized linear model as an approximation for the Miettinen and Nurminen method adjusted for stratification factors.

<sup>c</sup>MACE is defined as death, non-fatal myocardial infarction, and/or stroke.

## Time to First MACE

Hazard Ratio (95% CI)

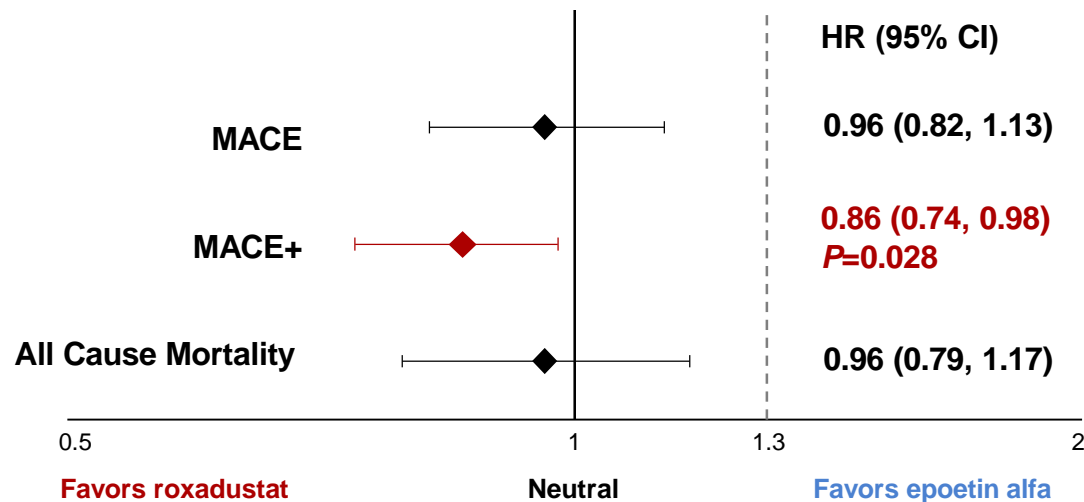
MACE<sup>c</sup> 0.81 (0.52, 1.25)

# DD: Pooled Cardiovascular Safety Endpoints

- Risk of MACE and all-cause mortality in roxadustat patients were not increased compared to epoetin alfa in DD patients\*
- Roxadustat patients had a lower risk of MACE+ than epoetin alfa patients

## Time to Event Endpoints Using Cox Model\*\*

DD (ROCKIES, HIMALAYAS, SIERRAS), N=3880



## MACE+ Components Incidence Rates, N (%)

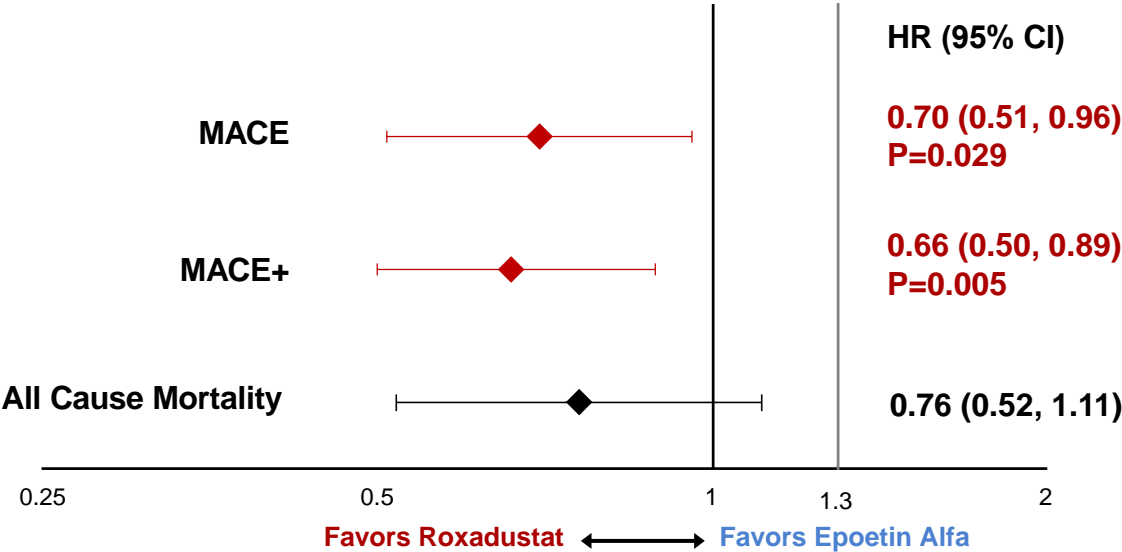
Events	Roxadustat	Epoetin Alfa
n	1940	1940
Death (all-cause mortality)	207 (10.7%)	232 (12.0%)
Myocardial Infarction	103 (5.3%)	109 (5.6%)
Stroke	45 (2.3%)	50 (2.6%)
Unstable Angina	18 (0.9%)	22 (1.1%)
Congestive Heart Failure	120 (6.2%)	166 (8.6%)

# Incident Dialysis Pool: Cardiovascular Safety Analyses

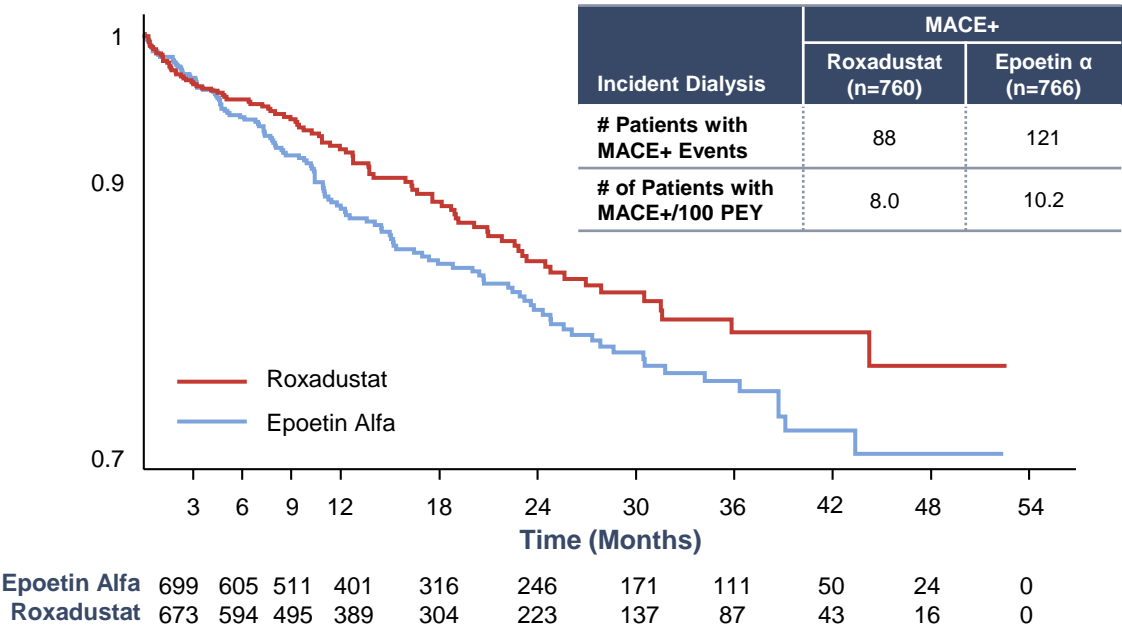
- Roxadustat had 30% lower risk of MACE and 34% lower risk of MACE+ than epoetin alfa\* and with a trend towards lower all-cause mortality relative to epoetin alfa, in incident dialysis patients

## Time to Event Endpoints Using Cox Model

ID (ROCKIES, HIMALAYAS, SIERRAS), N=1526



## Proportion of Patients Without MACE+ Over Time



# Oncology Anemia Market Opportunities

## Addressing Under-Served Patient Populations

### Chemotherapy-Induced Anemia (CIA)

**1.3million** patients undergo chemotherapy each year in the US

- 30%-90% cancer patients receiving chemotherapy develop anemia.<sup>1</sup>
- 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 from \$4 billion as of 2006.

### Myelodysplastic Syndromes (MDS) Anemia

**60-170k** US prevalence


- Annual incidence rate: 4.9/100K adults in U.S.<sup>2</sup>; 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 dose in MDS typically **5x** that used in CKD

- 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.

# 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
- \$375 million in milestone payments relating to submission, approval, and first sale of roxadustat in DD-CKD and NDD-CKD in the U.S. and Europe.
  - \$130 million on EMA submission (paid)
  - \$245 million on approvals and first commercial sale

	 <b>astellas</b> Japan, EU, etc.	 <b>AstraZeneca</b> US, China, ROW	<b>Payments Received/Billed through June 30, 2020</b>
<b>\$ Millions</b>			
<b>Equity Investment in FibroGen</b>	\$81	\$20	\$101
<b>Upfront, Non-Contingent</b>	\$360	\$402	\$762
<b>Development and Reg. Milestones</b>	\$543	\$571	\$384
<b>Commercial Milestones</b>	\$15	\$653	\$0
<b>POTENTIAL TOTAL</b>	<b>\$918 M</b>	<b>\$1,626 M</b>	<b>\$1,146M of \$2,544M</b>

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

**FibroGen China**

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# China: Roxadustat Commercialization Underway

## FibroGen-AZ Roxadustat China Partnership

### FibroGen

- FibroGen is Innovator and Marketing Authorization Holder (MAH)

- **Medical Affairs**
- **Pharmaco-Vigilance**
- **Clinical & Regulatory**
- **Manufacturing**



- **Marketing**
- **Market Access**
- **Sales**
- **Key Accounts**

### AstraZeneca

- AstraZeneca China is the largest multinational pharma in China, with annual revenue exceeding \$4 billion
- Staff of 15,000 in China
- Track record of commercial success

**50/50 Profit Share**

# Roxadustat in China: Positive Momentum and Upwards Trajectory

## NDA Approval

- Dialysis (DD) Approved Dec 2018
- Non-Dialysis (NDD) Approved Aug 2019

## National Reimbursement

- Inclusion in National Reimbursement Drug List
- Effective Jan 2020 for DD and NDD

## Pricing

- ~\$2,000 Patient Price per Year
- ~\$1,500 Ex-Factory per Year
- 95.5 RMB per 50 mg Capsule

## Large Dedicated Field Team

- 400+ Reps
- 30+ MSLs

## Hospital Listings

- Listed in hospitals representing >45% of CKD Anemia Market Opportunity
- Prioritizing Top Accounts and Targeting Broad Coverage

## Net Sales

- 1Q 2020 - \$5.0M
- 2Q 2020 - \$15.7M

# China: Potential Markets – Differentiated Solution

~120 Million People in China are Living with CKD

## Largest Dialysis Market in the World

Convert Installed Base –  
*Substitute Roxadustat for  
ESA*

Win Incident Patients –  
*Direct to Roxadustat  
Instead of ESA*

10%

2017  
**600k**  
Dialysis Patients

Anemia Treatment Rate - 90%  
Treatment Rate with ESA – 90%

## 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

# Pamrevlumab



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Fibrosis

# Pamrevlumab: Targeting High Need Medical Indications

## Idiopathic Pulmonary Fibrosis (IPF)

- FDA Fast Track and Orphan Drug Designation
- ZEPHYRUS randomized placebo-controlled, double-blind Phase 3 study enrolling
- Plan to initiate ZEPHYRUS-2 randomized placebo-controlled, double-blind Phase 3 study in 2020
- Primary endpoint of change in forced vital capacity (FVC) from baseline

## Pancreatic Cancer (LAPC)

- FDA Fast Track and Orphan Drug Designation
- Randomized placebo-controlled, double-blind Phase 3 study enrolling

## Duchenne Muscular Dystrophy (DMD)

- FDA Orphan Drug Designation
- EMA Orphan Medicinal Product Designation
- LELANTOS Phase 3 study enrolling

## COVID-19

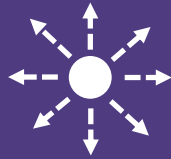
- Italian BOREA Phase 2/3 study enrolling
- U.S. Phase 2 Acute study IND enrolling
- U.S. Phase 2 Post-acute study planned

# IPF Patients Need New Therapeutic Options



## Orphan Disease

- U.S. prevalence of ~44,000 to 135,000<sup>1</sup>
- U.S. incidence of ~21,000 to 52,000<sup>1</sup> cases per year
- Incident and mortality are on the rise, and prevalence is expected to increase with the aging population<sup>2</sup>



## Progressive

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

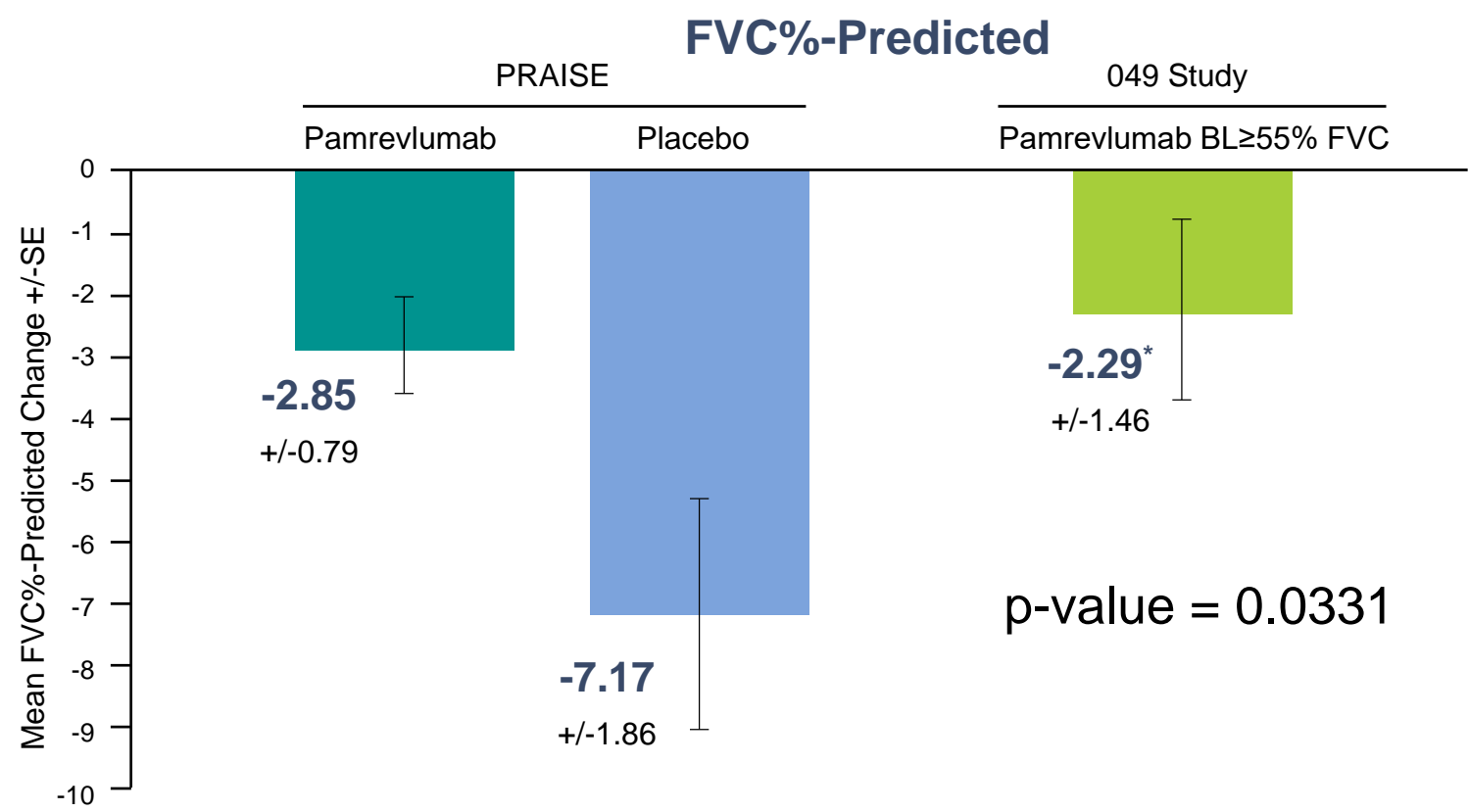


## Current Treatments

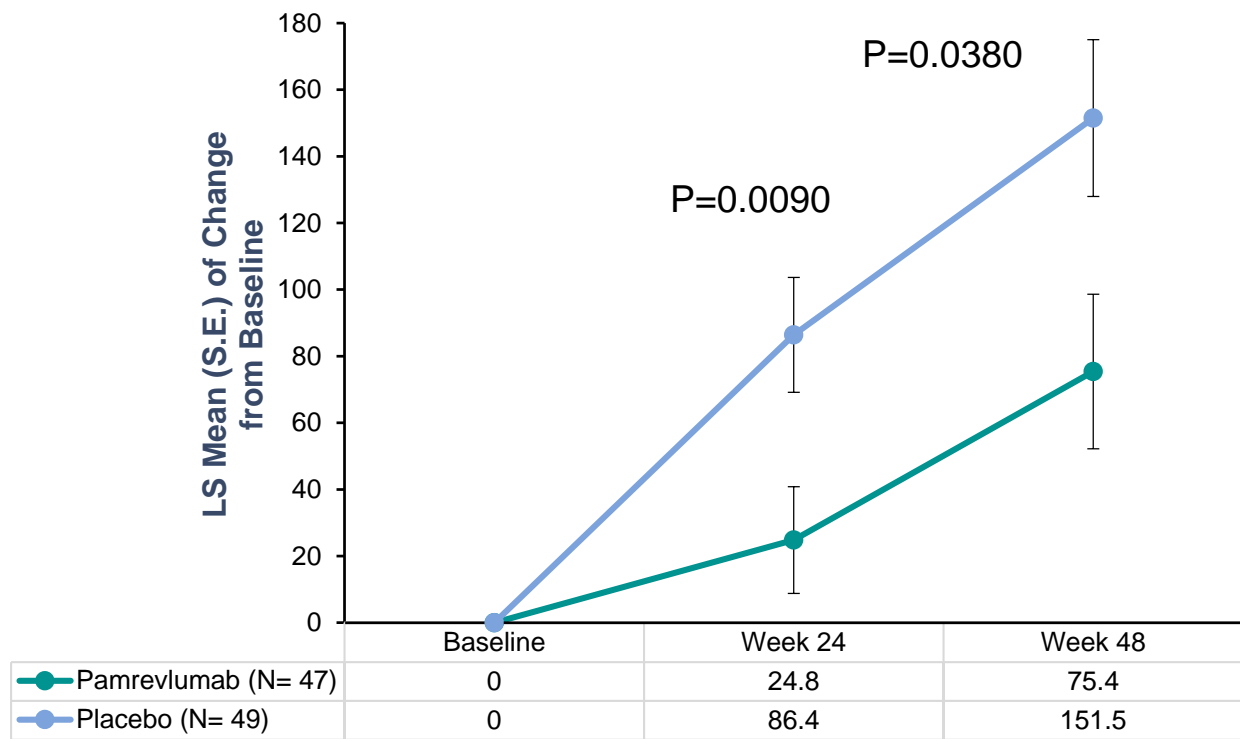
- Slow pulmonary function loss
- Modest effect on slowing disease progression
- No demonstration of reversal
- Require side effect management
- Esbriet and Ofev combined 2019 sales >\$2.8B

# Met Primary Efficacy Endpoint by Slowing Decline in FVC Percent Predicted

Consistent with Results from Phase 2 Open-Label Study (Study 049)



# Pamrevlumab Attenuated Progression of Fibrosis

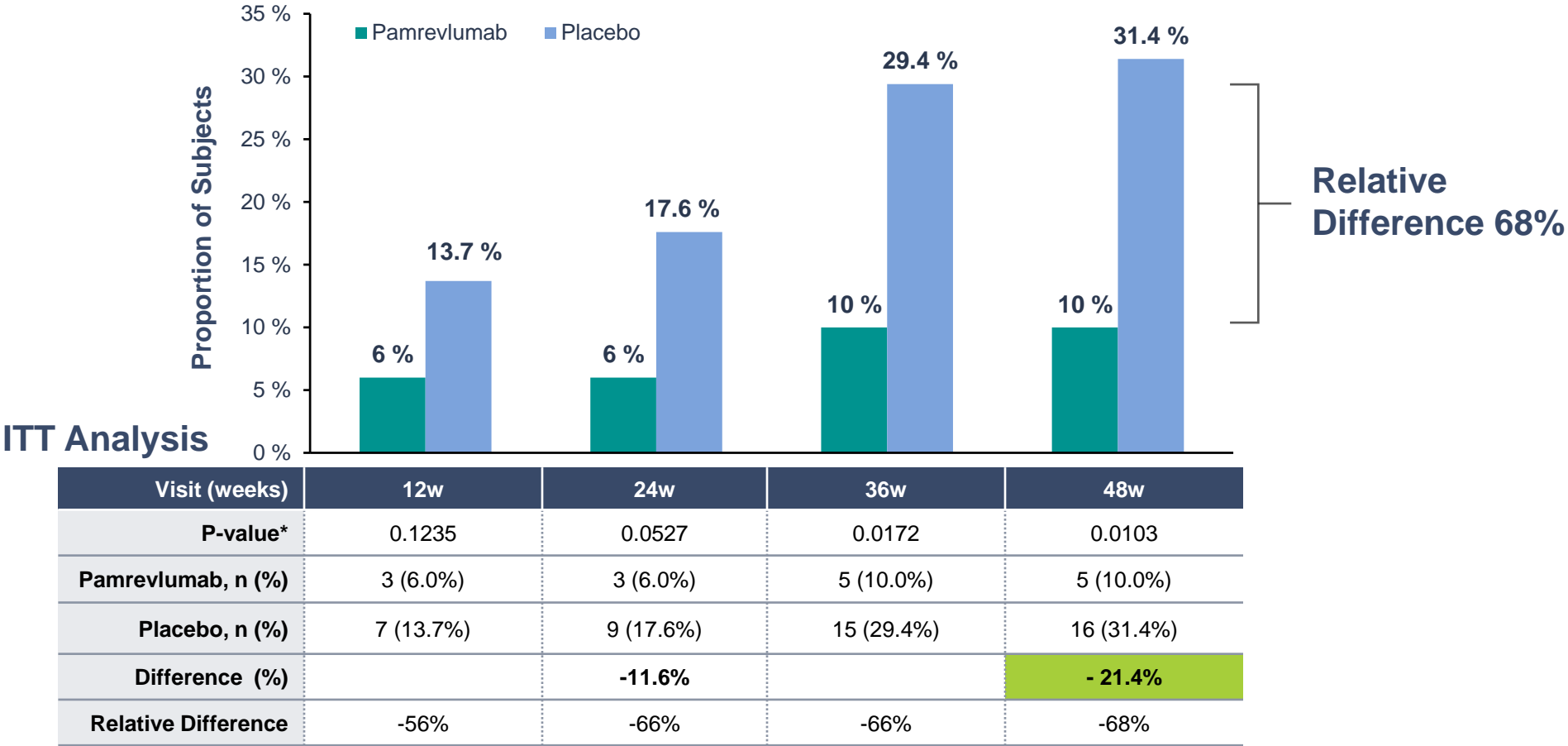


- Absolute differences in QLF changes from baseline to Weeks 24-48 between pamrevlumab arm and placebo arm were 61.6 ml and 76.2 ml, respectively
- First reported statistically significant results for attenuation of fibrosis by qHRCT
- Change in fibrosis (lung structure) correlates with change in FVC % 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 $\geq 10\%$ 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, or
    - 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



# LAPC Patient Population Lacks Treatment Options

## Addressing Under-Served and Growing Patient Population



### 55K New US Patients Dx Annually<sup>1</sup>

- **~27,700** (50%) present with no detectable metastases
- **~9,700** (15-20%) classified as resectable
- **~18,000** (30-35%) with locally advanced unresectable disease



### 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

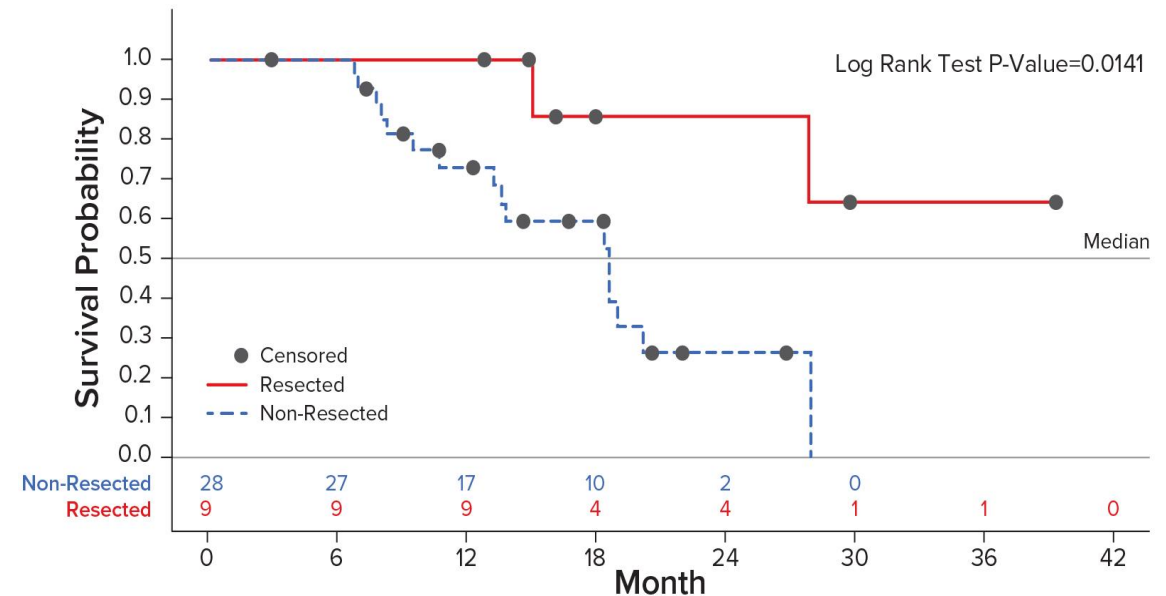
- **50%** survive 17-27 months
- **~20%** survive 5 years

# 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



	N	Event	Censored	Median (95% CI)
Non-Resected	28	16 (57.1%)	12 (42.9%)	18.56 (13.27, 20.21)
Resected	9	2 (22.2%)	7 (77.8%)	NE (15.01, NE)

# 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 ~260 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 post-completion of enrollment for resection and resectability
- Long-term overall survival follow-up for all subjects



LAPIS

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

# Pamrevlumab DMD Program

## Design

- Open-label, single-arm Phase 2 study in 21 non-ambulatory boys, 12 years of age and older

## One-Year Administrative Analysis

- Results of endpoints assessed in the DMD study show potential to mitigate decline in:
  - Lung function (FVC change)
  - Upper extremity muscle function
  - Cardiac function
  - Muscle and cardiac fibrosis by MRI imaging
- Favorable results in comparison to natural disease history
- Expect to publish two-year data before year end
- LELANTOS, a Phase 3 global clinical trial of pamrevlumab in DMD, enrolling
  - Trial will enroll approximately 90 patients randomized 1:1 to placebo
  - Treatment period of 52 weeks.

# Upcoming 2020 Milestones

## ROXADUSTAT

- Publication of Phase 3 roxadustat data
  - Individual studies
  - Pooled analyses
- Potential roxadustat U.S. approval—PDUFA 12/20/20
  - Dialysis-dependent CKD patients
  - Non-dialysis-dependent CKD patients

## PAMREVLUMAB

- Idiopathic Pulmonary Fibrosis (IPF) Phase 3
  - Initiate ZEPHYRUS-2 Phase 3 study
- Duchenne Muscular Dystrophy (DMD)
  - Publish Phase 2 data from 079 Study
- COVID-19
  - Initiate U.S. Phase 2 Post-acute study 3Q 2020





# Thank You

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