



# FibroGen, Inc. Corporate Presentation

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August 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 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.

# Strategic Objectives: Three Areas of Focus

**1**

**Ensuring regulatory and commercial success of roxadustat**

**2**

**Developing pamrevlumab in three high value indications: LAPC, DMD, IPF**

**3**

**Expanding our clinical development pipeline by evaluating both internal and external opportunities to address**

# Company Overview

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## Company Mission

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

## Employees

~600  
worldwide

- ~350 US
- ~250 ex-US

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## Cash as of June 30, 2021

\$ 640.5 million

- \$120 million roxadustat milestones based on EU approval
- Estimated 2021 ending cash to be in the range of \$480-\$490 million

# 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
- Approved in Europe, Chile, and South Korea for both NDD-CKD and DD-CKD
- U.S. FDA issued CRL for NDA for roxadustat for the treatment of anemia of chronic kidney disease (CKD)
- ROW submissions to date include, Canada, Mexico, Australia, and several other countries

### Chemotherapy-Induced Anemia (CIA)

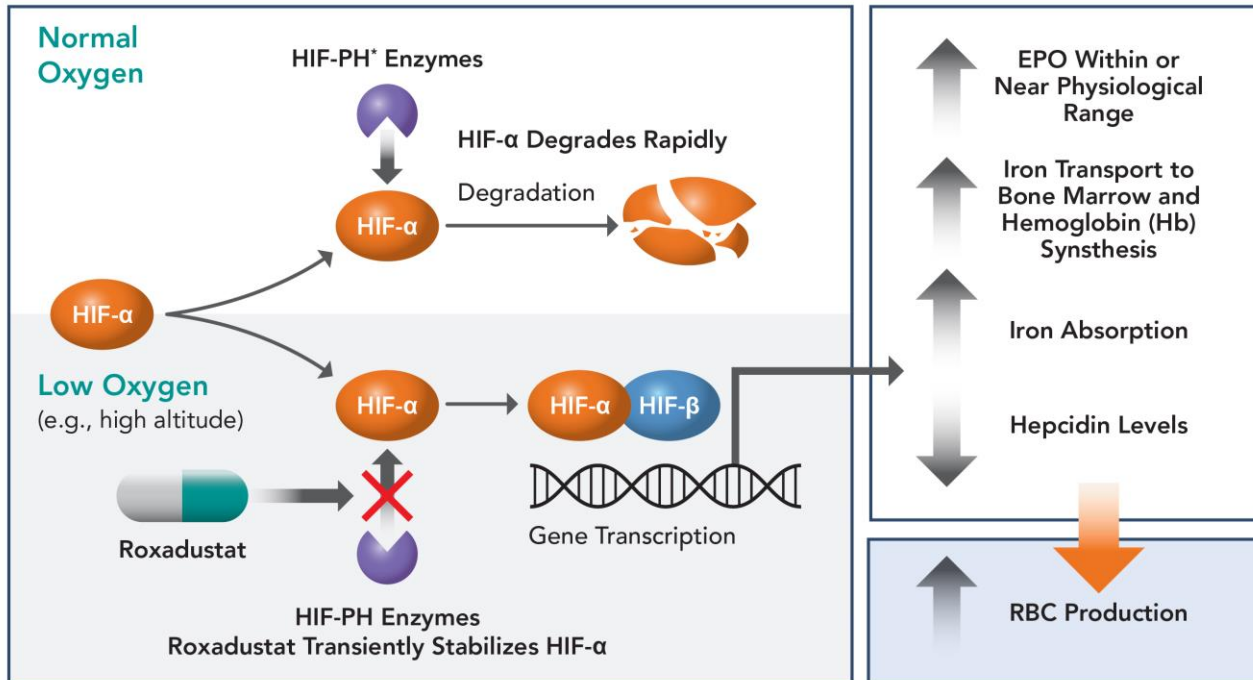
- WHITNEY Phase 2 study enrollment completed

### 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



## 2019 Nobel Prize In Physiology or Medicine

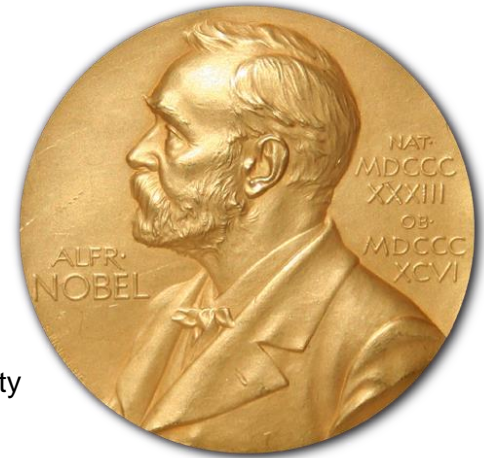
*"for their discoveries of how cells sense and adapt to oxygen availability."*

**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 Needs

## PAMREVLUMAB

### Locally Advanced Unresectable Pancreatic Cancer

- LAPIS Phase 3 study enrolling

### Duchenne Muscular Dystrophy

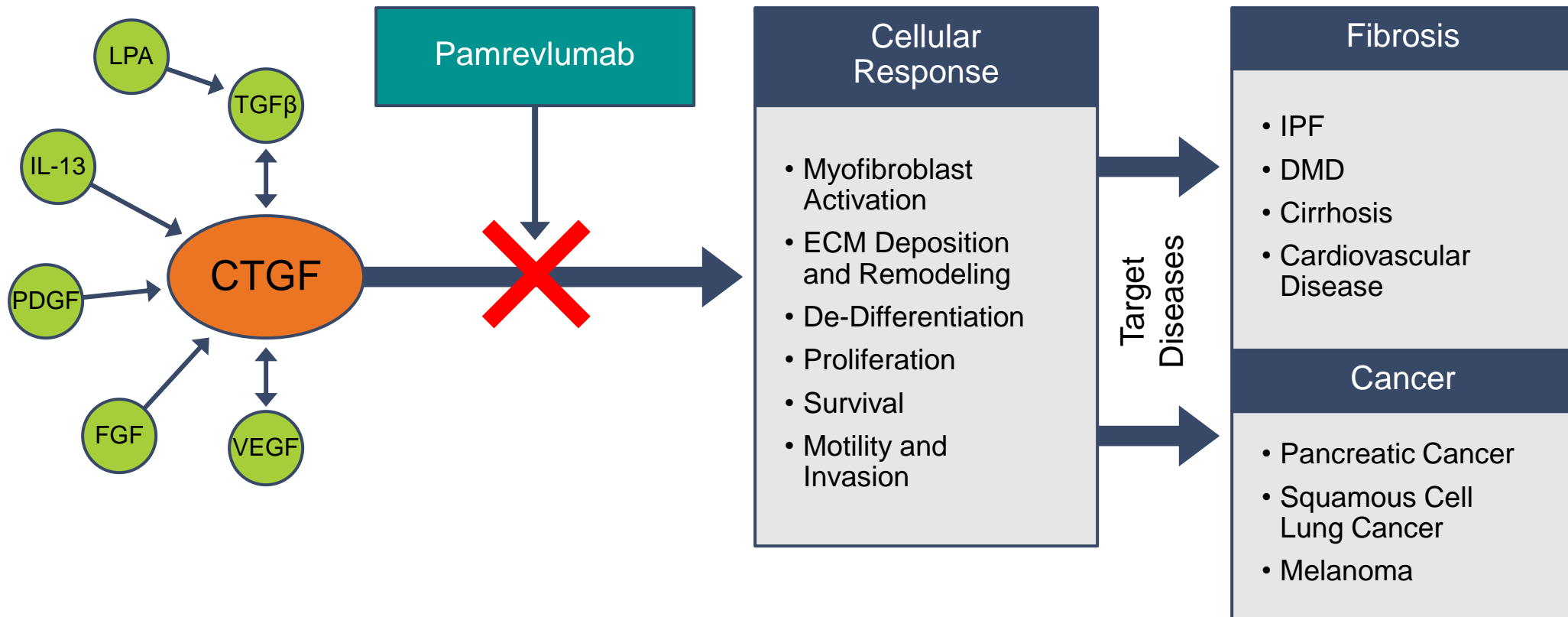
- LELANTOS (non-ambulatory) Phase 3 study enrolling
- LELANTOS-2 (ambulatory) Phase 3 study enrolling

### Idiopathic Pulmonary Fibrosis

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

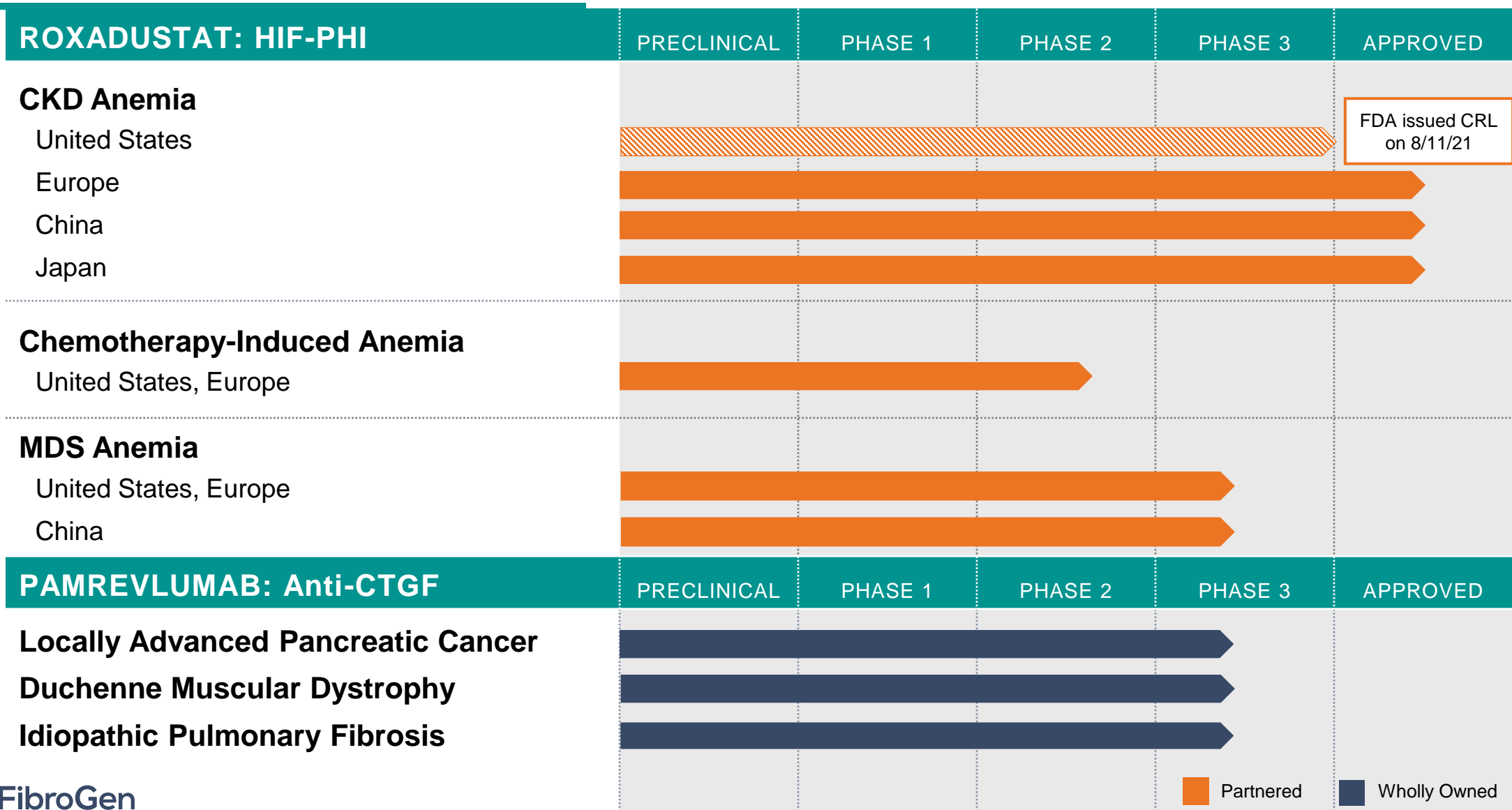
# Pamrevlumab: Innovative Treatment for Fibrosis and Fibroproliferative Disease

- **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



# Transformative Partnership with HiFiBio Therapeutics

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## Enables up to three INDs in 2023

- FibroGen is accessing three new monoclonal antibodies against exciting targets: Galectin-9, CXCR5, and CCR8
  - Galectin-9 - Oncology Target: reported role in acute myeloid leukemia (AML) and immune resistance in many solid tumors
  - CXCR5 - AutoImmune and Oncology Target: primary interest is autoimmunity, but also opportunities in B-cell lymphomas
  - CCR8 - Oncology Target: broad potential in solid tumors

# Roxadustat

An abstract geometric design in the top right corner of the slide. It features several light blue lines of varying thicknesses intersecting at different angles. There are also two small, solid light blue circles positioned near the top of the design.

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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 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 C-reactive protein (CRP)

# Roxadustat Cardiovascular Safety

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## 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 Chronic Kidney Disease-related Anemia in Non-dialysis Patients.	<i>OLYMPUS</i>	<a href="#"><i>Kidney International Reports</i></a>
Roxadustat for Treating Anemia in Patients with CKD Not on Dialysis: Results from a Randomized Phase 3 Study.	<i>ANDES</i>	<a href="#"><i>Journal of the American Society of Nephrology</i></a>
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).	<i>ALPS</i>	<a href="#"><i>Nephrology Dialysis Transplantation</i></a>
Efficacy and Cardiovascular Safety of Roxadustat for Treatment of Anemia in Patients with Non-Dialysis-Dependent CKD	<i>NDD Pooled</i>	<a href="#"><i>Clinical Journal of the American Society of Nephrology</i></a>
Roxadustat for anemia in patients with end-stage renal disease incident to dialysis.	<i>HIMALAYAS</i>	<a href="#"><i>Nephrology Dialysis Transplantation</i></a>
Roxadustat for the treatment of anaemia in chronic kidney disease patients not on dialysis: a phase 3, randomised, open-label, active-controlled study (DOLOMITES)	<i>DOLOMITES</i>	<a href="#"><i>Nephrology Dialysis Transplantation</i></a>
A Randomized Trial of Roxadustat in Anemia of Kidney Failure: SIERRAS Study	<i>SIERRAS</i>	<a href="#"><i>Kidney International Reports</i></a>

# 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

**39**  
million  
adults in the US  
have CKD<sup>1</sup>

**6**  
million  
US CKD patients  
have anemia<sup>1,2</sup>

Only  
**14.6%**  
of US patients were  
on ESA prior to  
initiating dialysis<sup>3</sup>

### 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



# 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%)<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

## 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 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

# Oncology Anemia Market Opportunities

## Addressing Under-Served Patient Populations

### Chemotherapy-Induced Anemia (CIA)

**~650,000** patients undergo chemotherapy each year in the US<sup>1</sup>

- 30%-90% cancer patients receiving chemotherapy develop anemia.<sup>2</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.

### Myelodysplastic Syndromes (MDS) Anemia

**60-170k** US prevalence<sup>3</sup>

- Annual incidence rate: 4.9/100K adults in U.S.<sup>4</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.

# 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 3Q 2021



NCT04076943

# 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  $\geq 56$  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

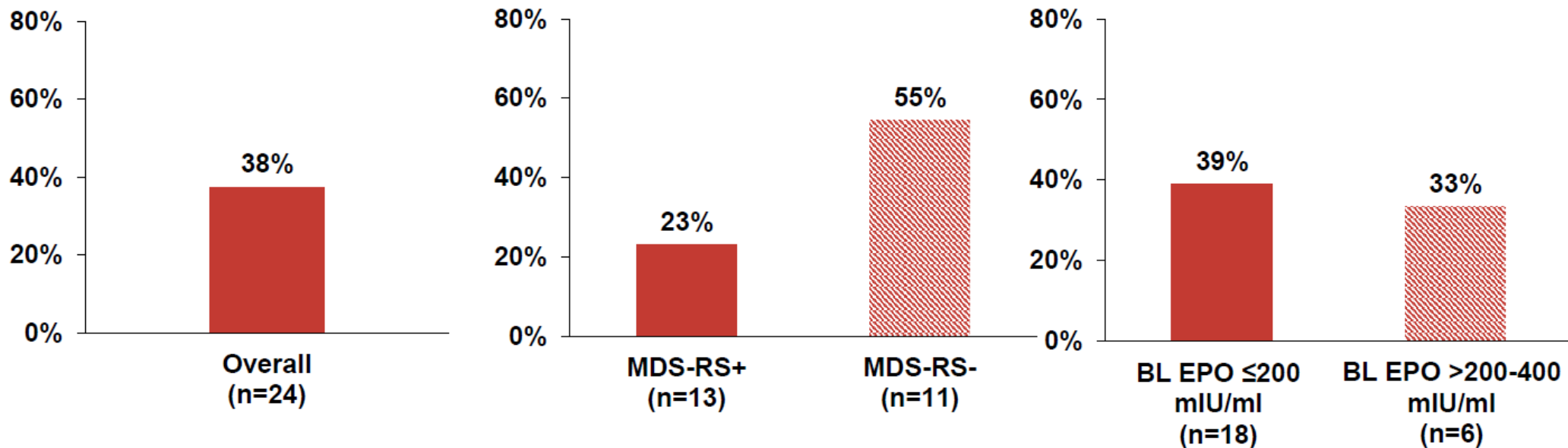
**Topline data expected 2H 2022 / 1H 2023**



NCT03263091

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

## Primary & Exploratory Endpoints: Transfusion Independence (TI) for $\geq 8$ 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
- \$120 million on EU approval

	 <b>astellas</b> Japan, EU, etc.	 <b>AstraZeneca</b> US, China, ROW	<b>Payments Received/Billed through June 30, 2021</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	\$399
<b>Commercial Milestones</b>	\$15	\$653	\$0
<b>POTENTIAL TOTAL</b>	<b>\$918 M</b>	<b>\$1,626 M</b>	<b>\$1,161M of \$2,544M</b>

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

**FibroGen China**

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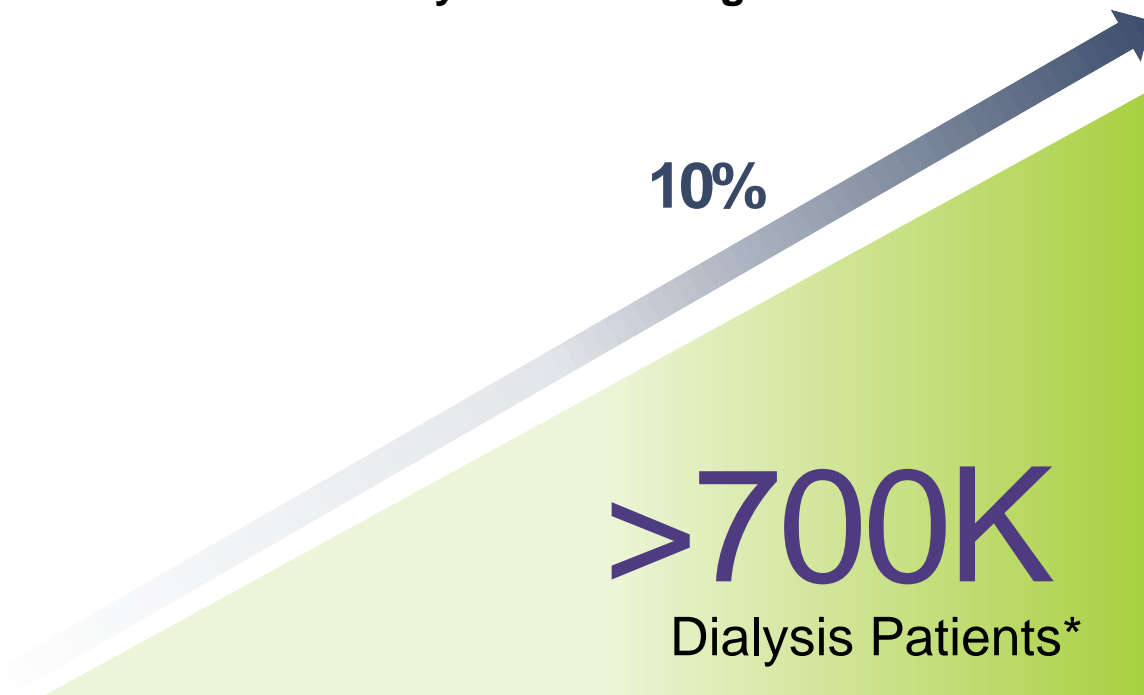




# China: Transforming the Treatment of CKD Anemia

## 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

# 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**



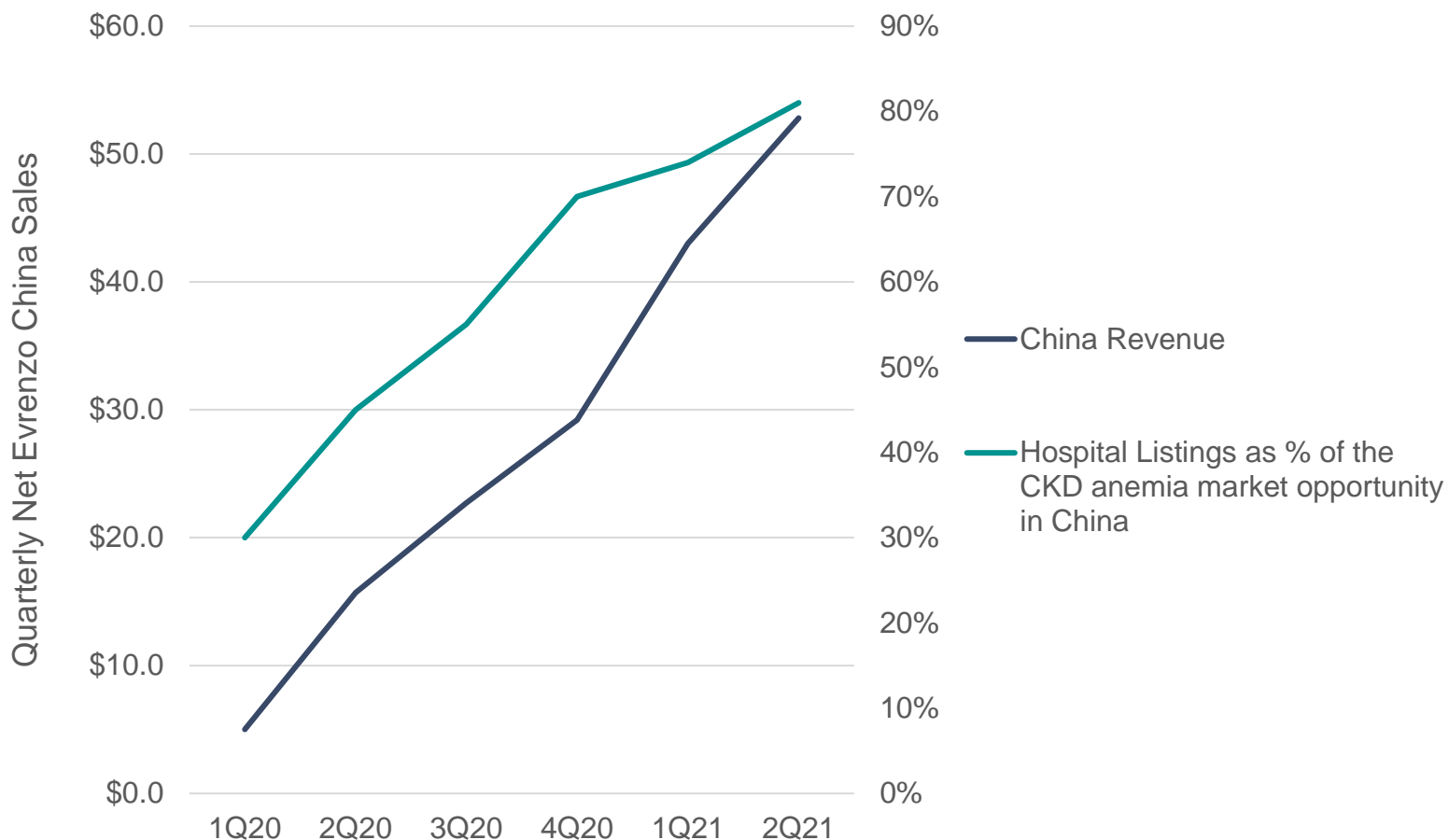
- **Marketing**
- **Market Access**
- **Sales**
- **Key Accounts**

### 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**

# CHINA: Second Quarter 2021 Roxadustat Results

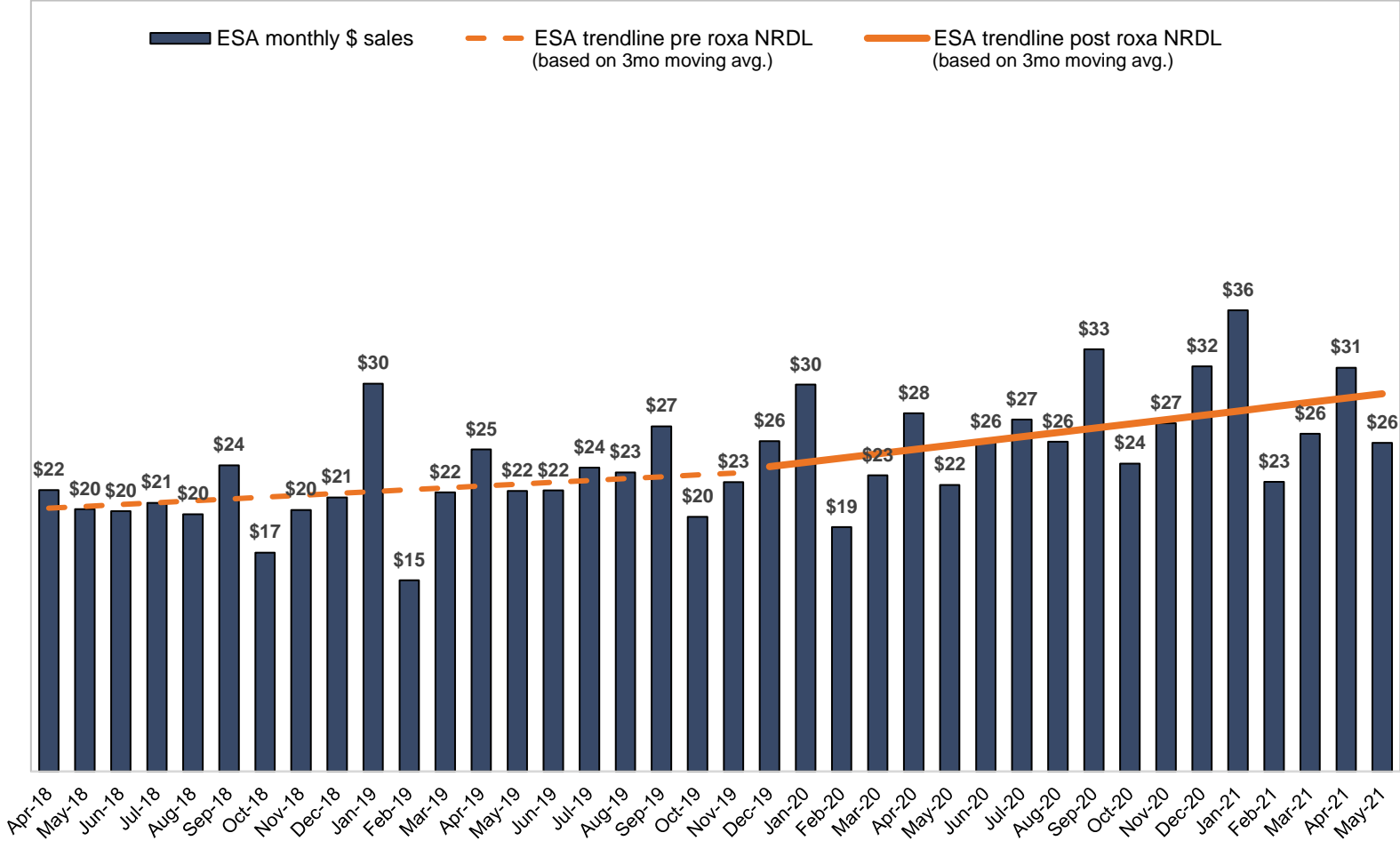


- Roxadustat net sales to distributors in China of \$52.8 million in second quarter 2021, \$96.3 million for first half 2021
- FibroGen net product revenue under U.S. GAAP of \$13.4 million in second quarter 2021, and \$28.8 million for first half 2021
- Broad utilization across all types of CKD anemia patients including:
  - Non-dialysis dependent
  - Incident dialysis
  - Hemodialysis
  - Peritoneal dialysis
- Hospital Listings now represents ~81% of the CKD anemia market opportunity

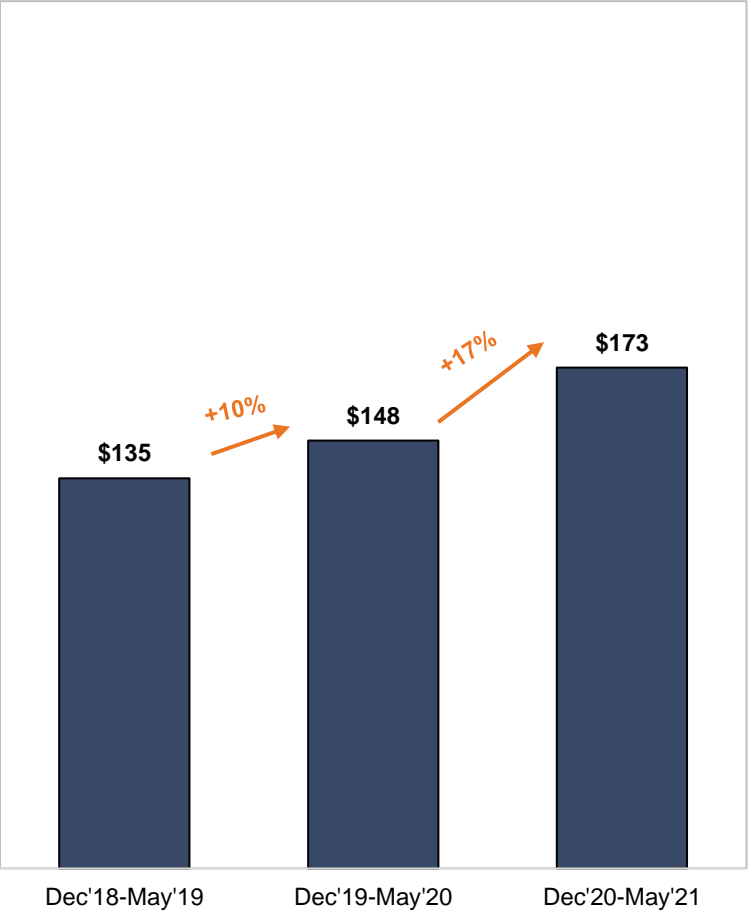


# CHINA: ESA Market Growth Has Accelerated Despite Strong Roxadustat Uptake

Monthly \$ Sales - ESA (\$M)



ESA \$ Sales in Last 6mo vs Same Period in Prior Yrs (\$M)

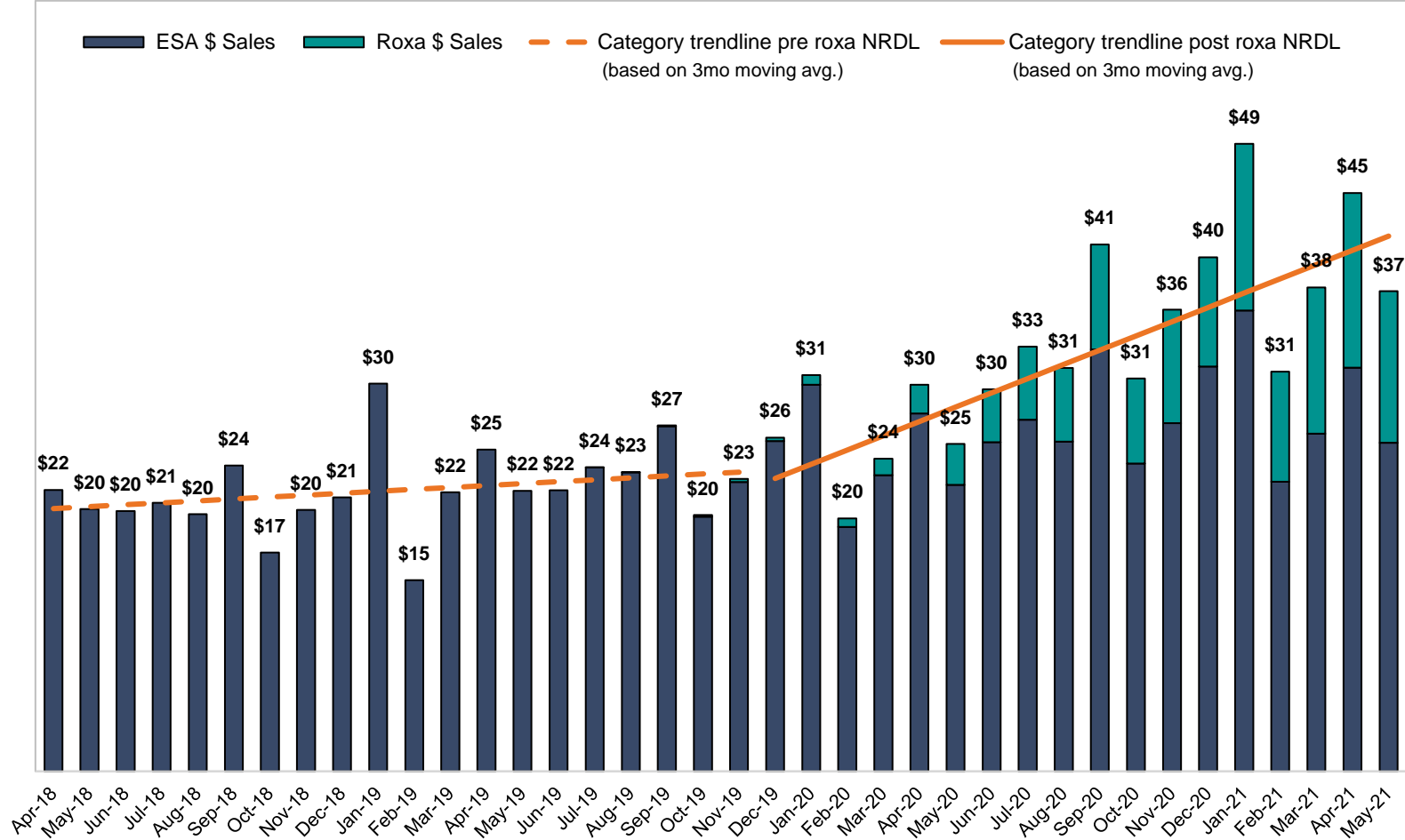


Source: IQVIA MIDAS, accessed July 19<sup>th</sup> 2021. Notes: Market definition includes B3C0 Erythropoietin Products and B3D0 HIF-PH Inhibitors (ATC4), does not include iron. No indication split applied, i.e., includes ESA sales outside of CKD. Discrepancies between IQVIA MIDAS and company-reported sales (\$ and volume) are due to data capture limitations and 'volume to \$' conversion based on list price

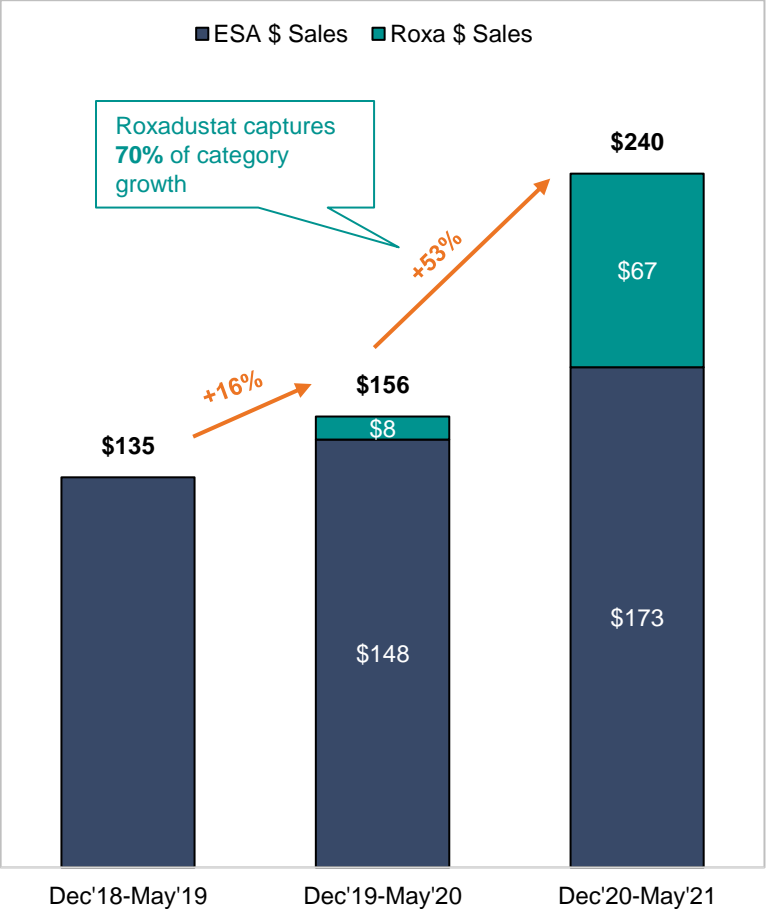


# CHINA: Roxadustat is Driving Expansion of the Anemia of CKD Category (HIF + ESA)

Monthly \$ Sales – HIF & ESA Category (\$M)



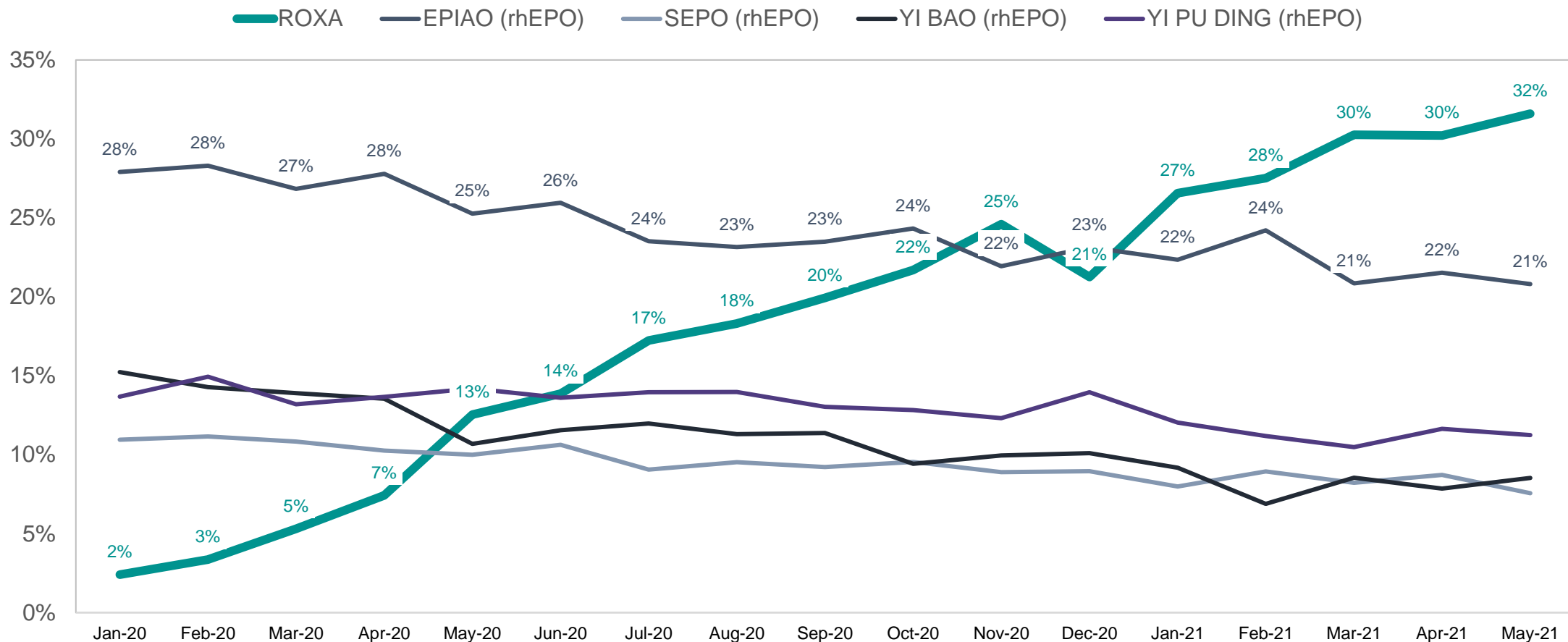
HIF + ESA \$ Sales in Last 6mo vs Same Period in Prior Yrs (\$M)



# CHINA: May 2021 marks the fifth month of category leadership for roxadustat based on \$ sales

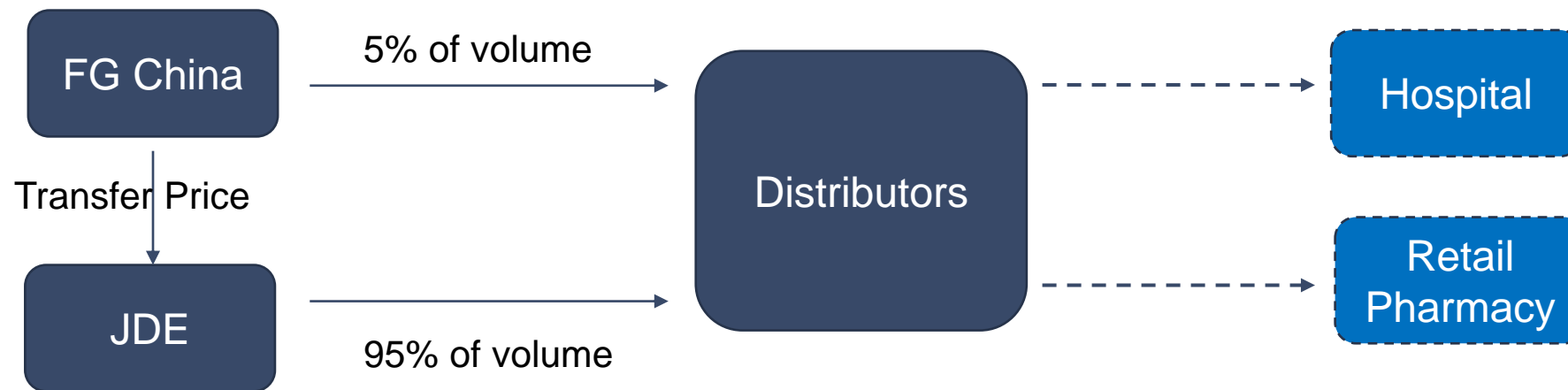


## Monthly Brand Share based on \$ Sales - Top 5 of ESA+HIF Market



# 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

# Pamrevlumab



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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



**>60K New US Patients Dx Annually<sup>1</sup>**

- **~45,000** (70-80%) of PDAC are metastatic<sup>2</sup>
- **~12,000** (20-30%) are locally advanced of which
- **~4,000** (1/3) are unresectable<sup>2</sup>



**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**

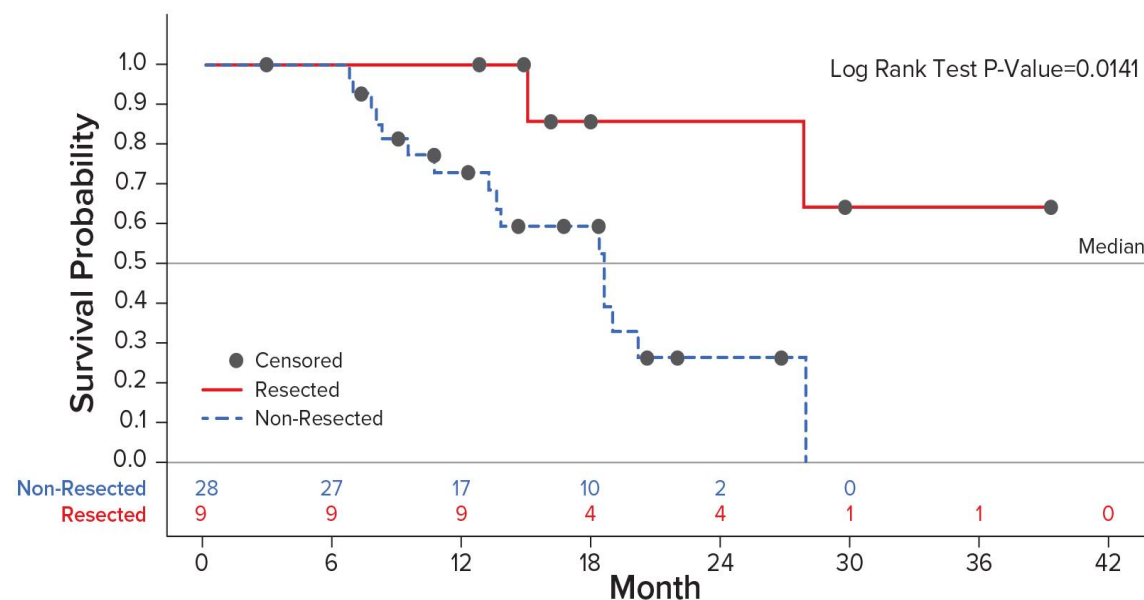
- **50%** survive 17-27 months
- **~20%** survive 5 years

# 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



# 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
- Interim assessment of Event Free Survival
- Long-term overall survival follow-up for all subjects



NCT03941093

# DMD Background

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- 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 non-ambulatory 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 52-week study will be eligible for rollover into an open-label extension study

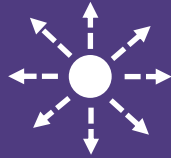


# IPF Patients Need New Therapeutic Options



## 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

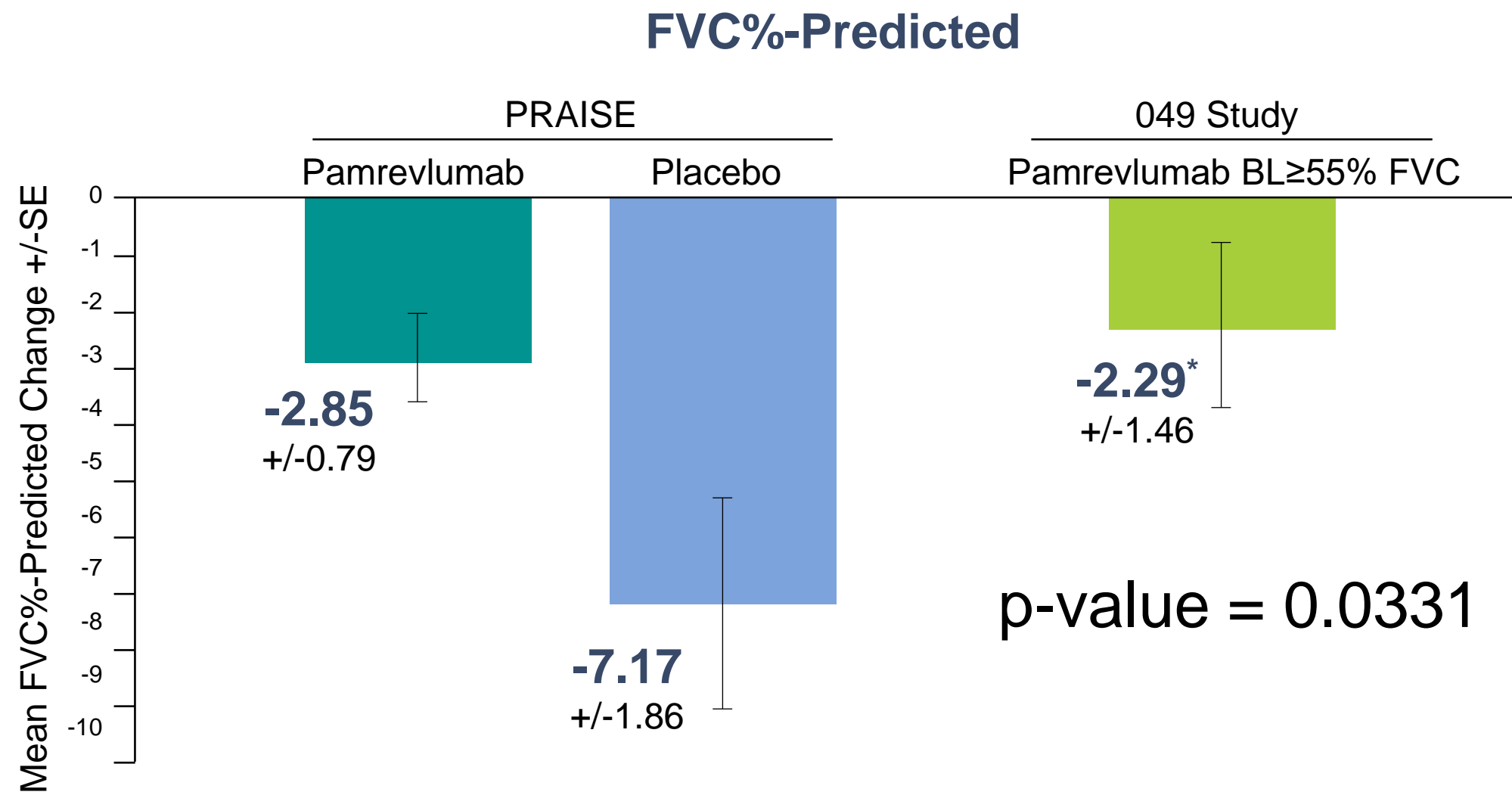


## Current Treatments

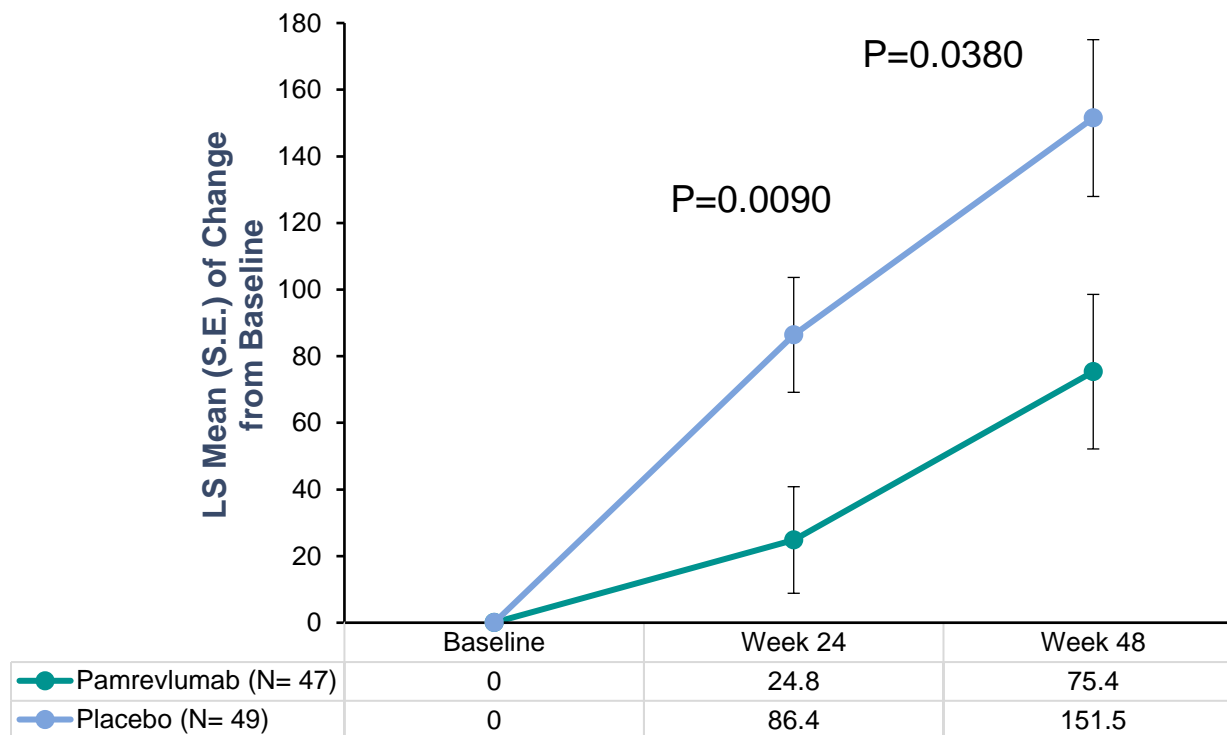
- Slow pulmonary function loss
- Modest effect on slowing disease progression
- No demonstration of reversal
- Require side effect management
- Esbriet and Ofev combined 2020 sales >\$3B



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



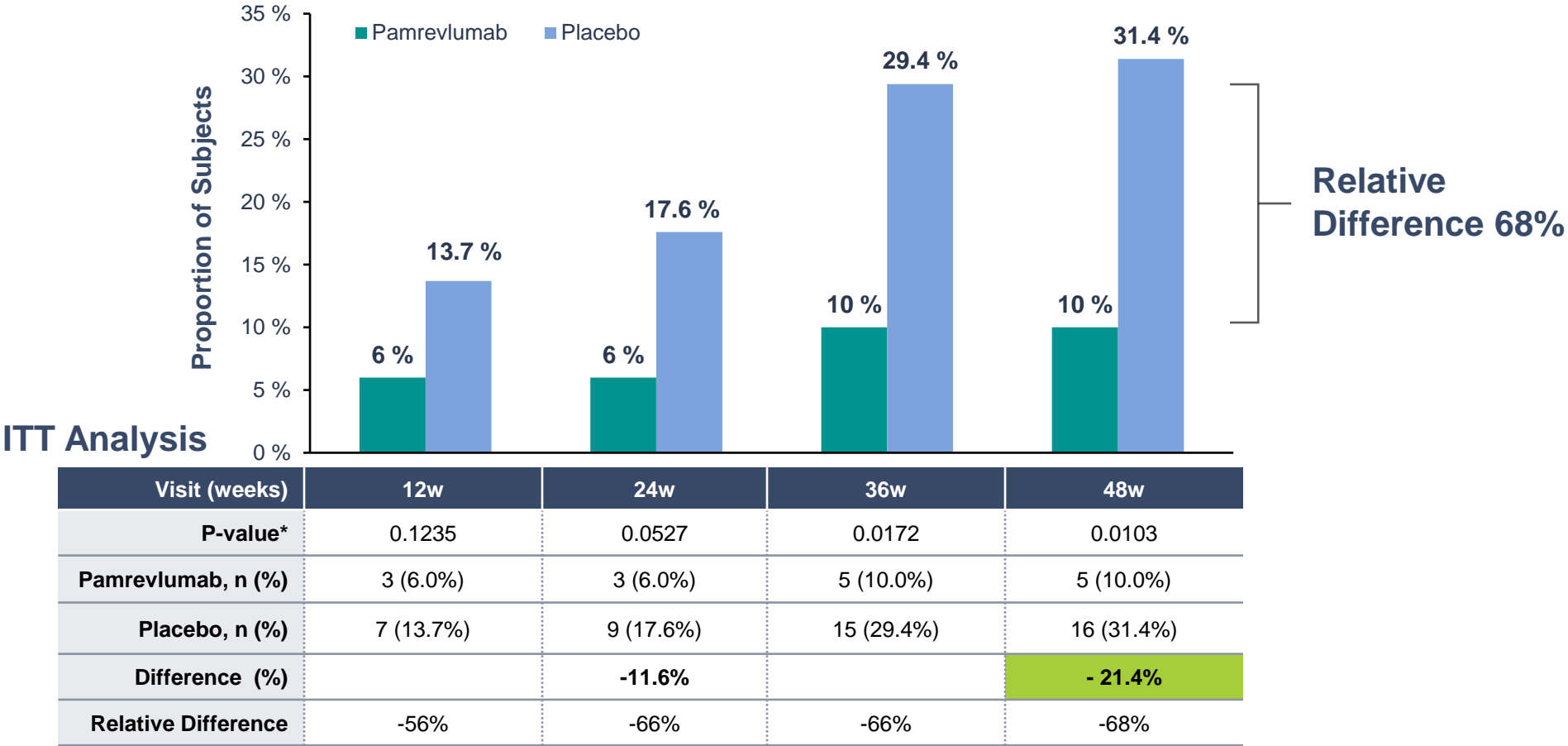
# Pamrevlumab Attenuated Progression of Fibrosis



- 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 $\geq 10\%$ 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
  - 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



NCT03955146



NCT04419558

# Upcoming Milestones

## ROXADUSTAT

### Chemotherapy-Induced Anemia

- WHITNEY Phase 2 topline data 3Q 2021

### Anemia Associated with MDS

- MATTERHORN Phase 3 topline data 2H 2022 / 1H 2023

## 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 1H 2023

### Idiopathic Pulmonary Fibrosis (IPF)

- ZEPHYRUS-1 Phase 3 study enrolling, topline data mid-2023

# Clinical Trial Timelines

Study Phase	Indication	Study Name	Enrollment Target	Topline Data
ROXADUSTAT				
2	CIA	WHITNEY	100 (closed)	3Q 2021
3	MDS	MATTERHORN	160	2H 2022 / 1H 2023
PAMREVLUMAB				
3	LAPC	LAPIS	280	2H 2022
3	DMD	LELANTOS-1	90	1H 2023
3	DMD	LELANTOS-2	90	TBD
3	IPF	ZEPHYRUS-1	340	Mid-2023
3	IPF	ZEPHYRUS-2	340	TBD



# Thank You

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For more information contact [ir@fibrogen.com](mailto:ir@fibrogen.com)