



# FibroGen, Inc. Corporate Presentation

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June 2022

# 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

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## Mission

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

## Employees

~575  
worldwide

- ~300 US
- ~275 ex-US

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## Cash as of March 31, 2022

\$ 565.4 million

- Estimated 2022 ending cash to be in the range of \$310-\$340 million

# Strategic Objectives: Three Areas of Focus

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**01**

**Developing pamrevlumab in three high value indications: Idiopathic pulmonary fibrosis (IPF), locally advanced pancreatic cancer (LAPC), and Duchenne muscular dystrophy (DMD)**

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**02**

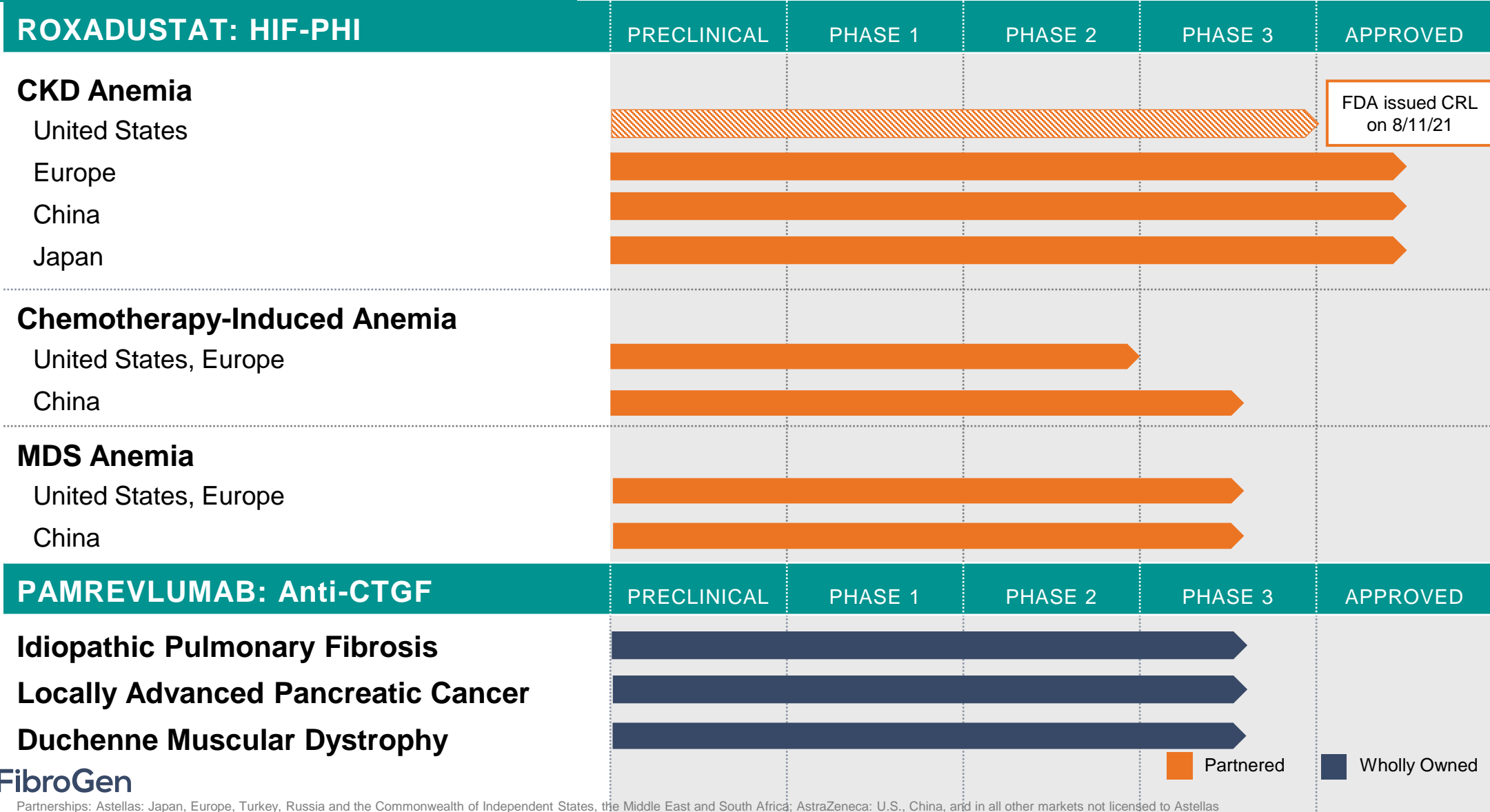
**Ensuring regulatory and commercial success of roxadustat in chronic kidney disease (CKD) and other indications**

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**03**

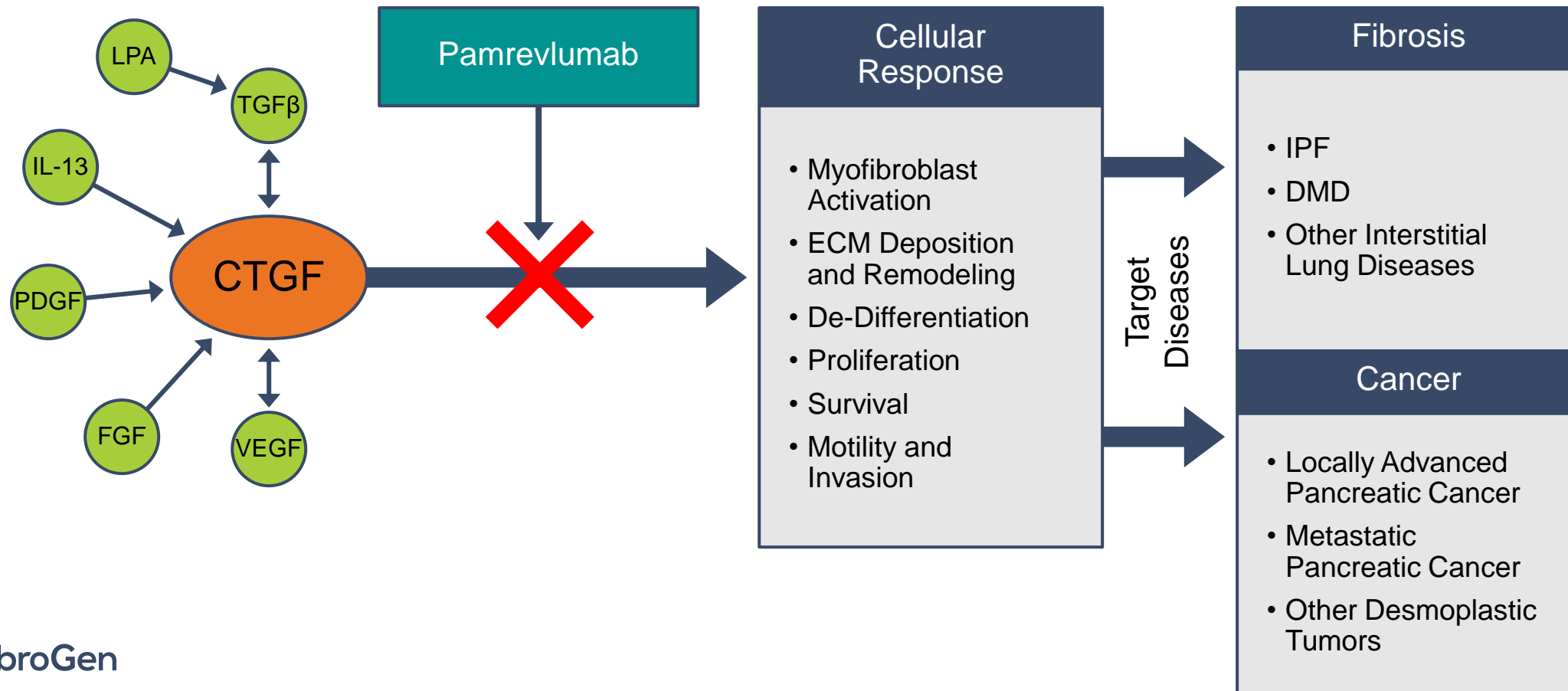
**Increasing research productivity to advance novel programs that leverage internal expertise and access external innovation**

# FibroGen Marketed and Late-Stage Portfolio



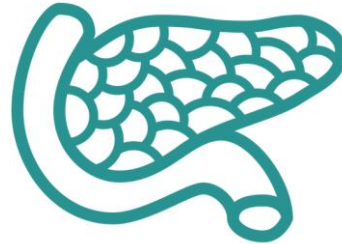
# Pamrevlumab: Innovative Treatment for Fibrosis and Fibroproliferative Disease

- **PAMREVLUMAB** – Fully human monoclonal antibody targeting activity of connective tissue growth factor, a central factor in fibrosis



# Current Status of Pamrevlumab Development

## PAMREVLUMAB



### Idiopathic Pulmonary Fibrosis

- ZEPHYRUS-1 Phase 3 Study **Enrollment Complete**
- ZEPHYRUS-2 Phase 3 Study **Enrolling**

### Locally Advanced Unresectable Pancreatic Cancer

- LAPIS Phase 3 Study **Enrollment Complete**

### Metastatic Pancreatic Cancer

- Precision Promise<sup>SM</sup> Platform Phase 2/3 *Sponsored by Pancreatic Cancer Network* - **Enrolling**

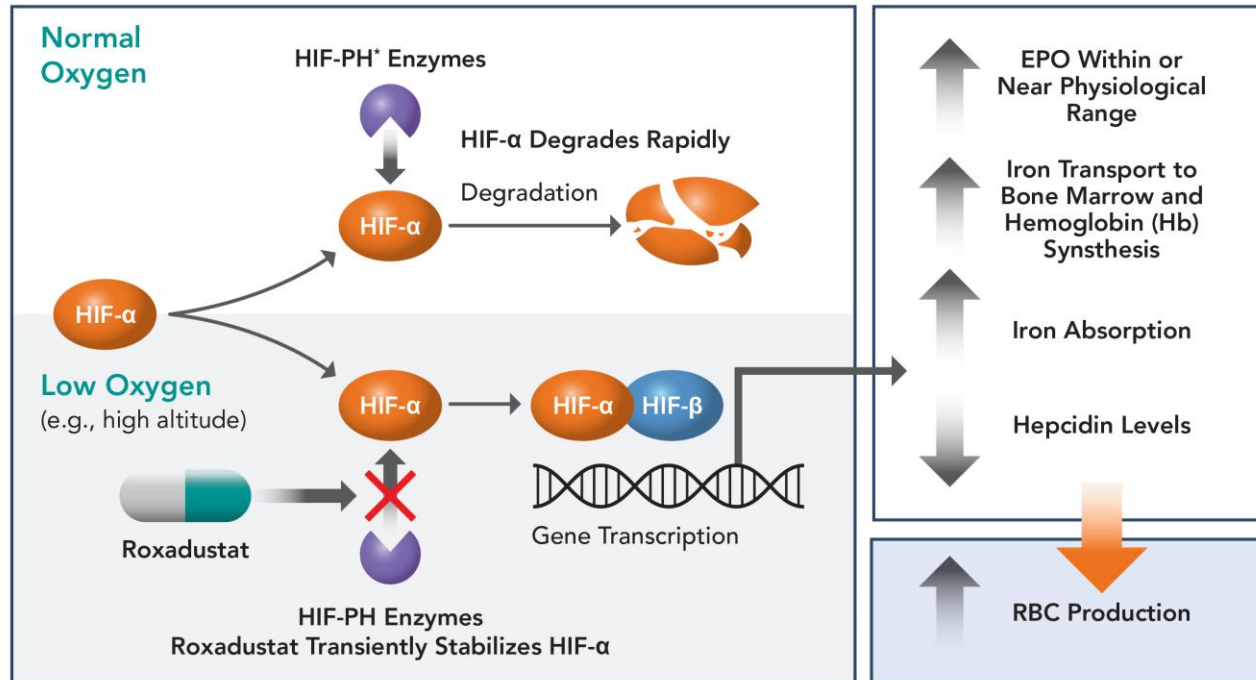
### Duchenne Muscular Dystrophy

- LELANTOS-1 (non-ambulatory) Phase 3 Study **Enrollment Complete**
- LELANTOS-2 (ambulatory) Phase 3 Study **Enrollment Complete**

# 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

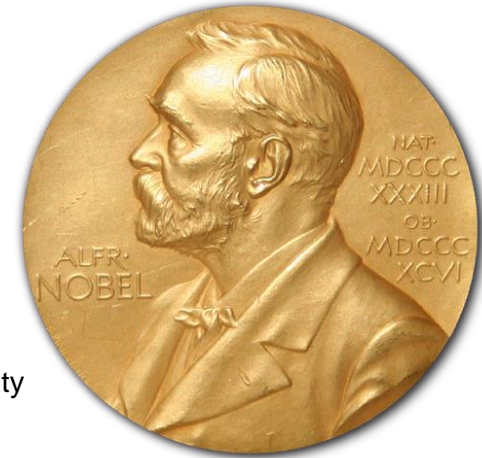
*"for their discoveries of how cells sense and adapt to oxygen availability."*

**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)



# Roxadustat Update

## Anemia of Chronic Kidney Disease (CKD)



Received European Commission Approval for First-in-Class EVRENZO™ (roxadustat) for the treatment of symptomatic anemia of chronic kidney disease (CKD) in adult patients.

- Astellas has launched EVRENZO™ in Germany, the United Kingdom, the Netherlands, Austria, and the Nordic countries.



Continued strong roxadustat performance in China.

Roxadustat is the number one brand based on value share in the anemia of CKD market in China.

# Pre-Clinical Pipeline:

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## Licensed programs in transformative partnership with HiFiBiO Therapeutics

- Galectin-9: antibody designed to inhibit target driven cancer stem cell self-renewal in acute myeloid leukemia (AML) and immune resistance in many solid tumors.
- CCR8: antibody designed to deplete suppressive T regulatory cells in the tumor microenvironment with broad potential activate immune responses in solid tumors.

## FibroGen fully owned proprietary assets

- Undisclosed: additional drug development programs leveraging FibroGen expertise in HIF and CTGF biology

# Pamrevlumab



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Fibrosis

# Pamrevlumab: A Unique Phase 3 Investigational Drug



## Novel, differentiated antifibrotic MOA

- First-in-class CTGF-targeting mAb
- *In vivo* efficacy in multiple preclinical models
- Potential disease-modifying mechanism across fibrotic diseases



## Phase 2 outcomes target serious unmet needs

- IPF: Observed benefit in lung function preservation with a differentiated safety profile
- PDAC: Safe and well tolerated with trend for improved resection rate and increased completion of chemotherapy cycles
- DMD: Safe and well tolerated with favorable outcomes vs historical data
  - Pamrevlumab can potentially be used in a broad range of DMD patients regardless of specific mutations



## Significant commercial potential

- Phase 3 programs in areas of high unmet medical need with limited late-stage competitive intensity
- Highly differentiated target indications with fibrotic components but independent risk profiles
- Esbriet and Ofev combined 2021 sales ~\$4.0B

# Pamrevlumab: Potential First in Class Antibody Targeting High Need Medical Indications

## Idiopathic Pulmonary Fibrosis (IPF)

- FDA Fast Track and Orphan Drug Designation
- ZEPHYRUS-1 Phase 3 Study **Enrollment Complete**
- ZEPHYRUS-2 Phase 3 Study **Enrolling**

## Pancreatic Cancer (LAPC)

- FDA Fast Track and Orphan Drug Designation
- LAPIS Phase 3 Study **Enrollment Complete**

## Metastatic Pancreatic Cancer

- Precision Promise<sup>SM</sup> Platform Phase 2/3  
Sponsored by Pancreatic Cancer Network  
**Enrolling**

## Duchenne Muscular Dystrophy (DMD)

- FDA Orphan Drug, Fast Track and Rare Pediatric Disease Designation
- EMA Orphan Medicinal Product Designation
- LELANTOS-1 Phase 3 **Enrollment Complete**
- LELANTOS-2 Phase 3 Study **Enrollment Complete**

# Pamrevlumab Commercial Opportunity

## Idiopathic Pulmonary Fibrosis

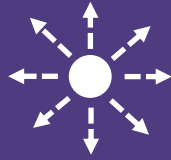
<b>Diagnosed Prevalence (US, EU, CN, JP)</b>	~330k
<b>2021 Branded Category Revenue</b>	~\$4.0B; +11% YoY
<b>Current Standard of Care</b>	Ofev (nintedanib – BI); Esbriet (pirfenidone – Genentech / Roche)
<b>SoC Limitations</b>	Disease progression; poor tolerability / adherence
<b>Late-Stage Competitive Intensity</b>	PRM-151 (Roche), BI-1015550 (BI)

# IPF Patients Need New Therapeutic Options



## Orphan Disease

- One in 200 over the age of 70 are living with IPF<sup>1</sup>
- U.S. prevalence of 200,000+<sup>1</sup>
- U.S. incidence of 50,000<sup>1</sup> cases per year



## Progressive

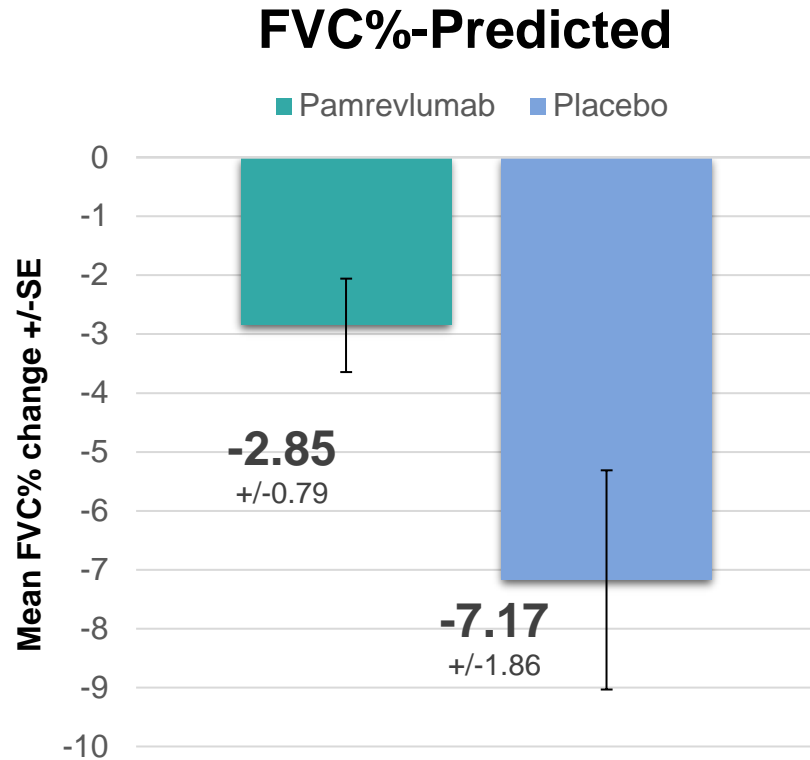
- Leads to irreversible loss of lung function with high morbidity and mortality rates
- Median survival of 3-5 years following diagnosis



## Current Treatments

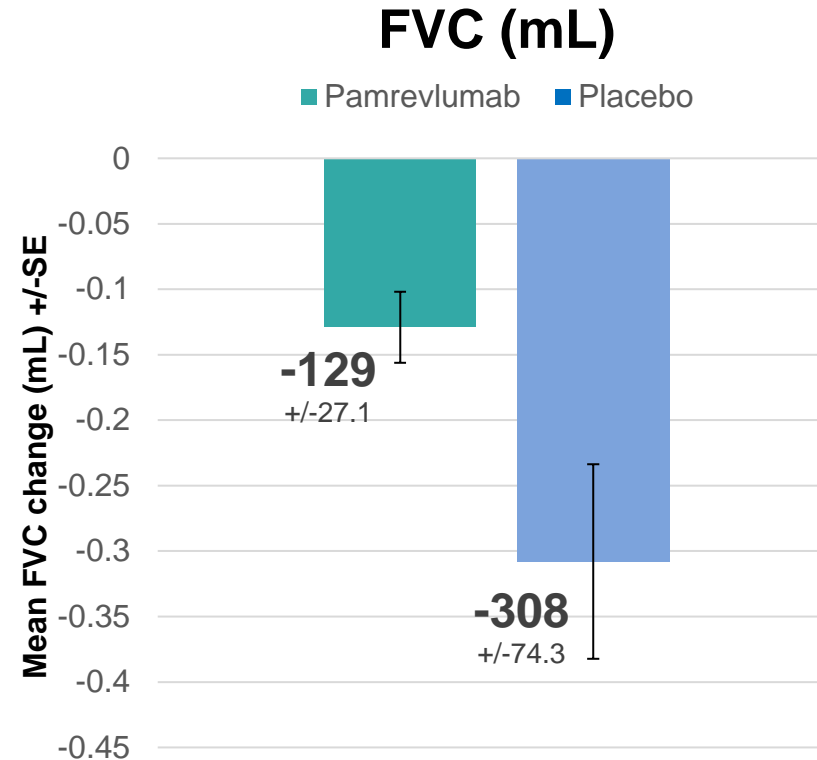
- Slow pulmonary function loss
- Modest effect on slowing disease progression
- Require side effect management
- Esbriet and Ofev combined 2021 sales ~\$4.0B

# PRAISE Phase 2: Efficacy Analysis, Primary Endpoint; Mean Change from BL at Week 48 in FVC



p-value = 0.033

FVC%-Predicted Difference: 4.33%  
Relative Difference: 60%

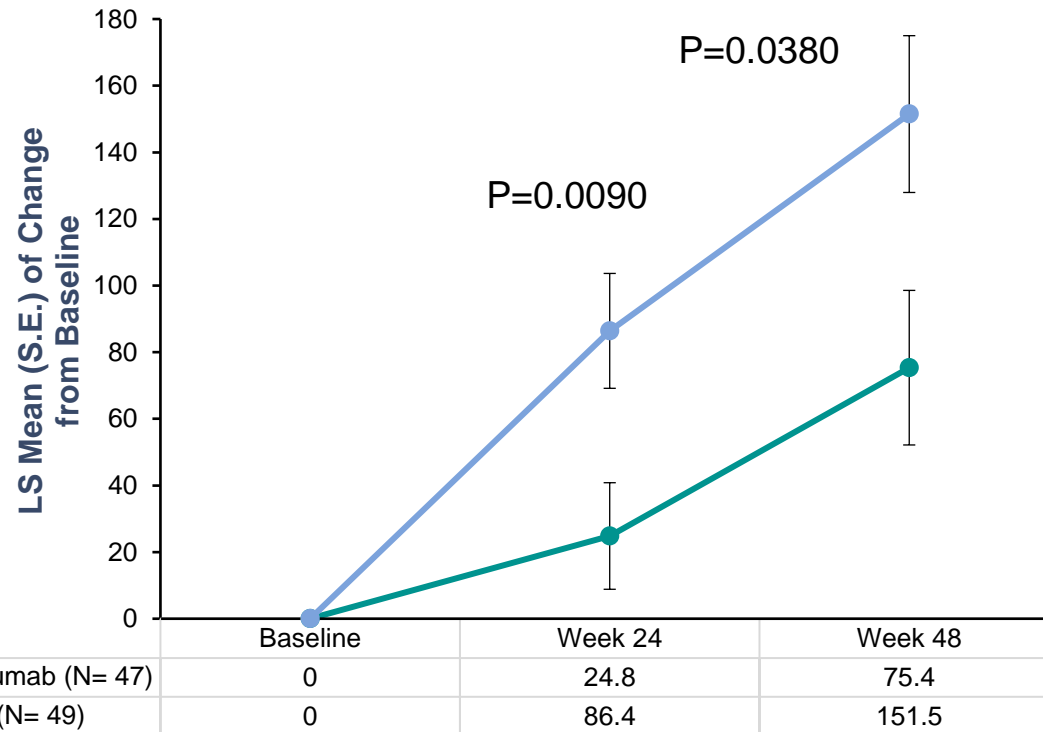


p-value = 0.025

Absolute FVC Difference: 178mL  
Relative Difference: 58%



# PRAISE Phase 2: Pamrevlumab Attenuated Progression of Fibrosis

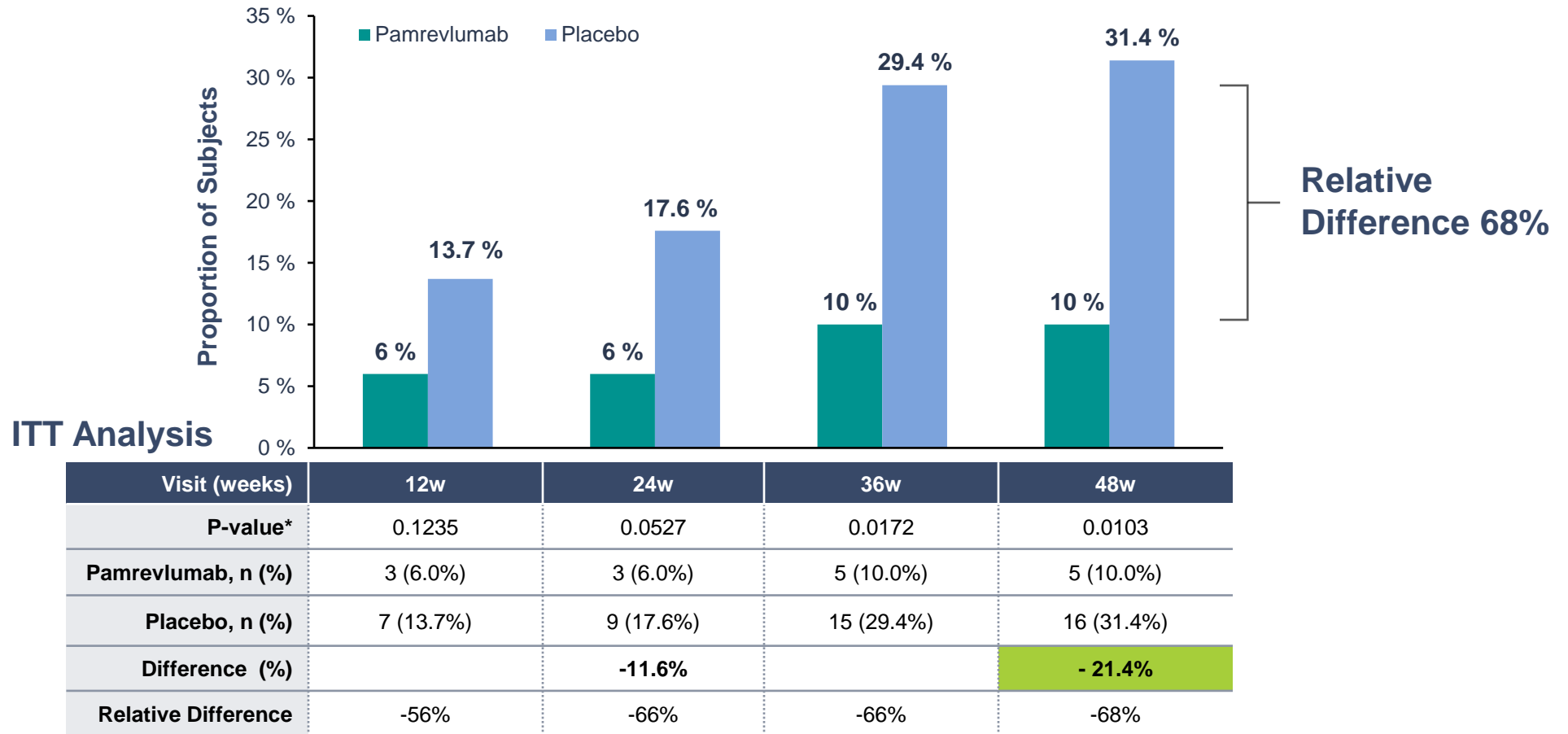


- Absolute differences in Quantitative Lung Fibrosis (QLF) changes from baseline to Weeks 24-48 between pamrevlumab arm and placebo arm were 61.6 ml and 76.2 ml, respectively
- First reported statistically significant results for attenuation of fibrosis by qHRCT
- Change in fibrosis (lung structure)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

Richeldi, et al. *Lancet Respir Med* 2020 Jan;8(1):25-33.

# PRAISE Phase 2: Attenuation of IPF Disease Progression

## IPF Disease Progression (FVC% Predicted Decline $\geq 10\%$ or Death) vs. Placebo



# Pamrevlumab IPF Phase 3 Program: ZEPHYRUS-1 and ZEPHYRUS-2

## Patient Population

- IPF diagnosis according to ATS/ERS/JRS/ALAT guidelines\*
  - ZEPHYRUS-1
    - 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



**Study Fully Enrolled**



**Study Enrolling**

# Pamrevlumab Commercial Opportunity

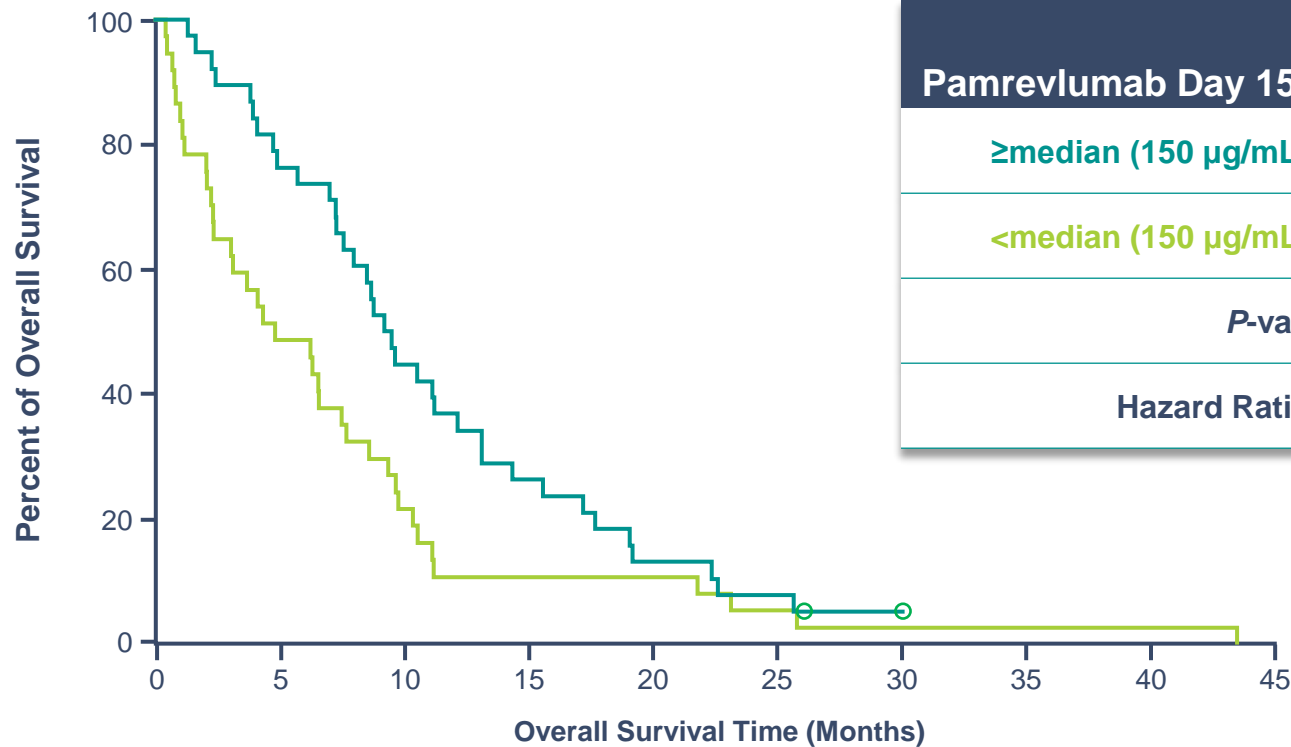
## Locally Advanced Pancreatic Cancer

<b>Diagnosed Prevalence (US, EU, CN, JP)</b>	~140k (non-metastatic)
<b>Branded Category Revenue</b>	N/A
<b>Current Standard of Care</b>	gemcitabine + nab-paclitaxel; gemcitabine + folfirinox
<b>SoC Limitations</b>	5-year Disease-Free Survival ~10% <sup>1</sup> ; No major therapeutic advances in decades, <sup>2</sup> with major therapy classes like IOs failing to offer survival benefits
<b>Late-Stage Competitive Intensity</b>	Limited in non-metastatic disease

1. Sources: GLOBOCAN ([link](#)) 2. Sources: SEER; Cancer.Net (for [NSCLC](#) and [H&N](#)); Dela Cruz, Charles S et al. "Lung cancer: epidemiology, etiology, and prevention." *Clinics in chest medicine* vol. 32,4 (2011): 605-44. doi:10.1016/j.ccm.2011.09.001 (for [SCLC](#))

# Phase I in Locally Advanced or Metastatic Pancreatic Ductal Adenocarcinoma Cancer Patients

## Improved OS with Higher Pamrevlumab Exposure



Pamrevlumab Day 15 C <sub>min</sub>	n	Median OS (Months)	1-Year OS Rate
≥median (150 µg/mL)	38	9.0	34.2%
<median (150 µg/mL)	37	4.4	10.8%
<i>P</i> -value		0.024 Log Rank Test	0.026 Fisher's
Hazard Ratio (95% CI)		0.59 (0.37 – 0.94)	

Empty circles represent censored subjects (2 subjects alive at data cut-off date).  
Picozzi V et al. JCCT 2017.

# 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

- Event-free survival
- Patient-reported outcomes

## Study Design

- Double-blind, placebo-controlled
- Enrolled 284 subjects at sites globally
- Randomization 1:1 to pamrevlumab + gemcitabine/nab-paclitaxel/FOLFIRINOX or to placebo + gemcitabine/nab-paclitaxel/FOLFIRINOX
- 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



**Study Fully Enrolled**

# Pamrevlumab Commercial Opportunity

## Duchenne Muscular Dystrophy

<b>Diagnosed Prevalence (US, EU, CN, JP)</b>	~70k
<b>2021 Branded Category Revenue</b>	~\$0.75B
<b>Current Standard of Care</b>	corticosteroids; anti-sense oligonucleotides / exon-skipping
<b>SoC Limitations</b>	Continued disease progression; tolerability; need for confirmed gene mutation; biomarker benefit only (exon-skipping therapies)
<b>Late-Stage Competitive Intensity</b>	Dystrophin-targeted therapies (gene-based and exon-skipping); Limited anti-fibrotic therapies

# Duchenne Muscular Dystrophy (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



# Phase 2 MISSION Study in DMD

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## First Time an Antifibrotic Has Shown Potential to Slow Disease Progression in Non-ambulatory DMD

- Mechanism of action may mitigate fibrosis in non-ambulatory DMD patients, irrespective of the causative genetic mutation
- Phase 2 Study 079 (MISSION) performed in non-ambulatory DMD subjects, showed pamrevlumab may slow DMD disease progression
- Promising safety profile, with no major SAEs leading to discontinuations
- Pamrevlumab can potentially be used in a broad range of DMD patients regardless of specific mutations
- Limitations: This study was limited by lack of an internal control group

# LELANTOS-1 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
- Enrolled 99 subjects at sites globally
- Randomized 1:1 to receive pamrevlumab plus systemic corticosteroids, or placebo plus systemic corticosteroids, for up to 52 weeks



NCT04371666

**Study Fully Enrolled**

# LELANTOS-2 Pamrevlumab DMD Phase 3 Study

## Patient Population

- Males 6-12 years old with ambulatory DMD

## Primary Endpoint

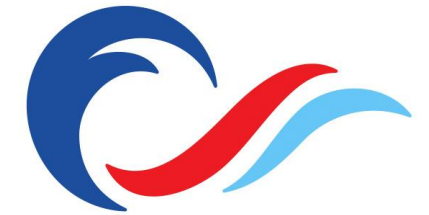
- Ambulatory function assessment, measured by the change in North Star Ambulatory Assessment (NSAA) from baseline to Week 52

## 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



LELANTOS  
TWO

NCT04632940

**Study Fully Enrolled**

# Roxadustat

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Anemia

# Roxadustat: An Innovative Approach to Addressing Anemia

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

An oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) based on Nobel Prize winning science that stimulates a coordinated erythropoiesis response.

## Strategic Partnership 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, and all other markets not licensed to Astellas



Complete response letter for U.S. NDA.

EVRENZO™  
Approved in Europe

EVRENZO™ Approved in Japan

艾瑞卓® Approved in China

## Additional Indications Under Evaluation

- Anemia associated with myelodysplastic syndromes (MDS) – Phase 3
- Anemia associated with chemotherapy induced anemia (CIA) – Phase 2

# Roxadustat Collaboration Economics

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Royalty/Transfer Price in low 20% range in U.S./EU and ROW

China 50/50 profit split

All development costs and commercialization costs paid by partners, ex-China

Regulatory and/or commercial milestones available under our collaboration agreements

# 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

# Roxadustat

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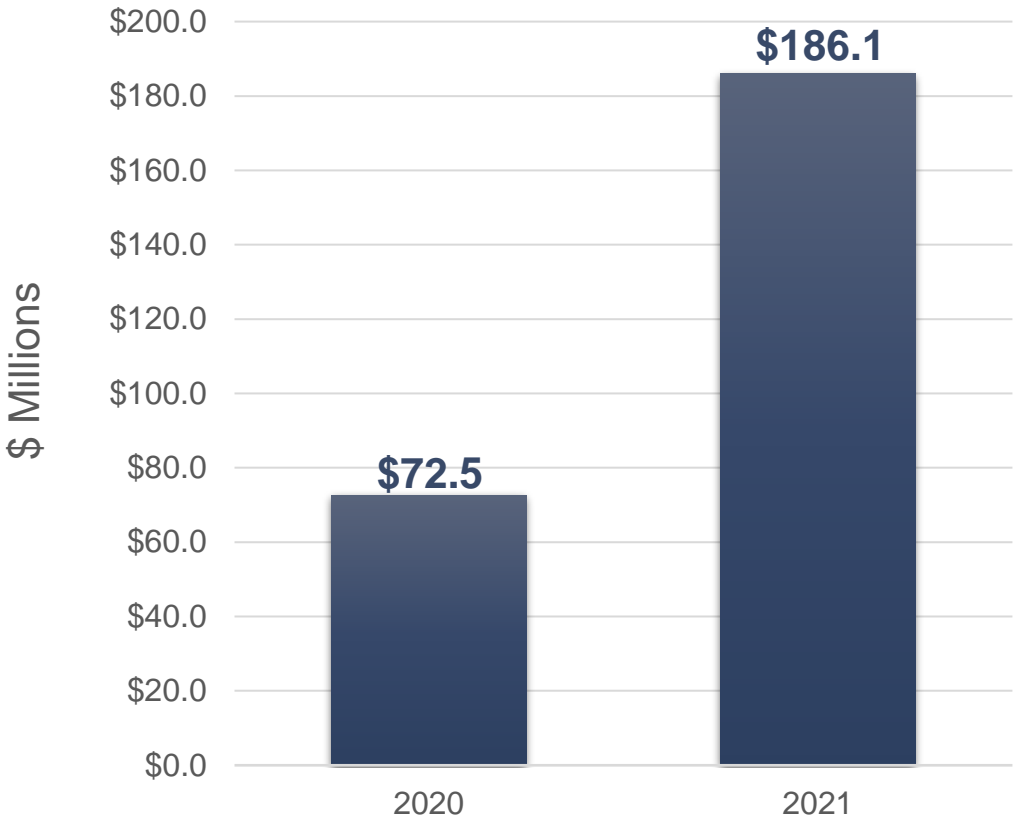
China





# CHINA: Significant Year Over Year Roxadustat Net Sales Growth

### China Roxadustat Net Sales



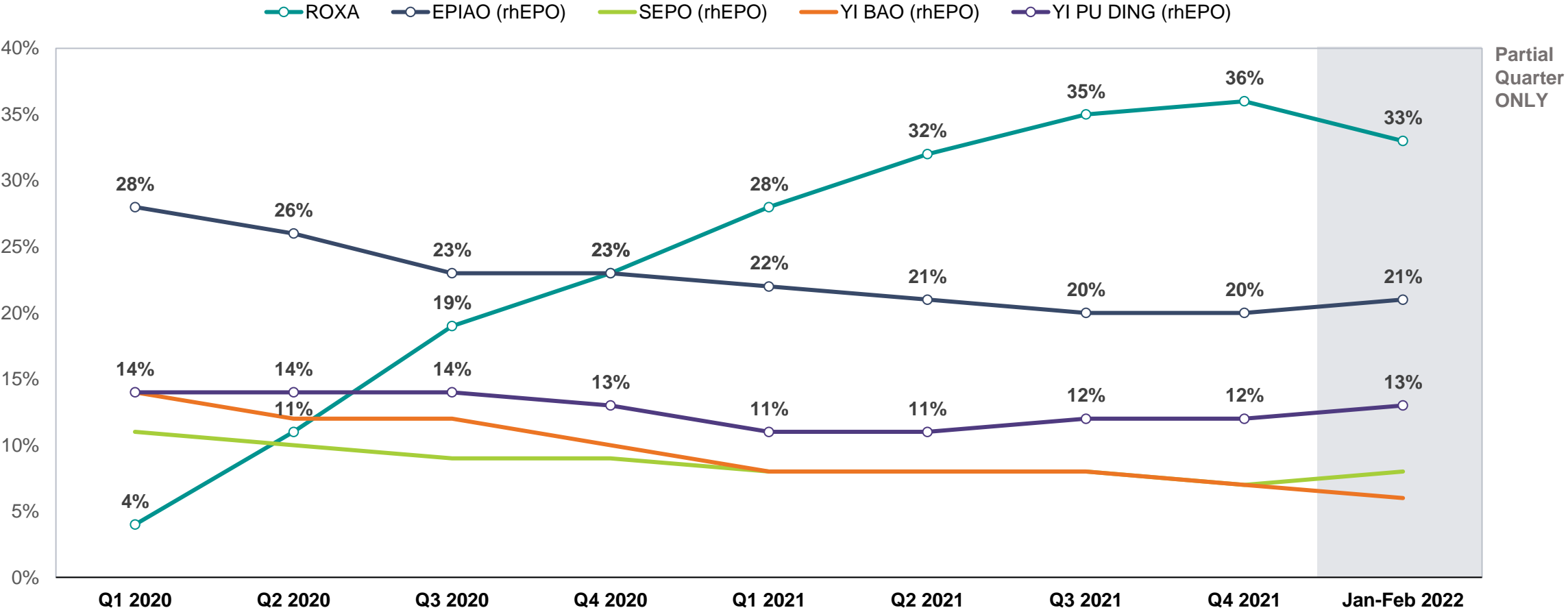
- ✓ Roxadustat net sales to distributors in China of \$43.5 million in first quarter 2022 compared to \$43.5 million a year ago\*
- ✓ FibroGen net product revenue under U.S. GAAP of \$18.9 million in first quarter 2022

\*Total roxadustat net sales in China includes sales made by the distribution entity as well as FibroGen China's direct sales, each to its own distributors. The distribution entity jointly owned by AstraZeneca and FibroGen is not consolidated into FibroGen's financial statements.



# CHINA: Roxadustat Maintains ESA + HIF Category Leadership Based On \$ Sales

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



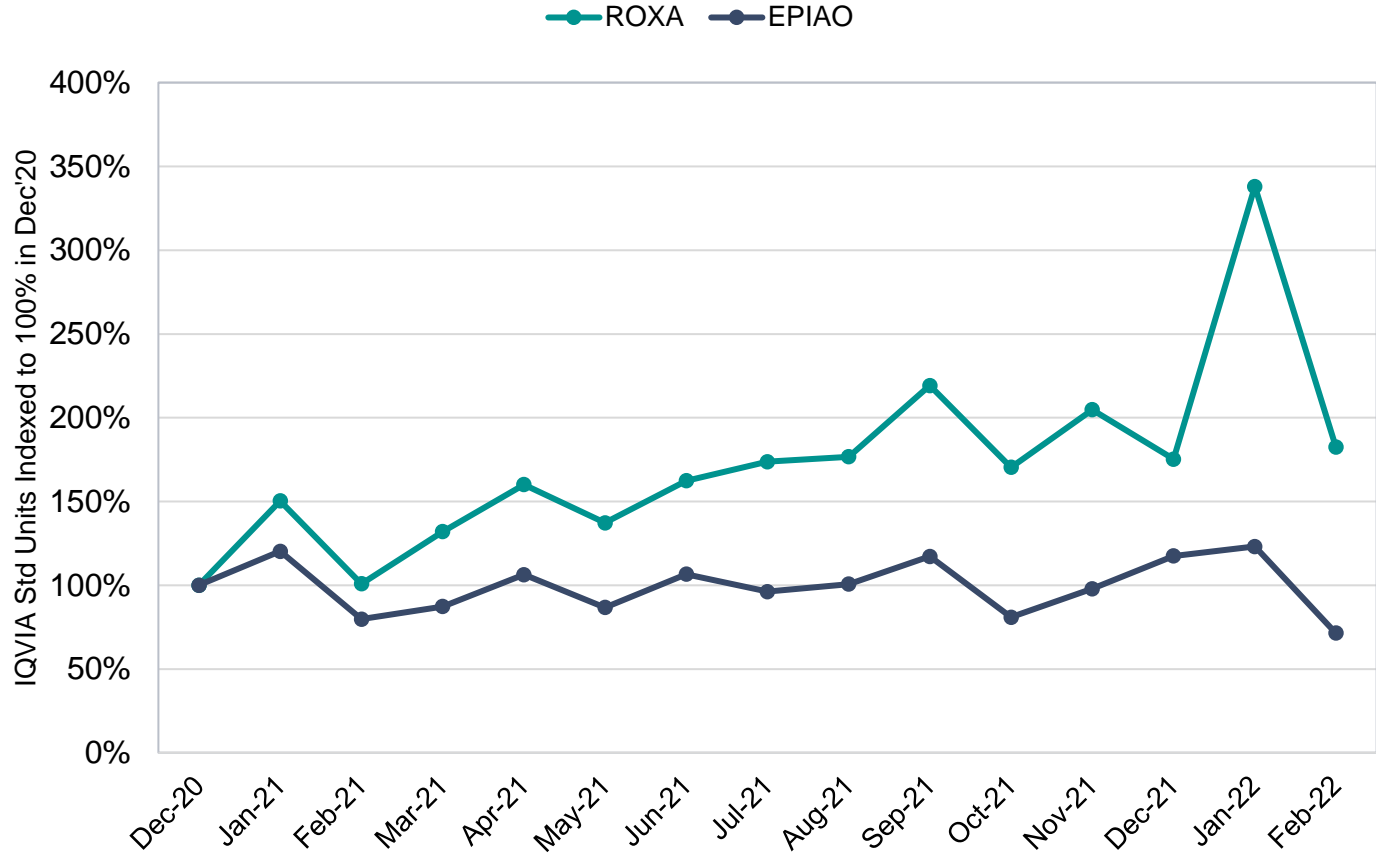
Partial Quarter ONLY

Source: IQVIA MIDAS, accessed Apr 14<sup>th</sup> 2022. 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 Unit Volume in last 3 months doubled versus prior year; EPIAO volume flat

IQVIA MIDAS Standard Units indexed to 100% in Dec '20



IQVIA Standard Units – Roxadustat vs EPIAO

	Quarter Ending Feb '21	Quarter Ending Feb '22	% Growth
Roxadustat	2,872,530	5,690,745	98%
EPIAO	3,418,561	3,556,255	4%

Source: IQVIA MIDAS, accessed Apr 14<sup>th</sup> 2022. 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 distribution channel dynamics (MFG → Distributor → Hospital)

# Clinical Trial Timelines

Study Phase	Indication	Study Name	Enrollment Target	Topline Data
<b>PAMREVLUMAB</b>				
3	LAPC	LAPIS	284*	1H 2024 – OS endpoint
3	DMD (non-ambulatory)	LELANTOS-1	99*	1H 2023
3	DMD (ambulatory)	LELANTOS-2	73*	2H 2023
3	IPF	ZEPHYRUS-1	356*	Mid-2023
3	IPF	ZEPHYRUS-2	340	TBD
<b>ROXADUSTAT</b>				
3	MDS	MATTERHORN	160	1H 2023

\*Study Fully Enrolled



# Thank You

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