



# FibroGen, Inc. Corporate Presentation

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January 2024

# 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.

# Investment Highlights

## Robust Oncology Pipeline with Significant Near-Term Catalysts

Pamrevlumab readouts for pancreatic cancer: **Phase 3 LAPIS topline expected 1Q 24 and Precision Promise Phase 2/3 topline expected 2Q 24**, representing a multi-billion-dollar revenue opportunity

FG-3246 (CD46-targeting ADC) for mCRPC: data from Phase 1 and diagnostic studies in 2024, including a **Phase 1 monotherapy readout in 1Q 24**

FG-3165 (Galectin-9 targeting mAb) for solid tumors: **IND in 1Q 24**

FG-3175 (CCR8 targeting mAb) for solid tumors: **IND in 2025**

## Growing Roxadustat Revenue and Cash Flow

Strong and **growing revenue and cash flow stream** from roxadustat

**Approved in > 40 countries** and commercialized by AstraZeneca and Astellas

sNDA accepted in China for Anemia associated with CIA, **approval decision expected in mid-2024**

## Strong Balance Sheet

**\$283M** in cash as of September 30, 2023

Sufficient to fund operating plans into 2026

# Accomplished Leadership Team that is Highly Experienced in Bringing Medicines to Market



**Thane Wettig**  
Chief Executive Officer



**Christine Chung**  
SVP China Operations



**John Hunter, PhD**  
Chief Scientific Officer



**Rahul Rajan Kaushik, PhD**  
SVP Pharmaceutical Development,  
Technical Operations and Manufacturing



**Kirk Christoffersen**  
Chief Business Officer



**Michael D. Lowenstein, JD**  
Chief Legal Officer



**Juan Graham**  
Chief Financial Officer



**Tricia Stewart**  
Chief People Officer



**Elizabeth Bearby, PharmD**  
SVP Regulatory, Biometrics, Scientific  
Communications, and Clinical Project Management



# Robust Portfolio With Marketed and Late-Stage Assets

| Program  | Indication  | Preclinical   | Phase 1 | Phase 2 | Phase 3 | Commercialized | Status/<br>Anticipated Milestone                            |
|--|---|---|---------|---------|---------|----------------|---|
| <b>Pamrevlumab</b><br>Monoclonal antibody against connective tissue growth factor (CTGF) | Metastatic Pancreatic Cancer                            | Precision Promise <sup>SM</sup> (PanCan Phase 2/3 Design) |         |         |         |                | Topline Data Expected 1H 2024                               |
|  | Locally Advanced Unresectable Pancreatic Cancer (LAPC)  | LAPIS   |         |         |         |                | Topline Data Expected 1Q 2024                               |
| <b>Roxadustat</b><br>Small molecule HIF-PHI  | Anemia of Chronic Kidney Disease (CKD)                  | EVRENZO <sup>TM</sup> , 爱瑞卓 <sup>®</sup> Marketed*        |         |         |         |                |   |
|  | Chemotherapy-Induced Anemia (CIA)                       | CHINA Label Expansion Study                               |         |         |         |                | Approval Decision Expected Mid-2024                         |
| <b>FG-3246</b> (FOR46)<br>CD46-targeting ADC   | Metastatic Castration-Resistant Prostate Cancer (mCRPC) |   |         |         |         |                | Topline Phase 1 Results 1Q 2024. Phase 2 Initiation 2H 2024 |
| <b>FG-3165</b><br>Monoclonal antibody against Galectin-9 (Gal-9)                         | Solid Tumors  |   |         |         |         |                | IND 1Q 2024   |
| <b>FG-3175</b><br>Monoclonal antibody against C-C Motif Chemokine Receptor 8 (CCR8)      | Solid Tumors  |   |         |         |         |                | IND 2025  |

■ In-Licensed  
 ■ Commercial Partner  
 ■ Wholly-Owned

# Pamrevlumab

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mAb targeting connective tissue growth factor (CTGF) for pancreatic cancer treatment

# Pancreatic Cancer is in Dire Need of Novel Targets and Treatment Options

## 3<sup>rd</sup> leading cause of cancer mortality in the U.S.<sup>1</sup>

Most common form is pancreatic ductal adenocarcinoma (PDAC)

Usually diagnosed at an advanced stage of disease

**~60,000 patients/year** are expected to be diagnosed with pancreatic cancer **in the U.S. alone<sup>2</sup>**

Causing **50,550 deaths a year in 2023<sup>2</sup>**

## Lowest survival rate among all cancers

5-year disease-free survival in pancreatic cancer only **12.5%<sup>2</sup>** and as low as **~3%<sup>3</sup>** in metastatic cancer

**90%** of patients experience recurrence after curative resection<sup>4</sup>

## No major therapeutic advances in decades

**Chemotherapy<sup>5</sup>** (e.g., gemcitabine) +/- radiation is the established standard of care across stages of disease

Few therapies are available for specific sub-populations of patients, **offering only limited improvements** in OS and PFS<sup>5</sup>

Major therapy classes such as **immunotherapies have failed to demonstrate additional** survival benefits

OS=overall survival; PFS=progression free survival.

1. Hirshberg Foundation for Pancreatic Cancer Research. Pancreatic Cancer Facts. <https://pancreatic.org/pancreatic-cancer/pancreatic-cancer-facts/>. 2. National Cancer Institute. Cancer Stat Facts: Pancreatic Cancer. <https://seer.cancer.gov/statfacts/html/pancreas.html>. 3. Cancer.Net. Pancreatic Cancer: Statistics. <https://www.cancer.net/cancer-types/pancreatic-cancer/statistics>. 4. Shi XY, et al. *Sci Rep.* 2023;13(1):4856. 5. NCCN guidelines 2021

# Pamrevlumab Has Novel and Differentiated Anti-Tumor Activity

CTGF expression is elevated in pancreatic cancer<sup>1</sup>

CTGF drives multiple biological processes including cancer cell proliferation, migration, invasion, and metastasis that contribute to pancreatic tumor growth and disease progression<sup>1,2</sup>

## Pancreatic tumor preclinical models demonstrate that CTGF:

- Promotes proliferation
- Decreases apoptosis and promotes survival
- Supports invasion
- Stimulates fibroblast activation, proliferation, and ECM deposition
- Overexpression contributes to pancreatic tumor growth

## Pamrevlumab has multiple effects in pancreatic cancer preclinical models:

- Increased survival
- Promoted tumor cell apoptosis
- Reduced cell proliferation
- Decreased tumor vascularization

CTGF=connective tissue growth factor; ECM=extracellular matrix.

1. Shen YW, et al. *Trends in Molecular Medicine*. 2020;26(12):1064-1067. 2. Shen YW, et al. *Trends in Cancer*. 2021;7(6):511-524.

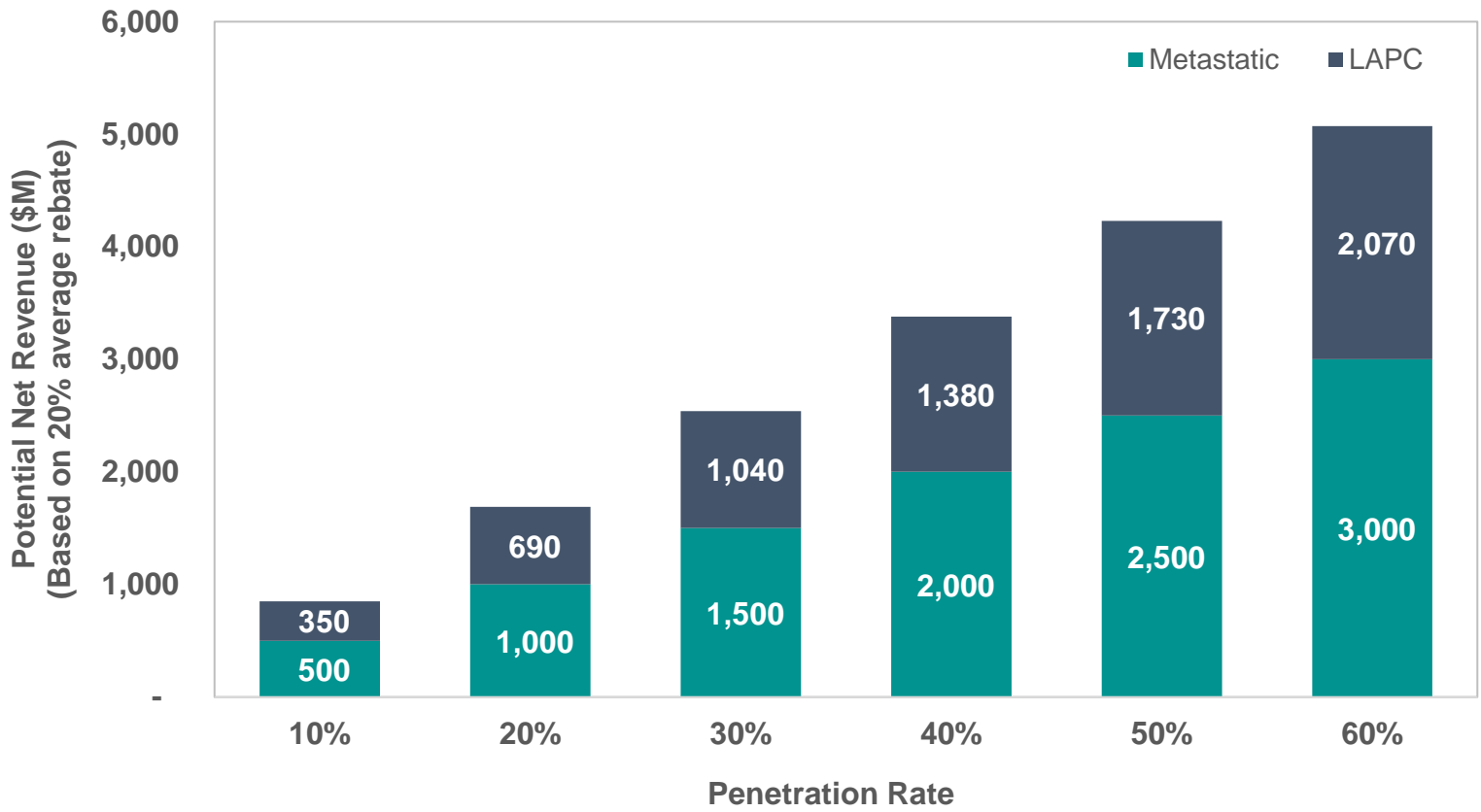


# Significant Commercial Opportunity in the U.S. for Pamrevlumab in Pancreatic Cancer

60,000 PDAC Cases/Year<sup>1</sup>  
 52% metastatic | 36% LAPC  
**52,800 patients**

Average Annual Cost of Therapy  
**\$200,000**

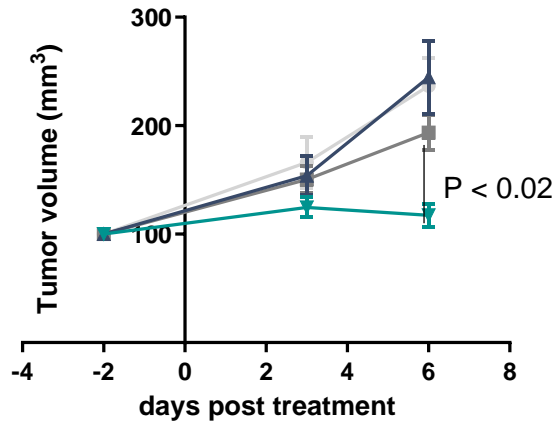
Total Addressable Market<sup>2</sup>  
**> \$8B**



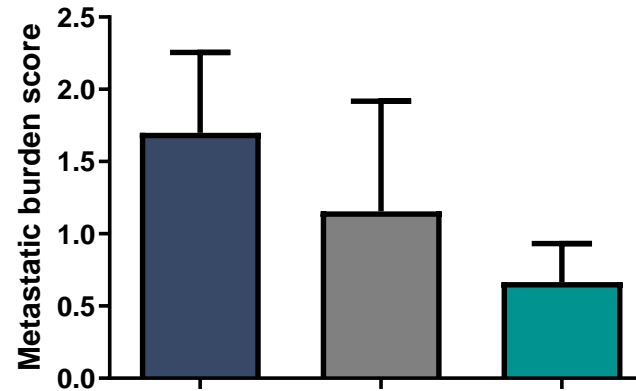
Pancreatic Cancer represents a multi-billion-dollar commercial opportunity for pamrevlumab in the U.S.

# Pamrevlumab Improved Survival in Mouse KPC Model of Pancreatic Cancer

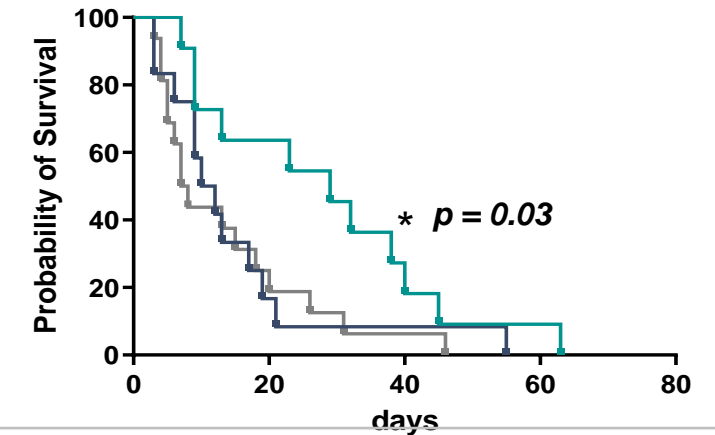
## Tumor Volume



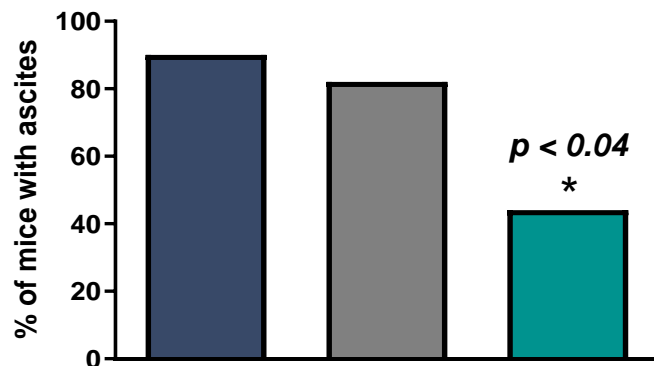
## Metastasis



## Survival



## Ascites



## Pamrevlumab in combination with gemcitabine:

- Vehicle
- Gem
- Pamrevlumab
- Gem+Pamrevlumab

- ✓ Slowed tumor growth
- ✓ Decreased metastatic burden (ns)
- ✓ Increased survival
- ✓ Inhibited formation of ascites

This study was done in a KPC mouse model, an established and clinically relevant model of pancreatic ductal adenocarcinoma. Neesse A et al., *PNAS*. 2013;110:12325-12330.

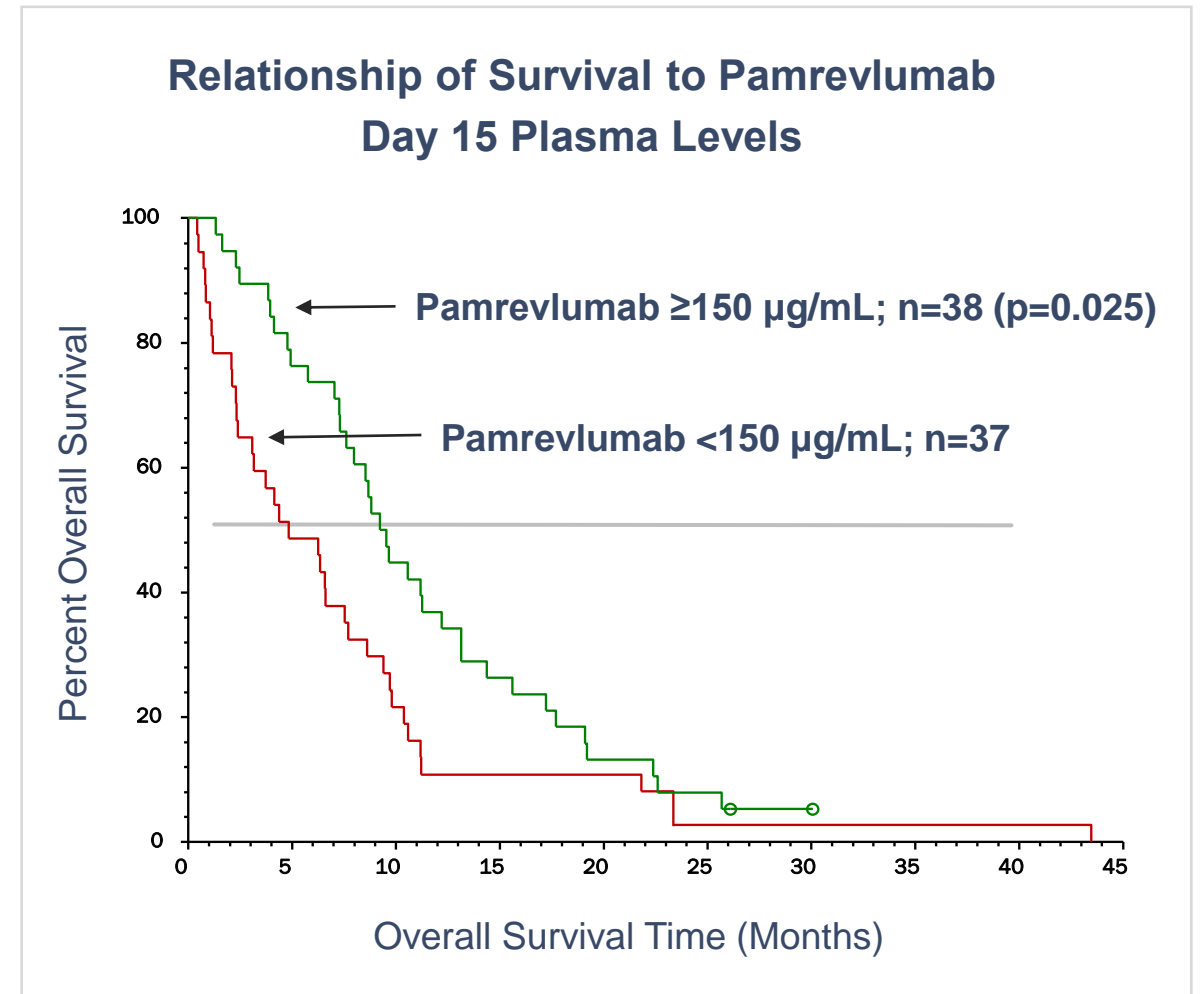
**Pamrevlumab is an investigational drug and is not approved for use by any regulatory authorities**

# Phase 1/2 Study of Pamrevlumab in Advanced Pancreatic Cancer Showed Exposure Related Increases in Survival

Dose and Exposure/Survival Response in Combination with Gemcitabine and Erlotinib

## Results in Advanced Disease (N=75; 88% metastatic)

- Exposure related increase in survival
- Positive exposure response relationship with pamrevlumab plasma level  $C_{min} \geq 150 \mu\text{g/mL}$ 
  - **2x median survival** (9.4 vs. 4.8 months) ( $p=0.025$ )
  - **>3x one-year survival** (37% vs.11%) ( $p=0.01$ )



# Pamrevlumab:

## A First-in-Class CTGF-targeting mAb in Late-Stage Development

### Novel, differentiated anti-tumor MOA

Demonstrated *in vivo* efficacy in multiple pancreatic cancer preclinical models

- Increased survival
- Promoted tumor cell apoptosis
- Reduced cell proliferation
- Decreased tumor vascularization

### Positive early clinical-stage outcomes in PDAC support continued investigation to address serious unmet medical needs

- Phase 1: Higher pamrevlumab drug exposure and lower baseline CTGF level were independently and significantly associated with prolonged PFS and OS (median survival and 1-Year OS rate)
- Phase 1/2: Safe and well tolerated with dose and exposure-related response, trend for improved resection rate, and increased completion of chemotherapy cycles

### Significant commercial opportunity

- Pancreatic cancer has a high unmet medical need with limited late-stage competitive intensity
- PDAC represents a potential multi-billion-dollar revenue opportunity

Key pre-clinical and clinical safety and efficacy studies available in SEC filing

MOA=mechanism of action; OS=overall survival; PDAC=pancreatic ductal adenocarcinoma; PFS = progression free survival.

***Pamrevlumab is an investigational drug and is not approved for use by any regulatory authorities***

# Pamrevlumab is in Two Late-Stage Studies Addressing ~90% of Diagnosed Pancreatic Cancer Patients Today



|                                       | Metastatic Pancreatic Cancer  | Locally Advanced Pancreatic Cancer  |
|---------------------------------------|---|---|
| % of patients diagnosed at this stage | <b>52%</b>  | <b>36%</b>  |
| Sponsor                               | Pancreatic Cancer Action Network  | FibroGen  |
| Study                                 | Precision Promise - NCT04229004   | LAPIS - NCT03941093   |
| Geography                             | US  | Global  |
| FDA Registrational Study              | Yes   | Yes   |
| Stage of Cancer                       | <b>Confirmed metastatic PDAC, First- or second-line therapy</b>                       | <b>Confirmed PDAC unresectable, per NCCN criteria 2018, with no prior therapy</b> |
| Pam Dosing in Active Arm              | <b>Unlimited 28-day treatment cycles until disease progression or discontinuation</b> | <b>Six 28-day treatment cycles of neoadjuvant therapy</b>                         |
| Primary Endpoint                      | Overall Survival  | Overall Survival  |
| Trial Completion Trigger              | Time-Based (12 months after last patient in)  | Event-Based   |
| <b>Topline Data Expected</b>          | <b>1H 2024</b>  | <b>1Q 2024</b>  |

# Precision Promise is a New Paradigm in Pancreatic Cancer Drug Development from the Pancreatic Cancer Action Network (PanCAN)

FibroGen established a standard research agreement with PanCAN with no royalties or equity

Precision Promise is PanCAN's groundbreaking trial aiming for **more efficient and faster time** to new treatments for pancreatic cancer patients

**Financial and operational support from PanCAN**

Pamrevlumab Precision Promise Ph2/3 study and regulatory path

**FDA-aligned registrational study design:**

- Trial design developed based on **FDA 2020 'Complex Innovative Designs' guidance<sup>1</sup>**
- Complete trial support from PanCan including facilitated FDA discussions throughout design, regulatory submission and review

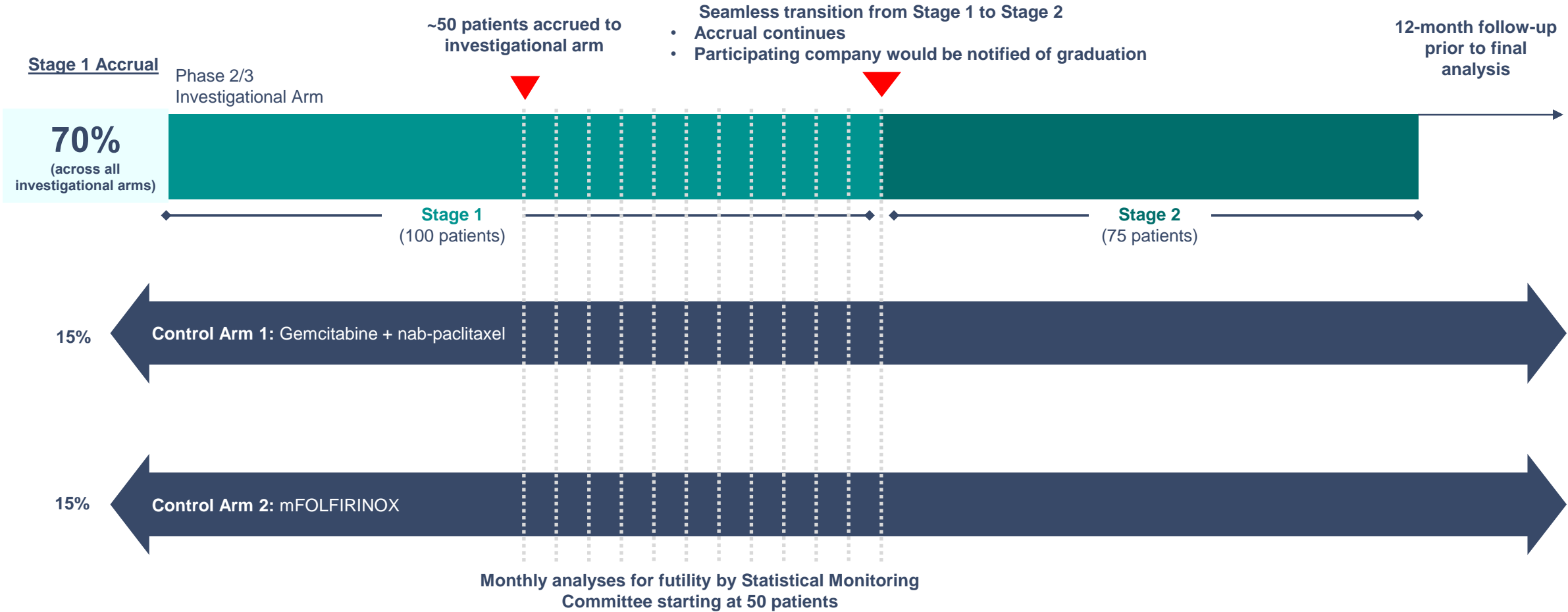
Includes 1<sup>st</sup> and 2<sup>nd</sup> line metastatic PDAC patients in Phase 2 and potentially included in Phase 3

**Independently conducted** by renowned experts in Pancreatic Cancer, trial strategy and statistical methods

**KOL engagement throughout study:** ~100 pancreatic cancer scientific & clinical leaders supporting the study

Topline Data Expected 1H 2024

# Precision Promise: An adaptive multi-arm registration trial in metastatic PDAC<sup>1</sup>



# Phase 3 LAPIS Study in Patients with Locally Advanced Pancreatic Cancer: Study Design

## Patient population

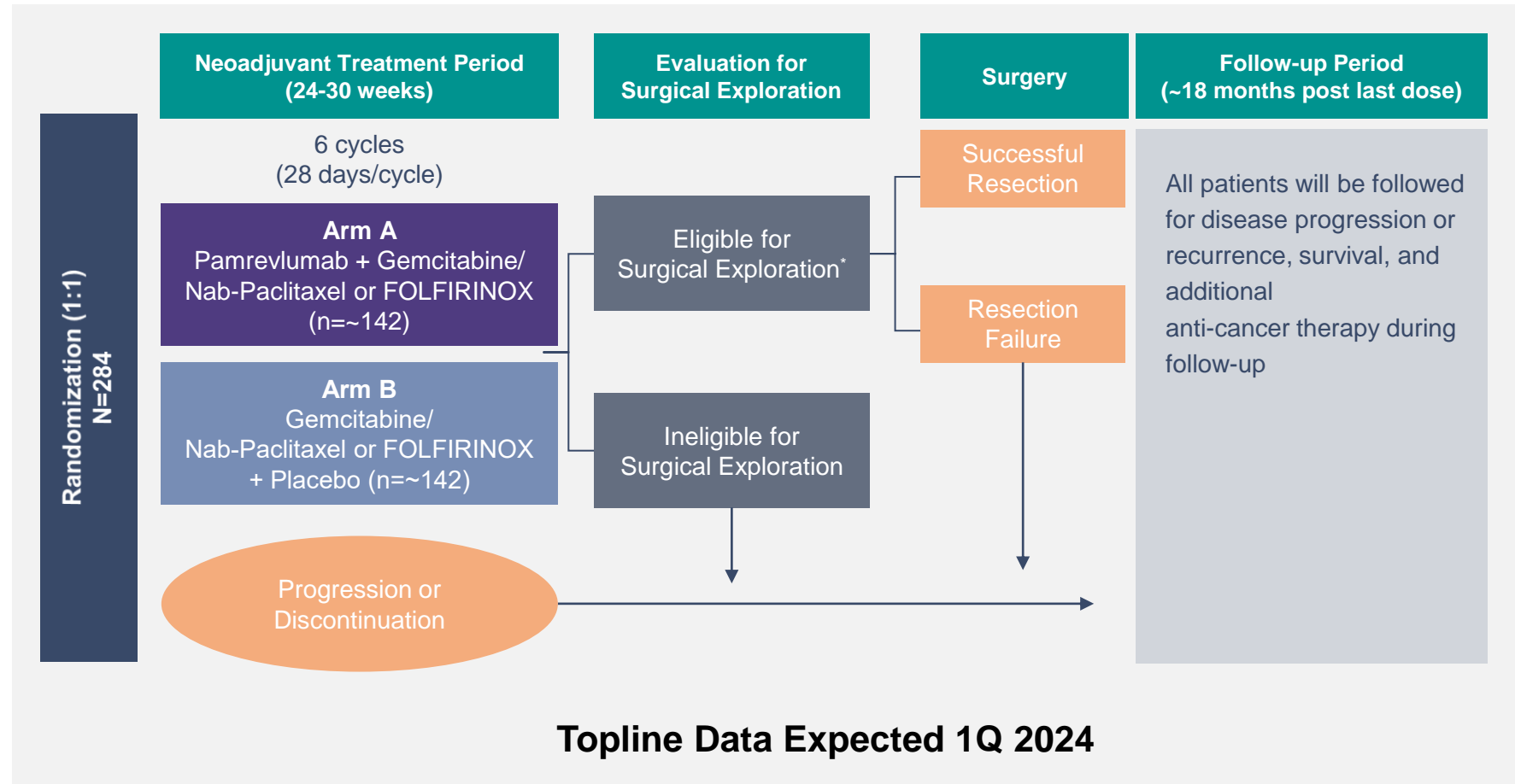
Locally advanced, unresectable pancreatic cancer  
 Measurable disease per RECIST 1.1  
 ECOG 0-1 (health status of patient)  
 No prior therapy

## Primary Endpoint

Overall survival (OS)

## Secondary Endpoints

Event-free survival  
 Patient-reported outcomes



NCT03941093



# Roxadustat

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Oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor, **based on 2019 Nobel Prize-winning science**, for the treatment of anemia



# Roxadustat: Revenue Generating with Established Strong Pharma Partners

## 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.

## Roxadustat Continues to be Approved in Additional Countries Worldwide

Roxadustat (爱瑞卓®, EVRENZO™) is **now approved in over 40 countries** including China, Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease ("CKD") patients on dialysis and those not on dialysis. Roxadustat continues to be approved in jurisdictions throughout the world, including recent marketing approvals in Mexico and South Africa.

## Additional Indications Under Evaluation

Anemia associated with chemotherapy-induced anemia (CIA) – sNDA accepted in China based on positive Phase 3 study reported in Q3'23. **Approval decision expected mid-2024.**



# Roxadustat Collaboration Economics



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



Co-Commercialized in China with 50/50 profit split



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

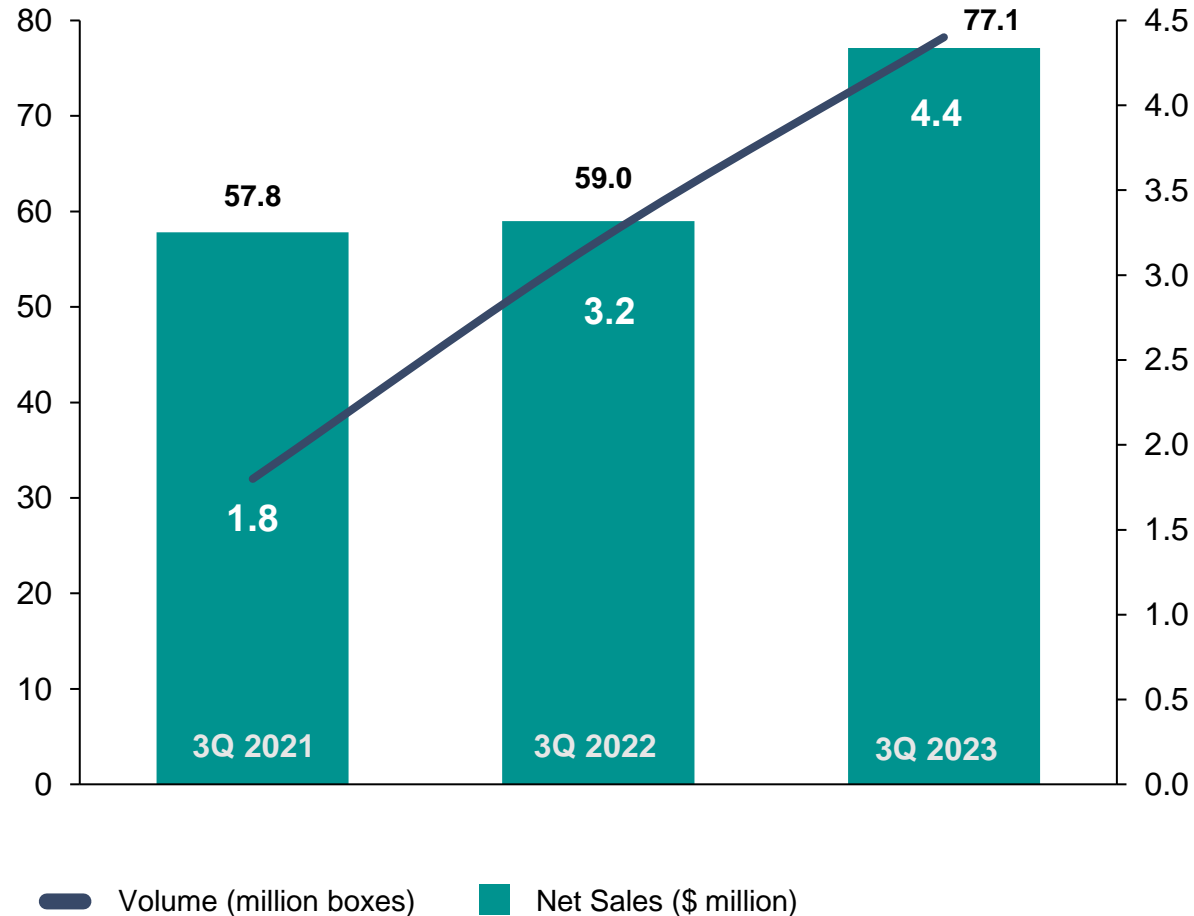


Regulatory and/or commercial milestones available under our collaboration agreements



# China: Continued Strong Performance from Volume Growth

## China Roxadustat Volumes & Net Sales



### 31% GROWTH IN SALES

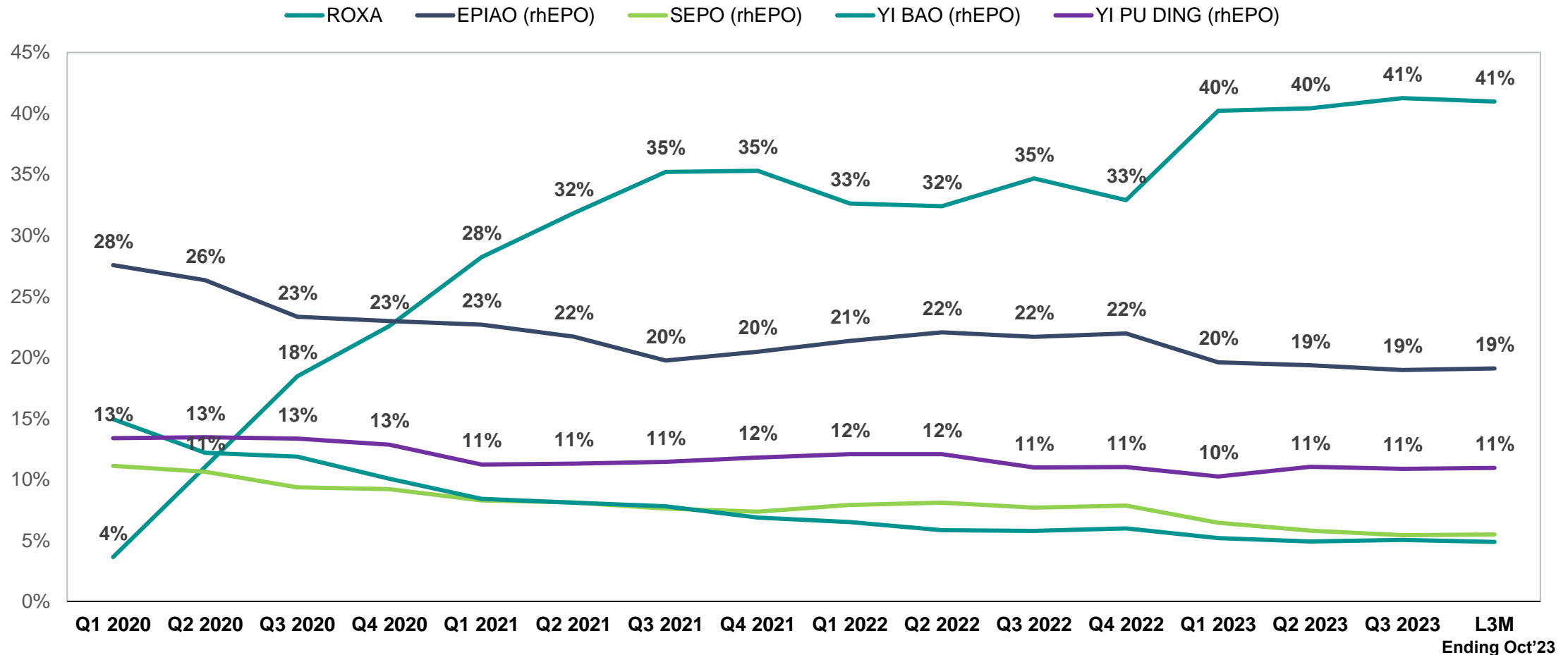
Roxadustat net sales to distributors in China of \$77.1 million in third quarter of 2023 compared to \$59.0 million a year ago\*

- Driven by an increase in volume of 37%



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

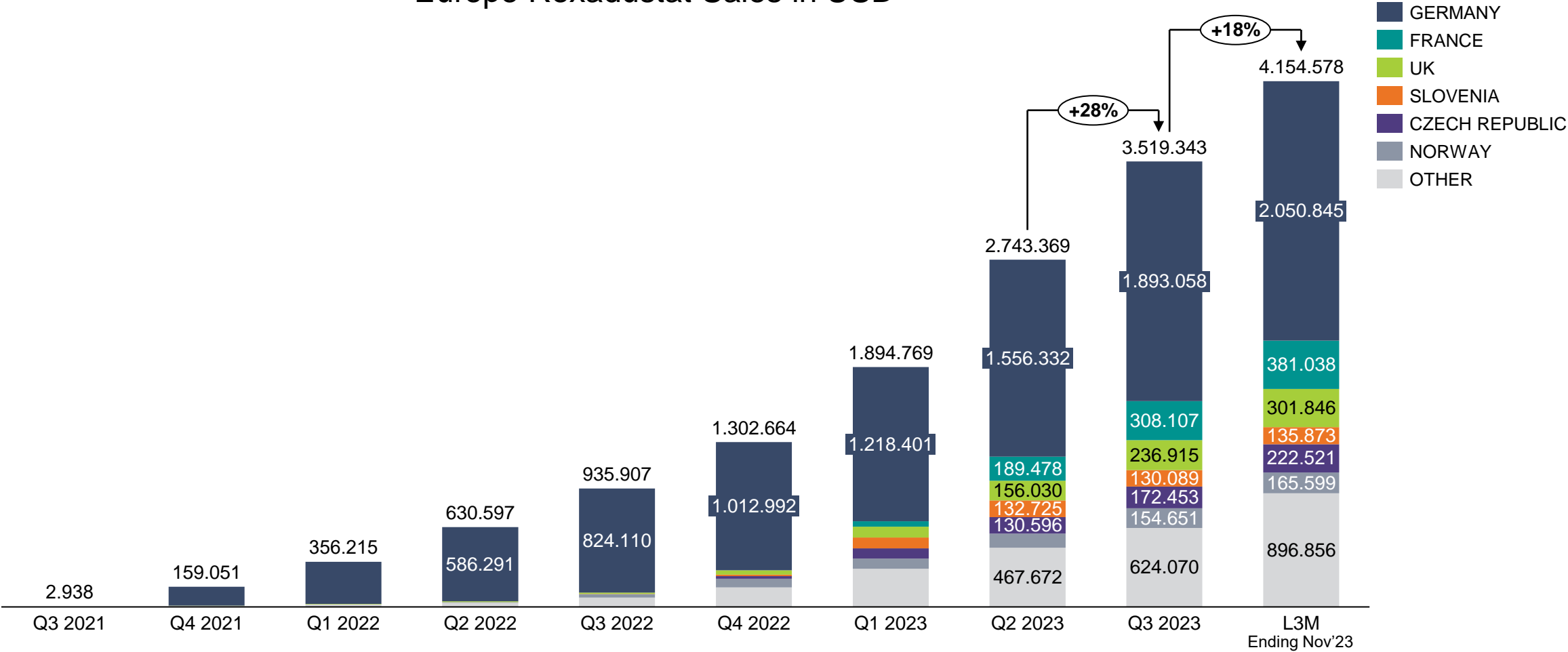
## Quarterly Brand Share based on \$ Sales - Top 5 of ESA+HIF Market





# Europe sales grew by ~30% in Q3 vs prior quarter primarily driven by Germany and France

Europe Roxadustat Sales in USD



Source: IQVIA MIDAS, accessed Jan 5<sup>th</sup>, 2024. 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

# Anemia from MDS is a High Unmet Need Opportunity

## High Unmet Need<sup>1</sup>

~70K patients live with MDS in the U.S.

- About **90% suffering from anemia** and its resulting impact on quality of life

### Acute lack of effective 2L treatments

- Current agents are effective only in <50% patients

Need for treatments that provide **durable response and the convenience of oral administration**, vs. current treatments (intravenous for ESAs and luspaterecept)

## Significant Opportunity

Targeted Phase 3 program could facilitate an approval in anemia from MDS

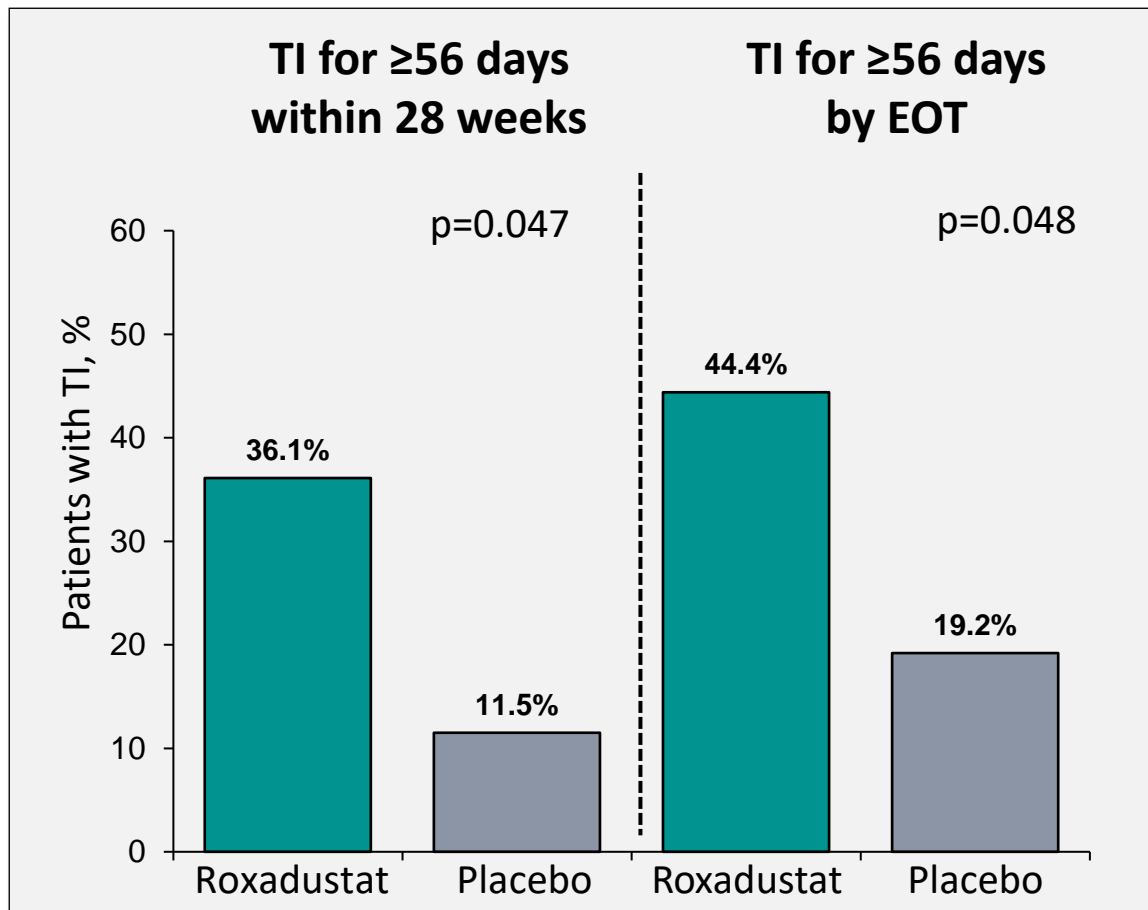
FDA Orphan designation would provide 7 years of data exclusivity in the U.S.\*

Potential high price point, low sales representative intensity and significant peak U.S. sales

**No other oral treatments for anemia of lower-risk MDS are commercially available or in late-stage development**

# Anemia of MDS: Phase 3 Development Opportunity Based on Results from MATTERHORN Phase III Trial

More Patients With a Higher Transfusion Burden<sup>a</sup> Receiving Roxadustat Achieved TI vs Placebo



| % (95% CI)                                   | Roxadustat (n=36) | Placebo (n=26)   | Roxadustat vs placebo             |
|--|-------------------|------------------|-----------------------------------|
| TI for ≥56 days within 28 weeks <sup>b</sup> | 36.1% (20.8–53.8) | 11.5% (2.4–30.2) | OR: 3.823 (0.961–15.204); p=0.047 |
| TI for ≥56 days by EOT <sup>b</sup>          | 44.4% (27.9–61.9) | 19.2% (6.6–39.4) | OR: 3.369 (1.014–11.189); p=0.048 |

<sup>a</sup>Higher transfusion burden defined as ≥2 pRBC units Q4W



# Additional Oncology Programs

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# FG-3246 is a CD46-Targeting Antibody-Drug Conjugate (ADC) with First-in-Class Potential

## First-in-class potential

Binds a unique epitope on CD46 that is preferentially expressed on tumor cells

ADC composed of anti-CD46 monoclonal (YS5) conjugated to cytotoxic payload monomethyl auristatin E (MMAE) via cleavable linker (mc-vc-PAB)

- MMAE is a clinically and commercially validated payload (used in 5 out of 13 approved ADCs)
- MMAE kills dividing cells by disrupting microtubule polymerization and blocking cell division

FG-3246 has demonstrated efficacy against CD46 expressing tumors in both preclinical and clinical studies

## Encouraging early data in Phase 1 studies

- Monotherapy activity in heavily pretreated mCRPC and multiple myeloma patients
- Safety profile consistent with other MMAE-based ADCs

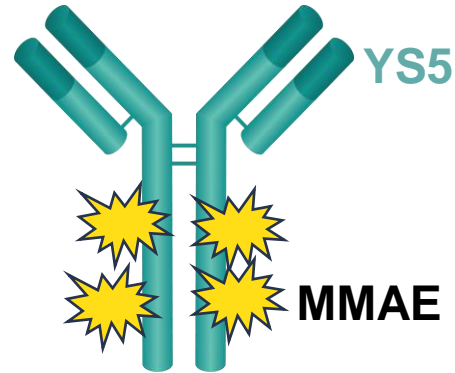
## PET46: Biomarker driven opportunity with PET biomarker targeting CD46 for patient selection

- Utilizes the same targeting antibody as FG-3246 (YS5) coupled to the radionuclide zirconium-89 (<sup>89</sup>Zr)
- Demonstrated specific targeting of and uptake by CD46 positive tumors in preclinical studies
- Currently under development at UCSF

# FG-3246 and PET46 Demonstrated On-Target Activity in Preclinical Studies

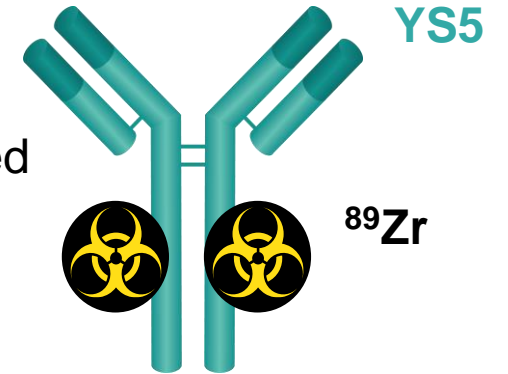
## FG-3246:

demonstrated efficacy against CD46 expressing tumors

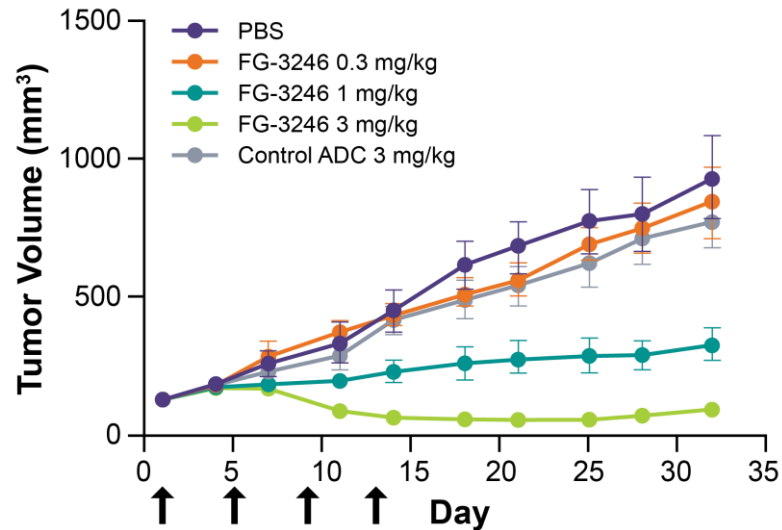


## PET46:

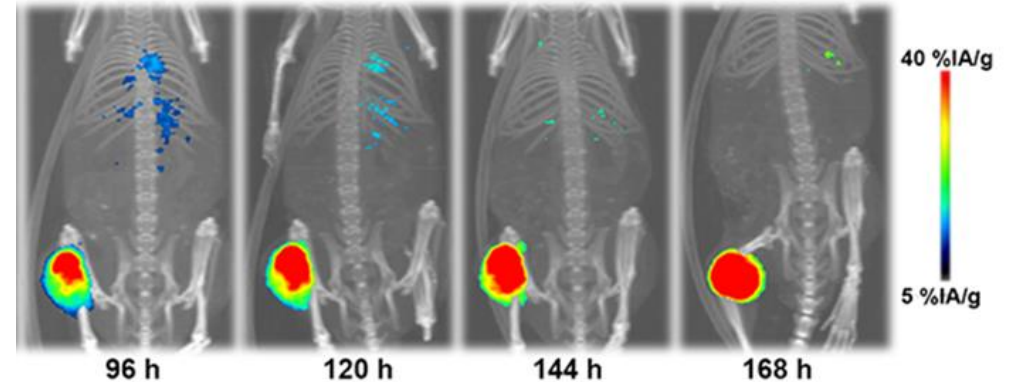
<sup>89</sup>Zr biomarker demonstrated specific uptake in CD46 positive tumors



### DU145 tumor growth



### DU145 tumor imaging



# FG-3246 is Clinically Active in Heavily Pretreated mCRPC Patients<sup>1</sup>

Interim data from Phase 1 dose escalation and expansion study – median of 5 prior lines of therapy

PSA50 response rate = 45%

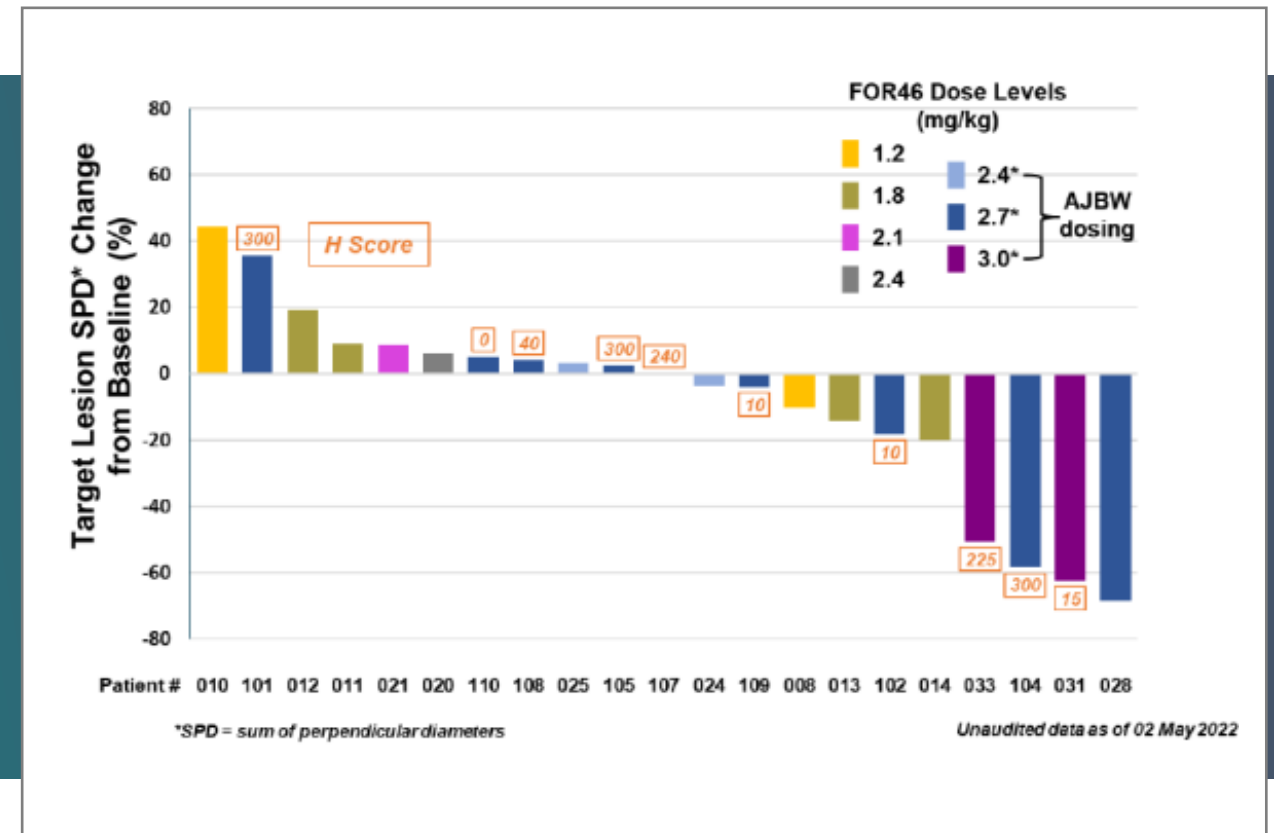
- Median duration of response ≥ 16 weeks

ORR = 19%

- 4 partial responses in 21 evaluable patients
- Responses seen at two highest study doses

Safety profile consistent with other MMAE-based ADCs

Additional patient data available following study completion



# Ongoing and Planned FG-3246 Clinical Studies

Multiple studies generate value inflection points for the program

| Stage      | Study   | NCT#        | Status                 | Expected Readout |
|------------|---|-------------|------------------------|------------------|
| Phase 1    | Monotherapy dose escalation and expansion safety study in patients with mCRPC (N=53)  | NCT03575819 | Active, not recruiting | 1Q 2024          |
| Phase 1    | FG-3246 combination with enzalutamide in patients with mCRPC (N=36)   | NCT05011188 | Active, recruiting     | Interim Mid 2024 |
| Diagnostic | PET46 imaging development study (N=24)  | NCT05245006 | Active, recruiting     | 2024             |
| Phase 2    | Open label study in patients with $\geq 2L$ mCRPC (N=100)<br>Initial imaging for CD46 expression with PET46<br>Retrospective analysis of correlation of PET positivity and efficacy | TBD         | Pending                | 2026             |

# Immuno-Oncology Programs for Solid Tumors with INDs Anticipated in 2024-2025

## FG-3165: Anti-Gal9 Antibody

- High affinity mAb targeting galectin-9 (Gal9) designed to reverse immune resistance in solid tumors
- In preclinical studies, FG-3165:<sup>1</sup>
  - Blocks Gal9 driven apoptosis of effector T cells
  - Reverses Gal9 mediated signaling in T cells
  - Disrupts dimerization of TIM-3 and VISTA
- Surrogate antibody exhibits *in-vivo* anti-tumor activity in combination with other checkpoint inhibitors

IND planned in 1Q 2024

## FG-3175: Anti-CCR8 Antibody

- High affinity mAb targeting CCR8 with enhanced antibody-dependent cellular cytotoxicity (ADCC) designed to selectively disrupt and deplete Tregs in the TME without affecting peripheral Treg
- Dual mechanism of action
  - Depletion of CCR8+ Tregs via ADCC
  - Disruption of Treg migration and potentiation by blocking CCL1 binding to CCR8
- CCR8 targeted Treg depletion exhibits potent *in-vivo* single agent anti-tumor activity in immune-competent mouse tumor models

IND planned in 2025

# Investment Highlights

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Strong and **growing revenue and cash flow stream** from roxadustat

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sNDA accepted in China for Anemia associated with CIA, **approval decision expected in mid-2024**

## Strong Balance Sheet

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Sufficient to fund operating plans into 2026



# Thank You

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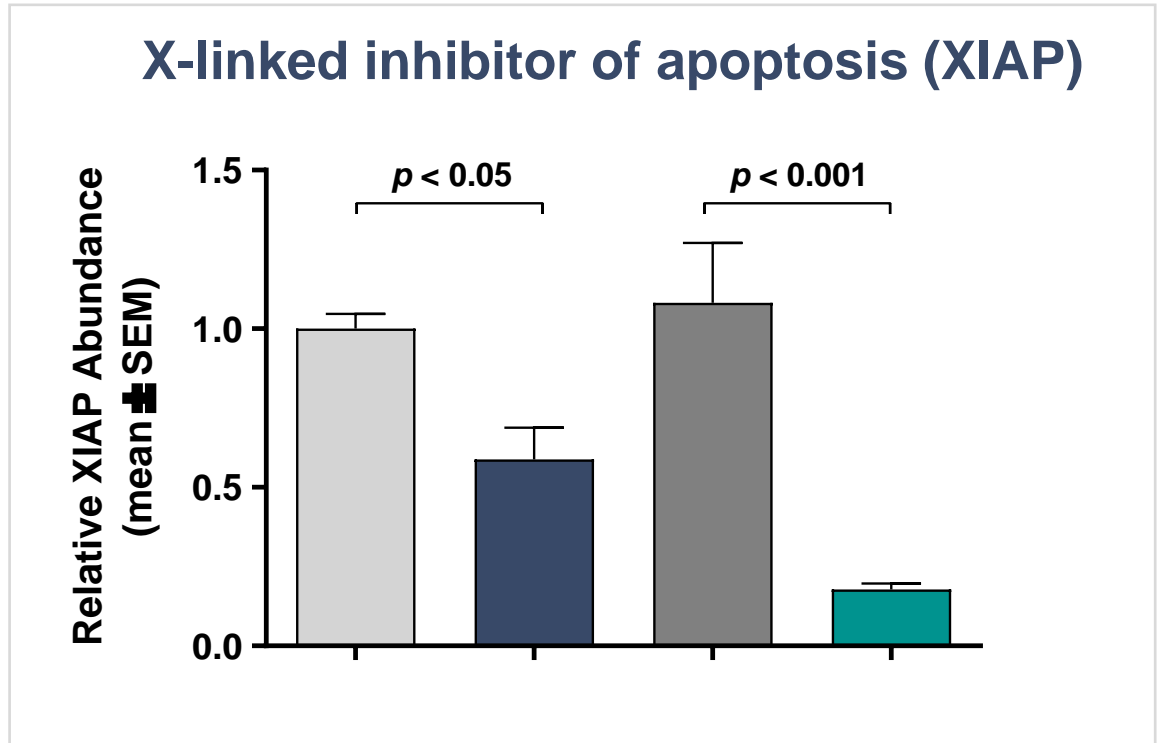
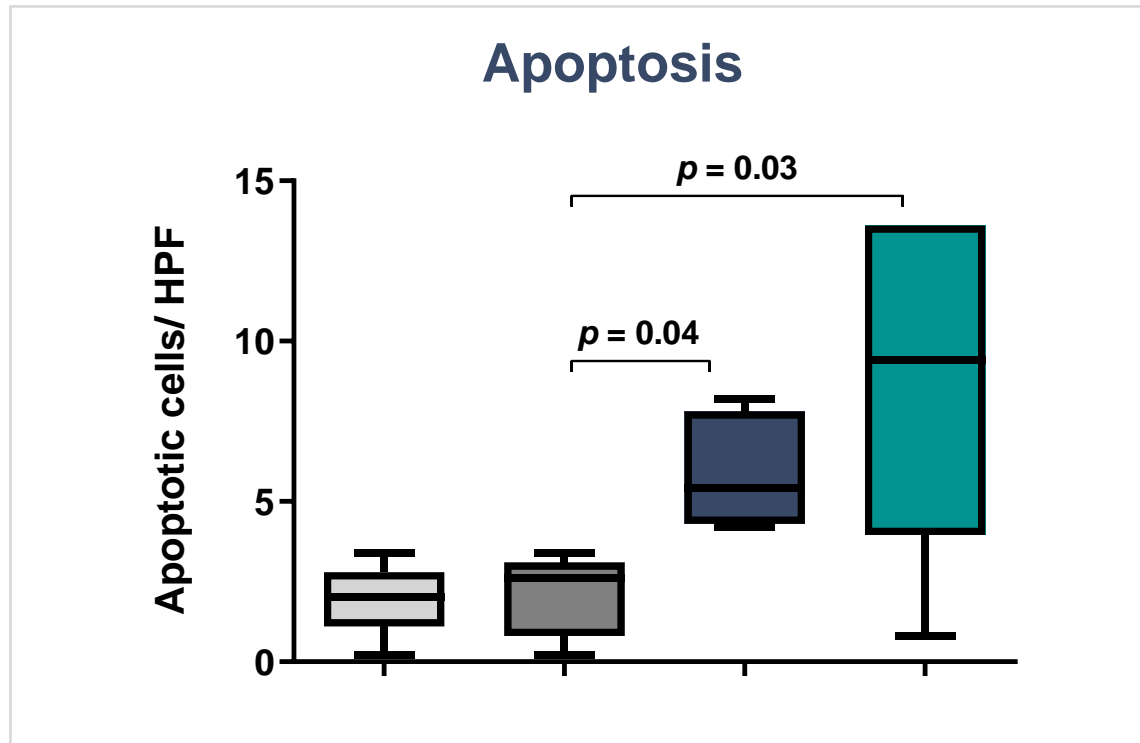
For more information contact [ir@fibrogen.com](mailto:ir@fibrogen.com)

**NASDAQ: FGEN**



# Pamrevlumab Increased Tumor Cell Apoptosis in KPC Mouse Model of Pancreatic Cancer

Pamrevlumab promoted tumor cell apoptosis and decreased expression of a protein that stops apoptotic cell death - XIAP. No observed effect on desmoplasia after 9 days.



□ IgG   □ Gem/IgG   □ Pamrevlumab   □ Gem+Pamrevlumab