



# FibroGen Reports Second Quarter 2023 Financial Results

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August 7, 2023



# Forward-Looking Statements

This presentation contains forward-looking statements regarding FibroGen’s strategy, future plans and prospects, including statements regarding the development and commercialization of the company’s product candidates, the potential safety and efficacy profile of its product candidates, and its clinical programs. These forward-looking statements include, but are not limited to, statements under the caption “Upcoming Milestones”, statements regarding the expected cost reduction savings, the statement that FibroGen expects its cash, cash equivalents, investments, and accounts receivable to be sufficient to fund its operating plans into 2026, and statements about FibroGen’s plans and objectives and typically are identified by use of terms such as “may,” “will,” “should,” “on track,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue” and similar words, although some forward-looking statements are expressed differently. FibroGen’s actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of its various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in FibroGen’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, each as filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and FibroGen undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

# Four Strategic Pillars to Drive Shareholder Value

1

## Pamrevlumab

Three upcoming late-stage read-outs, starting in 3Q 2023 through the 1H 2024

2

## Roxadustat

Continued strength of our China roxadustat business and accelerating growth of royalties from the Astellas territories

3

## Early-Stage Pipeline

Key milestones for our early-stage oncology pipeline in 2024

4

## Strong Cash Position

Strong cash position provides an extended runway to numerous value inflection points of our clinical assets

**Pamrevlumab**

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# Pamrevlumab: A 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 in fibrotic diseases



## Phase 2 outcomes support continued investment to meet serious unmet medical needs

- DMD: Safe and well tolerated with favorable outcomes vs historical data
  - Pamrevlumab can potentially be used in DMD patients regardless of specific mutations
- PDAC: Safe and well tolerated with trend for improved resection rate and increased completion of chemotherapy cycles



## Significant commercial potential

- Phase 3 programs in areas of high unmet medical need with limited late-stage competitive intensity
- Highly differentiated target therapeutic indications with fibrotic pathophysiology but independent risk profiles

# Recently Announced and Upcoming Pamrevlumab Milestones

2Q 2023

- Announced negative topline results from phase 3 LELANTOS-1 trial in non-ambulatory DMD
- Announced negative topline results from phase 3 ZEPHYRUS-1 trial in IPF
- Announced discontinuation of phase 3 ZEPHYRUS-2 trial in IPF

3Q 2023

- Expect to report topline results from phase 3 LELANTOS-2 trial in ambulatory DMD

1H 2024

- Expect to report topline results from phase 3 LAPIS trial in locally advanced unresectable pancreatic cancer in 1Q 2024
- Expect to report topline results from phase 2/3 Precision Promise trial in metastatic pancreatic cancer in 1H 2024

# Duchenne Muscular Dystrophy (DMD)

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# Pamrevlumab DMD Phase 3 Study: LELANTOS-2

## Patient Population

- Ambulatory males 6-12 years old with 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
- Enrolled 73 patients at sites globally
- Randomized 1:1 to receive pamrevlumab plus systemic corticosteroids, or placebo plus systemic corticosteroids, for up to 52 weeks
- Patients who complete the 52-week study will be eligible for rollover into an open-label extension study



**Topline Data Expected 3Q 2023**



# Pamrevlumab DMD Commercial Opportunity

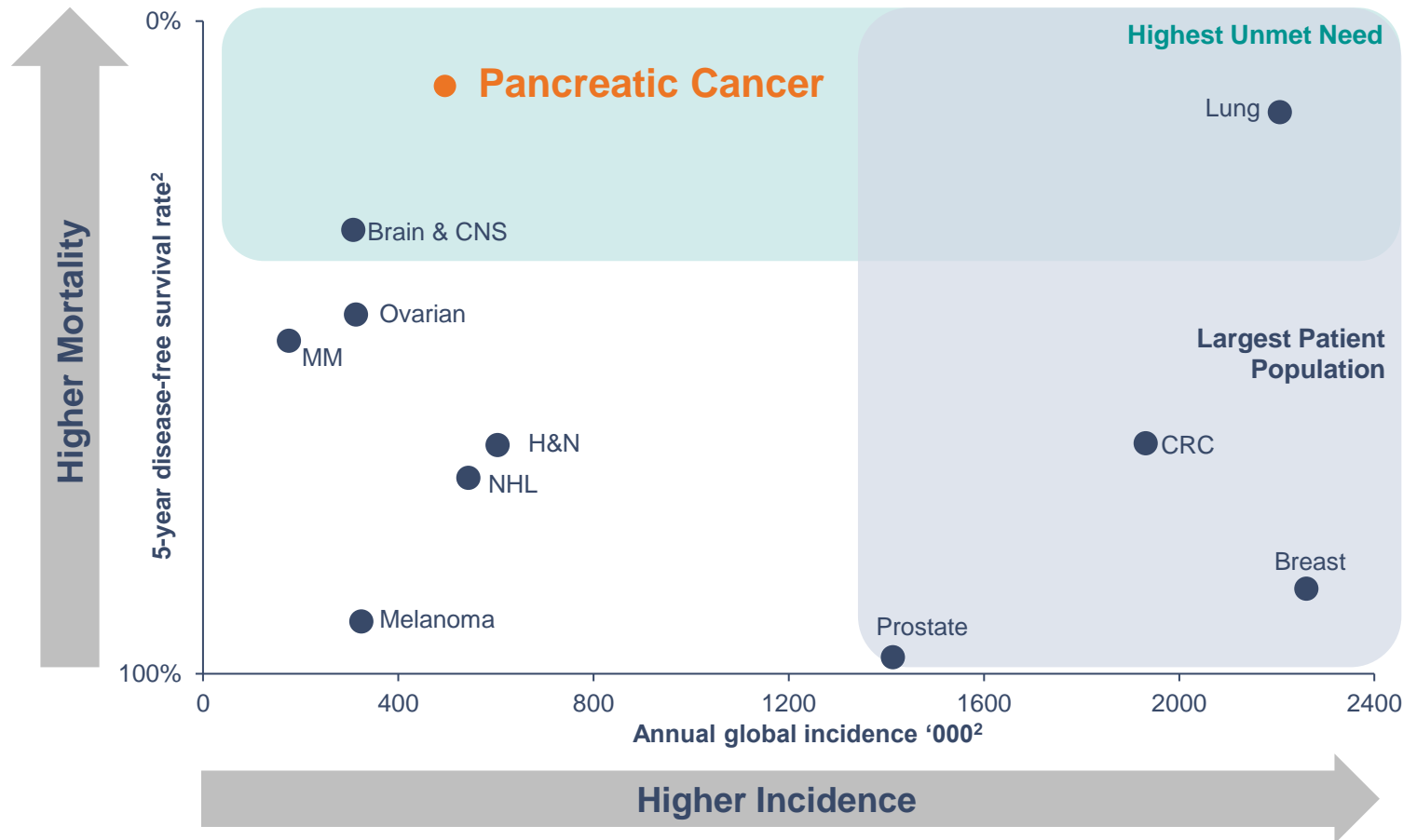
<b>Diagnosed Prevalence (US, EU, CN, JP)</b>	~60k
<b>2022 Branded Category Revenue</b>	~\$1.1B
<b>Current Standard of Care</b>	Corticosteroids; exon-skipping ASO's
<b>SoC Limitations</b>	Continued disease progression; tolerability; need for confirmed gene mutation; biomarker benefit only (exon-skipping therapies)
<b>Late-Stage Competitive Intensity</b>	Dystrophin-targeted therapies (gene-based and exon-skipping); Limited anti-fibrotic therapies

# Pancreatic Cancer

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# Pancreatic Cancer Is Among the Most Lethal Malignancies

Seventh leading cause of cancer mortality in the world with an estimated 466,000 deaths per year<sup>1</sup>



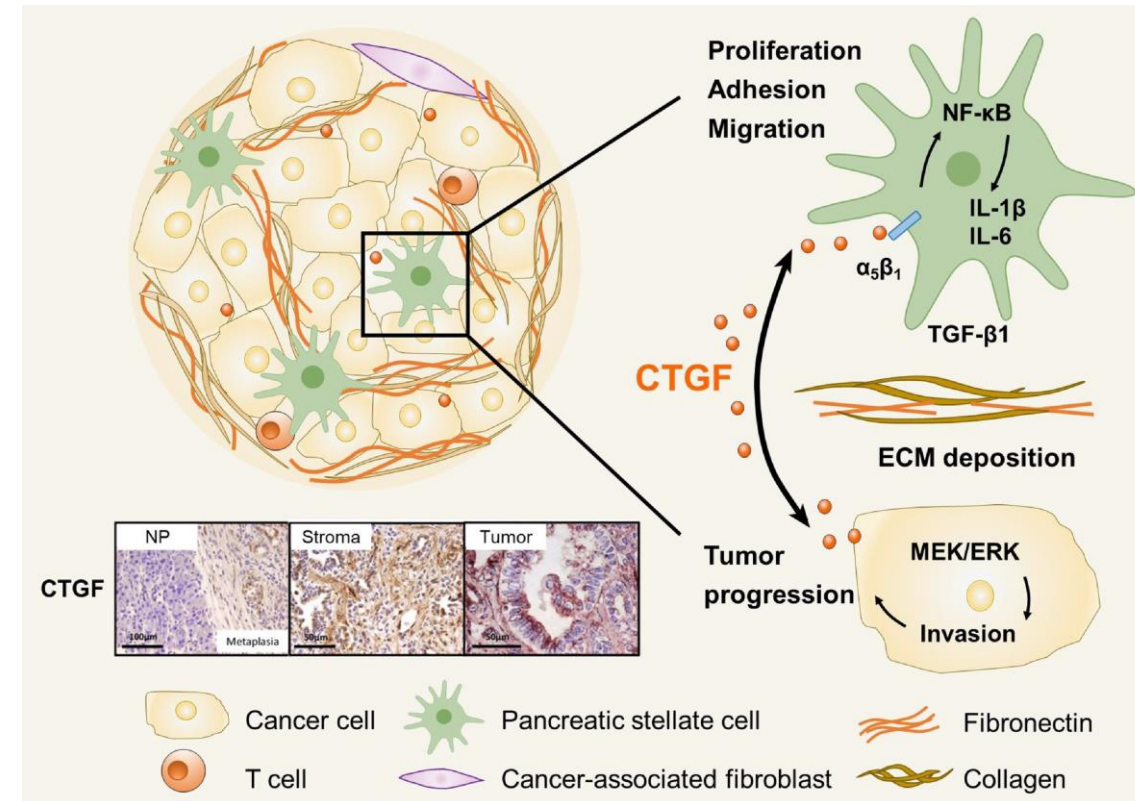
- 5-year disease-free survival in pancreas cancer only 12%<sup>1</sup>
- 90% of patients experience recurrence after curative resection
- **No major therapeutic advances** in decades, with major therapy classes like IOs failing to offer survival benefits
- **Chemotherapy** +/- radiation is the established standard of care across stages of disease

# Rationale for Pamrevlumab in Pancreatic Cancer

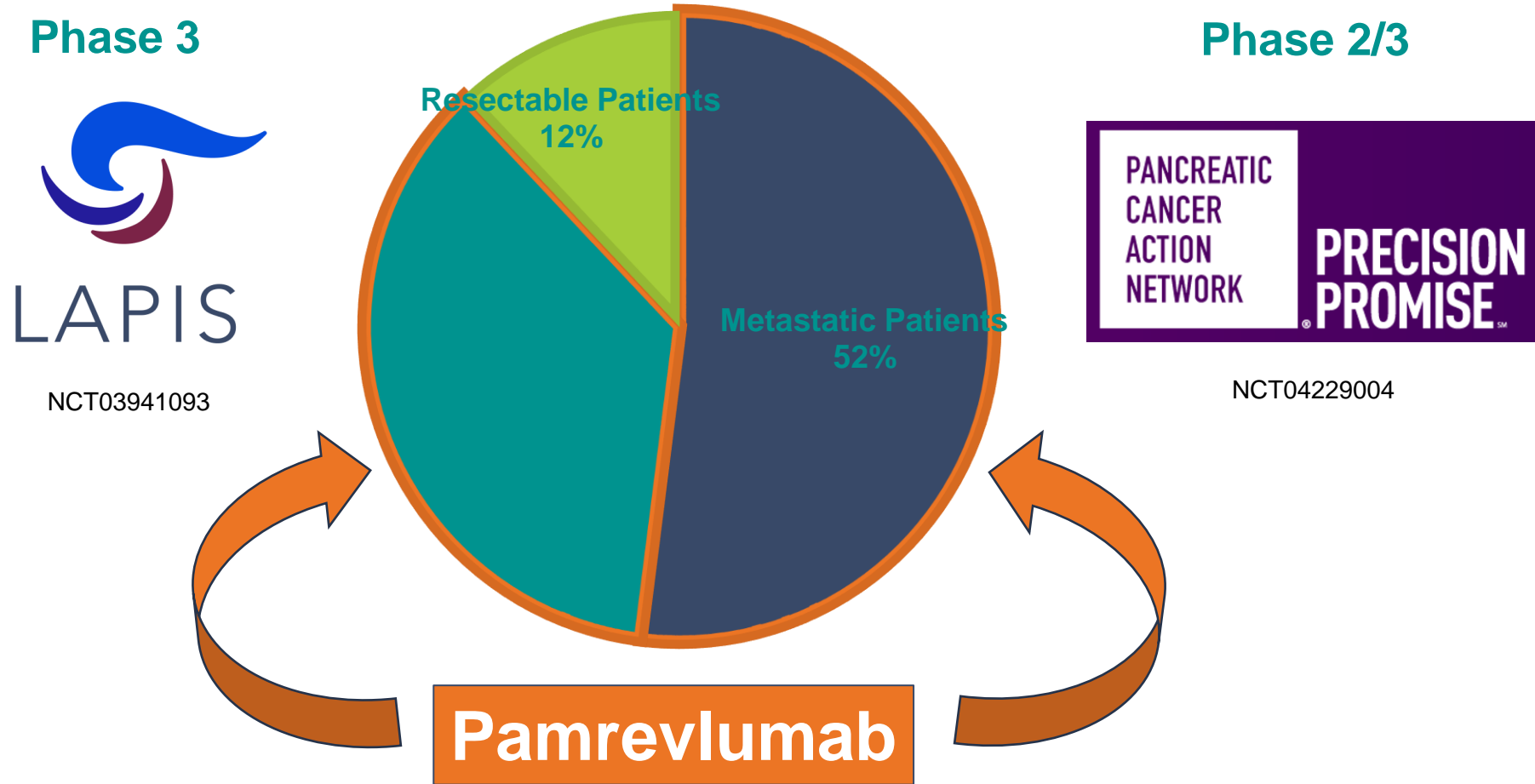
## Elevated expression of CTGF in human tumors and mouse tumor models

CTGF has multiple reported effects on tumor progression:

- **Modification of the tumor microenvironment**
  - Promotes the proliferation of stromal cells
  - Induces ECM deposition
  - Promotes angiogenesis
- **Promotion of metastasis**
  - CTGF inhibition reduces metastases in mouse pancreas cancer models
- **Enhances tumor growth and survival**
  - CTGF expression levels regulate pancreas tumor growth and cell survival in mouse cancer models



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



# Pamrevlumab LAPC Phase 3 Study: LAPIS

## 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 patients at sites globally
- Randomization 1:1 to pamrevlumab + gemcitabine/nab-paclitaxel or FOLFIRINOX or to placebo + gemcitabine/nab-paclitaxel or FOLFIRINOX
- Six cycles of neoadjuvant treatment followed by evaluation for surgical eligibility and possible resection
- Long-term overall survival follow-up for all patients



NCT03941093

**Study Fully Enrolled**

**Topline Data Expected 1Q 2024**

# P Cancer Drug Development

## In Pancreatic

- Adaptive platform trial | ***More efficient and faster time to an answer***
- Phase 2/3 registration study | ***FDA approved design***
  - Complete trial support up to FDA approval with facilitated FDA discussions
- Primary endpoint is overall survival | ***Definitive registration endpoint***
- 1st and 2nd line metastatic PDAC patients | ***Opportunity for a broader label***
- ~100 pancreatic cancer scientific / clinical leaders supporting | ***KOL engagement throughout study***
- Biomarkers, supportive care, research biopsies / samples | ***Comprehensive data package***
- PanCAN is the sponsor and supports the trial both operationally and financially | ***Lowers financial and operational barriers to entry***
  - Standard agreement with no royalties or equity

# Pamrevlumab Pancreatic Cancer Commercial Opportunity

## Locally Advanced Pancreatic Cancer

<b>Diagnosed Incidence (US / US, EU, CN, JP)</b>	~22k / ~93k
<b>Current Standard of Care</b>	gemcitabine + nab-paclitaxel; Folfirinox
<b>SoC Limitations</b>	5-year Disease-Free Survival ~15% <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
<b>Pamrevlumab Net Revenue Opportunity</b>	<b>\$1B+</b>

## Metastatic Pancreatic Cancer

<b>Diagnosed Incidence (US / US, EU, CN, JP)</b>	~32k / ~137k
<b>Current Standard of Care</b>	gemcitabine + nab-paclitaxel; Folfirinox
<b>SoC Limitations</b>	5-year Disease-Free Survival ~3% <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 metastatic disease
<b>Pamrevlumab Net Revenue Opportunity</b>	<b>\$2B+</b>

**Total Pamrevlumab Net Revenue Opportunity: \$3B+**



**Roxadustat**

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# Recently Announced and Upcoming Roxadustat Milestones

2Q 2023

- Announced negative topline results from phase 3 MATTERHORN trial in MDS
- Announced positive topline results from phase 3 China trial in CIA

3Q 2023

- Filed supplemental NDA for CIA in China

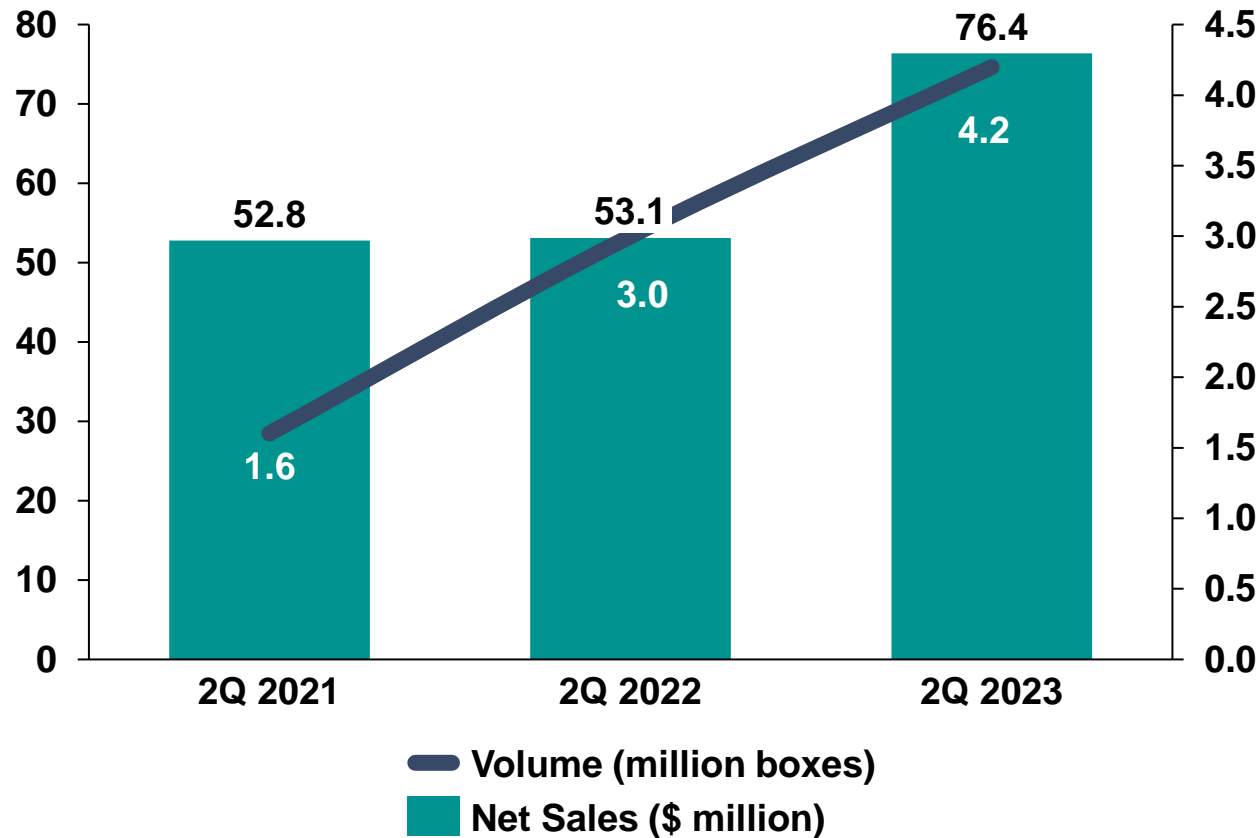
Mid 2024

- Expect approval and launch of CIA in China



# China: Continued Strong Performance from Volume Growth

## China Roxadustat Volumes & Net Sales



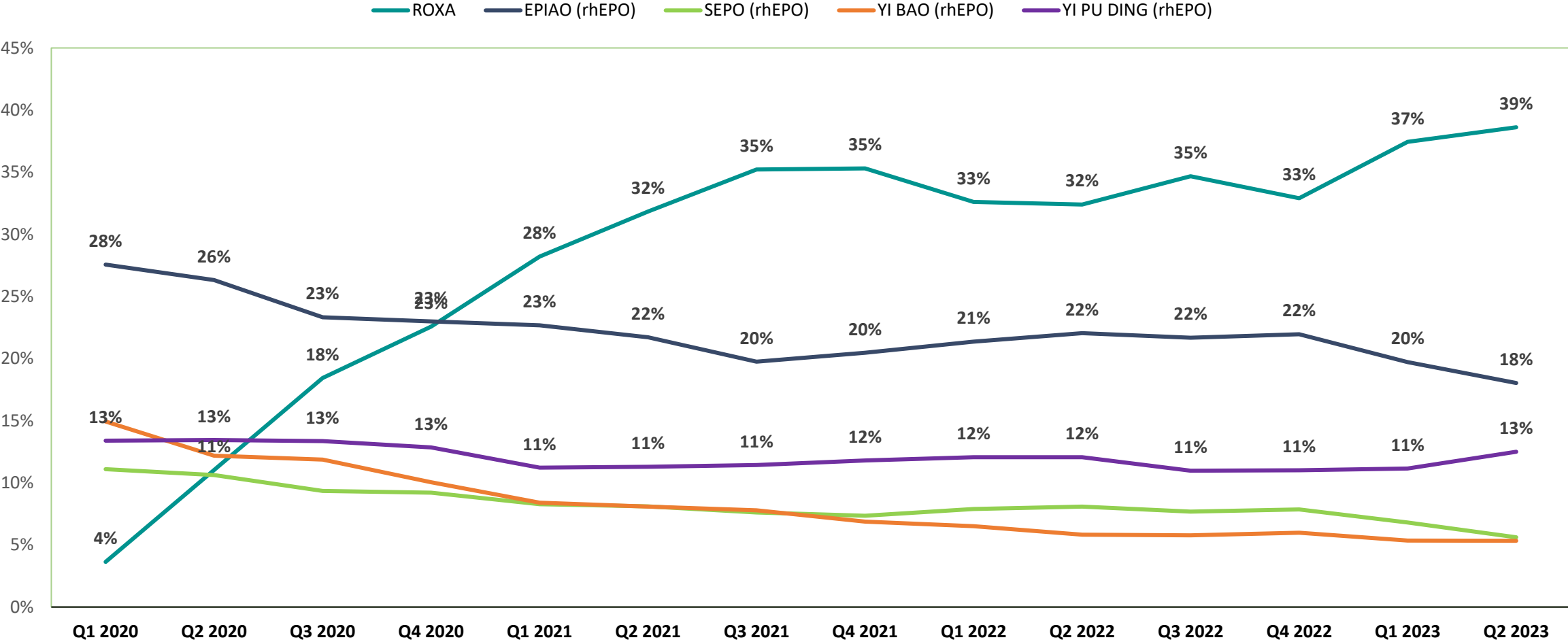
- ✓ Roxadustat net sales to distributors in China of \$76.4 million in second quarter of 2023 compared to \$53.1 million a year ago\*, representing 44% growth
  - ✓ Driven by an increase in volume of over 40%
- ✓ FibroGen net product revenue under U.S. GAAP of \$23.9 million in second quarter of 2023

\*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



Source: IQVIA MIDAS, July 2023. 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



# Early-Stage Oncology Pipeline

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# Fortis Therapeutics: Strategic Fit



## 1 Fortis' FOR46 (FG-3246) is a Unique, First-in-Class Opportunity

- Phase 1 antibody drug conjugate (ADC) against a novel target including a validated chemotherapy payload (vc-MMAE)
- Binds a unique epitope on CD46 present on cancer cells, including prostate and colorectal cancers, but absent in most normal tissues
- Clinically active with monotherapy activity in both solid tumors and heme-onc indications
- Well tolerated to date - side effects consistent with other vc-MMAE ADCs

## 2 Meaningful Opportunity Aligned with Corporate Strategy

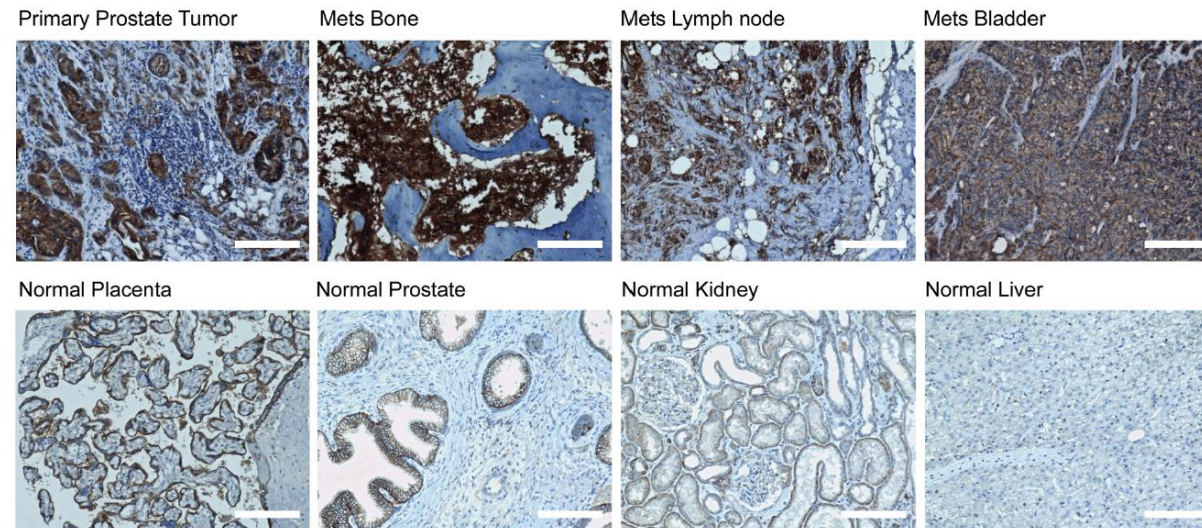
- First-in-class, best-in-class potential
- Biomarker driven oncology opportunity - PET biomarker targeting CD46 for patient selection (PET46)
- Anticipate the initiation of a Phase 2 trial in metastatic castration-resistant prostate cancer (mCRPC) in 2H 2024 with potential in other CD46 expressing cancers

## 3 Favorable Deal Structure

- Exclusive license for FG-3246 with Fortis Therapeutics, no upfront consideration
- FibroGen will conduct and fund future research, development, and manufacturing of FG-3246 and PET46
- During the four-year evaluation period, FibroGen has the option to acquire Fortis Therapeutics for \$80 million, and Fortis is eligible to receive up to a total of \$200 million based on various regulatory approvals

# FG-3246 for mCRPC and Other Solid Tumors

- ADC composed of anti-CD46 monoclonal (YS5) conjugated to cytotoxic payload monomethyl auristatin E (MMAE) via cleavable linker (mc-vc-PAB)
  - 5 out of 13 approved ADCs utilize MMAE as a payload
  - MMAE kills dividing cells by disrupting microtubule polymerization and blocking cell division
- FG-3246 targets a specific epitope on CD46 preferentially expressed (vs most normal tissue) on certain tumor types, including prostate and colorectal carcinomas

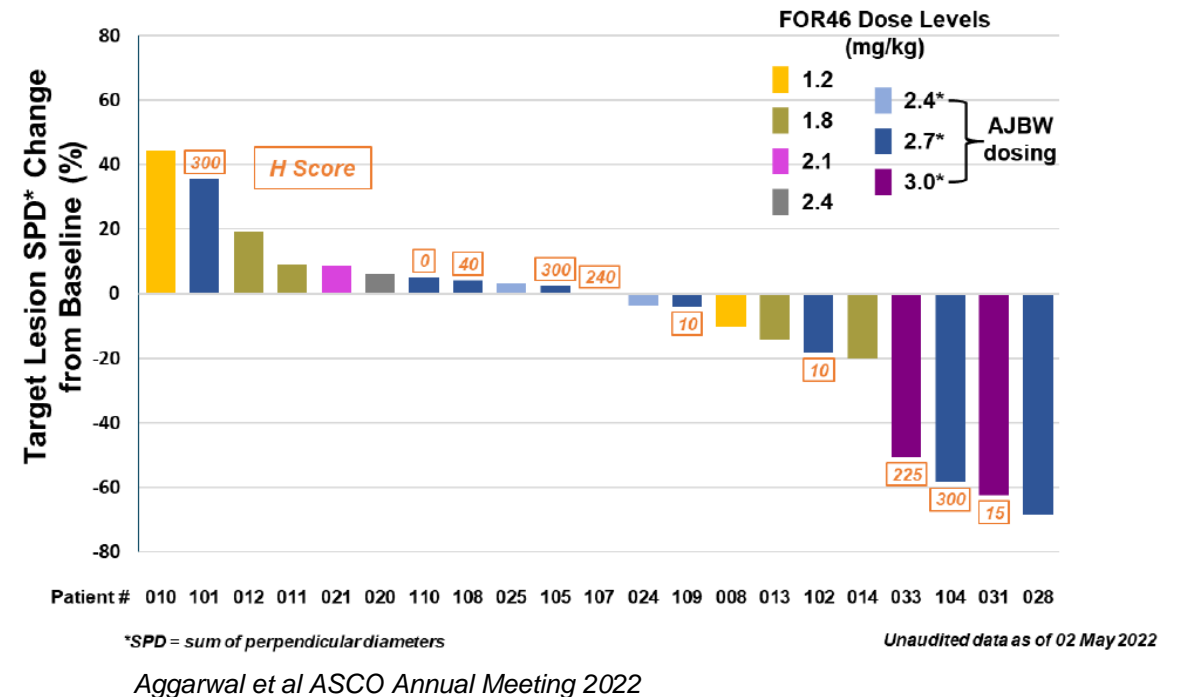


*Su et al JCI Insight 2018*

# FG-3246 is Clinically Active in Heavily Pretreated mCRPC Patients

## Phase 1 dose escalation and expansion study – median of 5 prior lines of therapy

- PSA50 response rate = 45%
  - Median duration of response  $\geq$  16 weeks
- ORR = 19%
  - 4 partial responses in 21 evaluable patients
- Safety profile consistent with other MMAE-based ADCs
- Additional patient data available following study completion





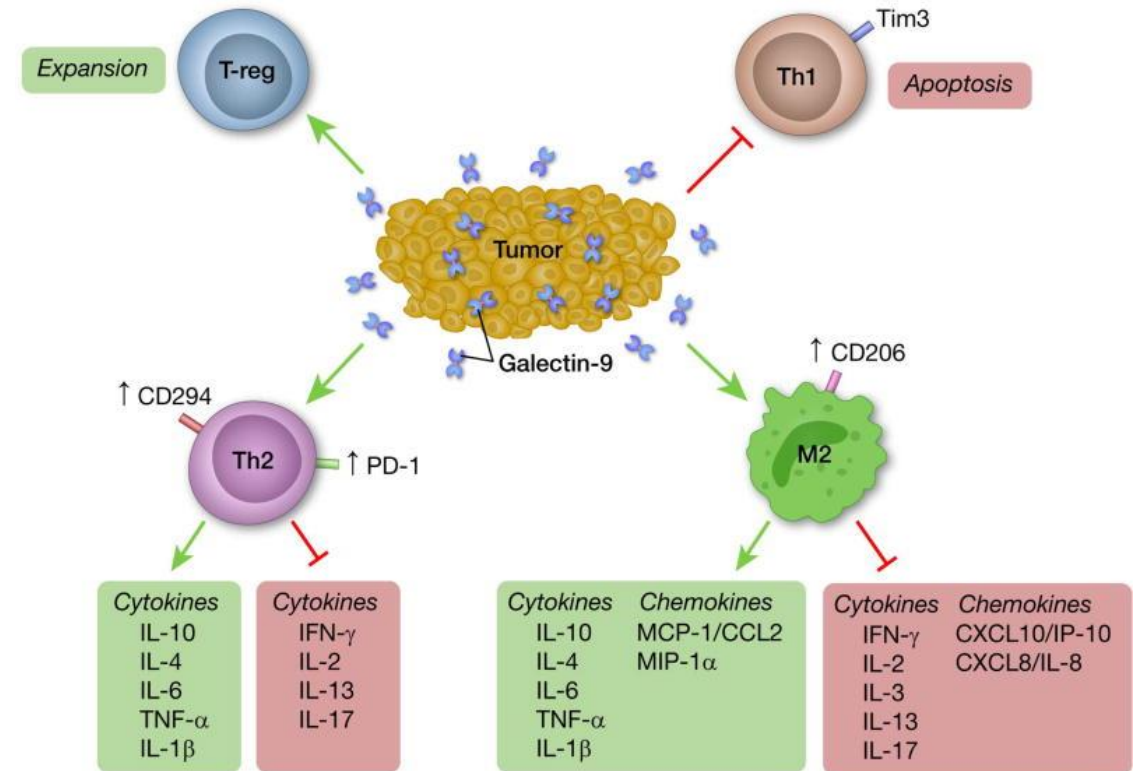
# Ongoing and Planned FG-3246 Clinical Studies

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	Late 2023/ Early 2024
Phase 1	FG-3246 combination with enzalutamide (n=36)	NCT05011188	Active, recruiting	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) Prescreening for CD46 expression with PET46 Retrospective analysis of correlation of PET positivity and efficacy	TBD	Pending	2026

# FG-3165: Anti-Gal9 Antibody for Immuno-Oncology

- High affinity monoclonal antibody against galectin-9 (Gal9) that counteracts Gal9-mediated immune suppression
- Clinically relevant *in vitro* biology
  - Blocks Gal9 driven apoptosis of effector T cells
  - Disrupts dimerization of TIM-3 and additional immunosuppressive lymphocyte receptors
- Surrogate antibody exhibits *in-vivo* anti-tumor activity in combination with other checkpoint inhibitors
- IND planned in 1Q 2024

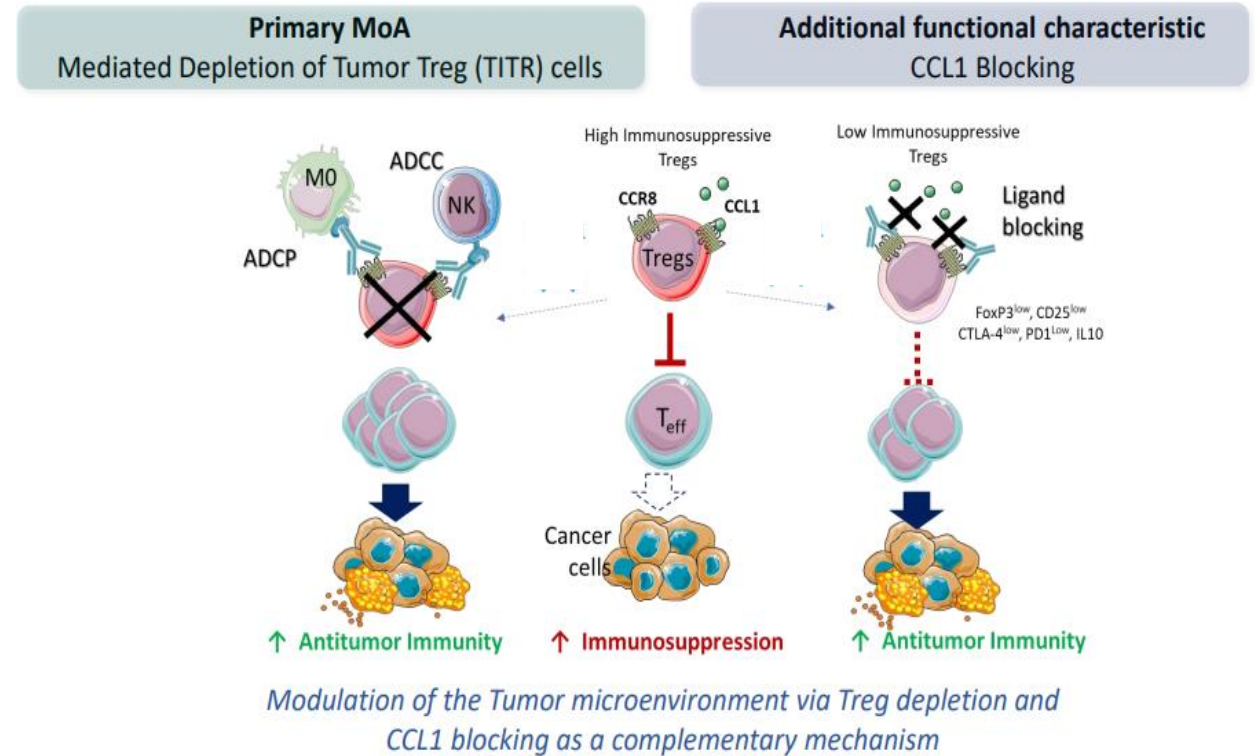


Enninga et al Melanoma Res 2016

# FG-3175: Anti-CCR8 Antibody for Immuno-Oncology

## Optimized variant of FG-3163 designed to address competitive clinical landscape

- High affinity monoclonal antibody against CCR8 with enhanced antibody-dependent cellular cytotoxicity (ADCC) activity
- 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 2H 2024



Kumar et al., AACR Annual Meeting 2022

# Financials

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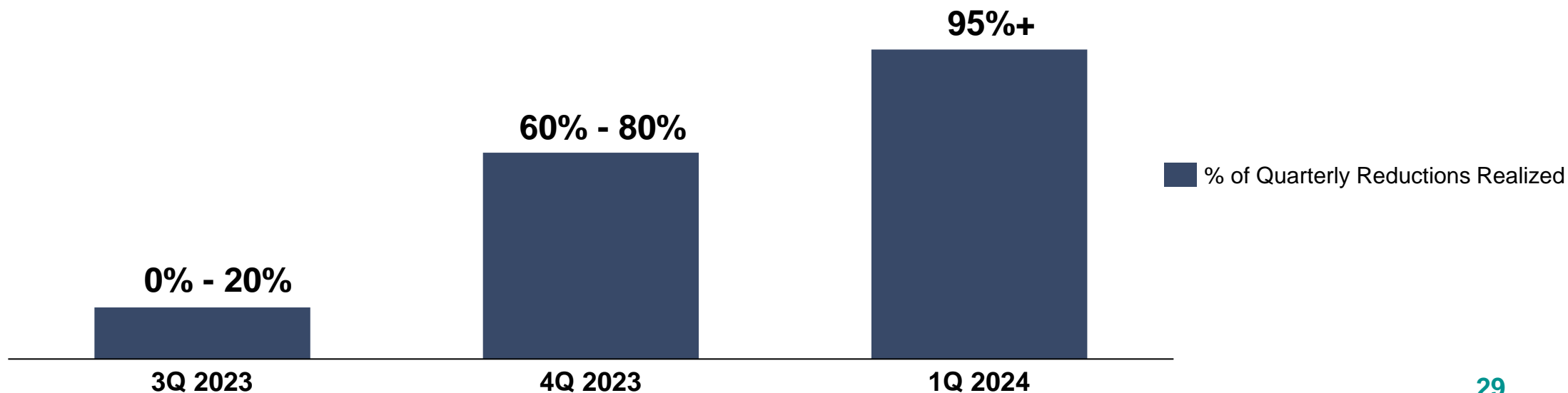


# Operating Expense Savings Ramp Over Coming Quarters

- Average total operating expenses excluding COGs and one-time charges was approximately \$105M per quarter in 1H 2023

	Three Months Ended March 31, 2023	Three Months Ended June 30, 2023	Quarterly Average Through June 30, 2023
<b>Operating expenses:</b>			
Total operating expenses	108,761	126,659	117,710
One-time Fortis charge	-	24,636	12,318
Total operating expenses less Fortis	108,761	102,023	105,392

- Excluding one-time expenses and charges, expected reductions of approximately \$100M - \$120M in annualized U.S. GAAP expenses, or \$25M - \$30M per quarter, starting in 3Q 2023, ramping in 4Q 2023, and completed in 1Q 2024





# Thank You

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