



FibroGen Reports Second Quarter 2024 Financial Results

August 6, 2024



Forward-Looking Statements

This presentation contains forward-looking statements regarding FibroGen's strategy, future plans and prospects, including statements regarding its commercial products and clinical programs and those of its collaboration partners Fortis and UCSF. These forward-looking statements include, but are not limited to, statements regarding the efficacy, safety, and potential clinical or commercial success of FibroGen products and product candidates, statements under the caption "Upcoming Milestones", statements regarding the expectation that cash, cash equivalents and accounts receivable will be sufficient to fund FibroGen's operating plans into 2026, and statements about FibroGen's plans and objectives. These forward-looking statements are typically 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, 2023, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, 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 presentation, except as required by law.

Late-Stage Pamrevlumab Program in Pancreatic Cancer Terminated



Pamrevlumab arm of PanCAN Precision Promise Phase 2/3 adaptive platform trial for the treatment of metastatic pancreatic ductal adenocarcinoma (mPDAC) did not meet primary endpoint.



LAPIS Phase 3 study of pamrevlumab in patients with locally advanced, unresectable pancreatic cancer (LAPC) did not meet primary endpoint.

FGEN Investment Opportunity

Focus on FG-3246 - a First-in-Class, CD46 Targeting ADC mAb

Compelling data from multiple Phase 1 studies in mCRPC reported in **2Q 2024**
Topline results from Phase 2 portion of FG-3246 + enzalutamide expected in **1H 2025**
Planned initiation of Phase 2 monotherapy dose optimization study in **1Q 2025**

Growing Roxadustat Revenue and Cash Flow

Growing revenue and cash flow stream from roxadustat; **approved in > 40 countries** and commercialized by AstraZeneca and Astellas

For 2024, FibroGen’s expected full year net product revenue under U.S. GAAP is raised to **\$135-\$150 million**, representing full year roxadustat net sales in China of **\$320-\$350 million**, due to continued strong underlying demand

Approval decision for chemotherapy induced anemia (CIA) sNDA in China **expected in 2H 2024**

Multiple Partnership Opportunities Across Pipeline

FibroGen regains rights to roxadustat in AZ territories (excluding China and South Korea): creating **potential partnership opportunities in indications such as anemia in patients with Low Risk-MDS**

Early oncology pipeline partnership opportunities:

- FG-3165 (Galectin-9 targeting mAb) for solid tumors (IND cleared and Phase 1 ready)
- FG-3175 (CCR8 targeting mAb) for solid tumors (Pre-clinical)

Strong Balance Sheet

\$147.1M in cash, cash equivalents, investments, and accounts receivable as of June 30, 2024

Expected to fund operating plans into 2026

An abstract geometric design in the top right corner of the slide. It features two small circles, one above the other, and several intersecting lines of varying thicknesses, all in a light blue-grey color.

FG-3246 and PET46 Program

Potential first-in-class anti-CD46 antibody drug conjugate (ADC) for metastatic castration-resistant prostate cancer and a companion PET imaging agent

Prostate Cancer Has a High Unmet Need for Treatment Options That Extend Survival in Late-Stage Disease

Prostate Cancer Facts

- 3.4 million men live with prostate cancer in the US
- Second most common cancer type after breast cancer.
 - ~13% of men will be diagnosed with prostate cancer at some point during their lifetime
- While most men diagnosed with prostate cancer can still live long lives, there are ~ 65K drug treatable cases in the US annually, where cancer has spread (metastasized) and become castrate resistant (mCRPC)
- 5-year survival in mCRPC is ~30%^{4,5}



Highest Unmet Needs in mCRPC

- Therapies that extend survival in patients who are ineligible or progressed on ARSI and/or chemo
- Therapies with novel MOAs for patients with advanced mCRPC who progressed on available treatment options
- Identification of predictive molecular markers in conjunction with novel therapies to inform patient selection
- Optimal combination and sequencing of therapies

FG-3246 – Potential First-in-Class ADC for the Treatment of mCRPC

FG-3246 Therapeutic

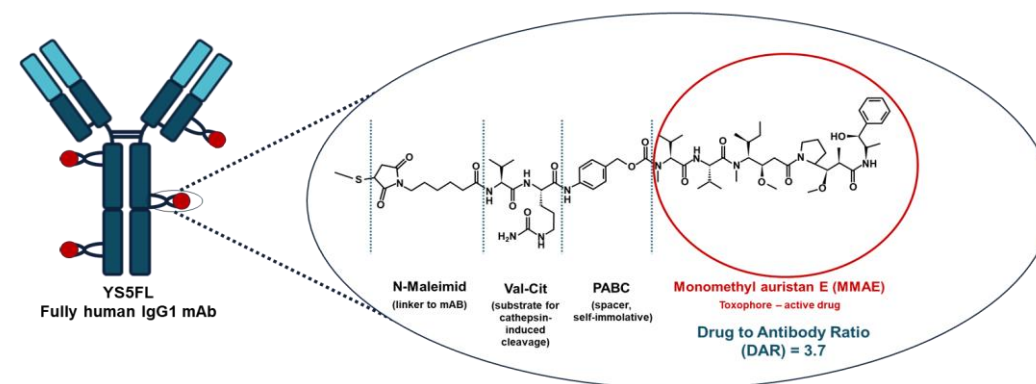
- Novel antibody-drug conjugate (ADC)
- Targeting antibody: YS5FL is a fully-human IgG1 monoclonal antibody to tumor-selective epitope of CD46
- Payload: MMAE - Potent anti-microtubule agent

CD46

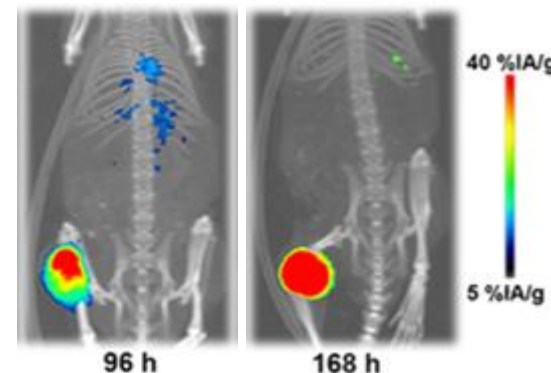
- Transmembrane protein negatively regulates the complement system
 - Upregulated during tumorigenesis
 - Binds both C3b + C4b
 - Helps tumors evade complement-dependent cytotoxicity (CDC)
- Overexpressed in prostate cancer, colorectal cancer, and other solid tumors vs. normal tissue

PET46 Biomarker

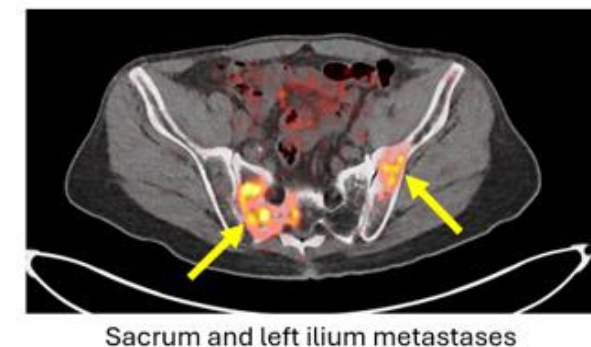
- Utilizes same targeting antibody as FG-3246
- ^{89}Zr biomarker demonstrated specific uptake in CD46 positive tumors



Mouse



Human



Development of a PET46, a CD46 Biomarker, is an Integral Part of the Development Strategy

- **Likely that patient selection biomarker is required** to achieve clinically differentiated profile in prostate cancer, based on early clinical data and highly competitive mCRPC market
- Estimate that 50%-70% of mCRPC patients will be CD46^{high}
- PSMA PET biomarker have demonstrated positive impact on patient outcomes

- **PET-based biomarker currently considered superior to CD46 IHC in prostate cancer** due to higher accuracy, applicability to patients with bone-only disease who are not amenable for IHC testing (~50% of advanced mCRPC)

- Exploratory Phase 2 trial required to assess utility of PET46 and CD46 IHC for patient selection and to select best patient selection strategy prior to Phase 3 trial

FG-3246 is Clinically Active in Heavily Pretreated mCRPC Patients

Data from Phase 1 dose escalation and expansion study:

Biomarker unselected and heavily pre-treated patient population with median of 5 prior lines of therapy

Efficacy Analysis Includes: Dose escalation cohorts-level ≥ 1.2 mg/kg, combined with cohort 1 (adenocarcinoma) of the dose expansion cohort

Median rPFS: 8.7 months

PSA Decline by >50%: 36%

ORR: 20%

Median Tumor DOR: 7.5 months

Safety: Adverse events consistent with those observed with other MMAE-based ADC therapies

rPFS: Radiographic progression free survival

PSA: Prostate specific antigen

ORR: Overall response rate

DOR: Duration of response

FG-3246 + Enzalutamide Showed Clinically Meaningful Efficacy Signals

Phase 1b combination results in biomarker unselected patients

- 1 The MTD and recommended Phase 2 dose of FG-3246 was established as 2.1 mg/kg adjusted body weight with primary G-CSF prophylaxis in combination with enzalutamide 160 mg daily
- 2 Preliminary anti-tumor activity was observed:
 - **Median rPFS: 10.2 months**
 - **PSA declines in 12/17 (71%)** of evaluable patients
- 3 Accrual is ongoing in Phase 2 with mandatory [⁸⁹Zr]-YS5 PET imaging performed during screening to determine its potential utility in patient selection

Topline results from Phase 2 portion of the study expected in 1H 2025

Data presented at ASCO 2024.

Varying Endpoints in Metastatic CRPC

Radiographic Progression-Free Survival

Survival endpoint that has been accepted for regulatory approval

BICR and use of standard criteria (PCWG3 + modified RECIST 1.1)

PSA50 and PSA90 response rates

Surrogate endpoint useful for gauging preliminary anti-tumor activity

May not be as applicable for all agents (e.g. radium-223)

Objective response rate

Surrogate endpoint useful for gauging preliminary anti-tumor activity

Requires measurable disease by RECIST 1.1 (only ~ 30-40% of mCRPC)

FG-3246 Clinical Studies

Multiple studies generate value inflection points for the program

Stage	Study	NCT#	Status	Recent & Anticipated Milestones
Phase 1	FG-3246 monotherapy dose escalation and expansion trial in patients with mCRPC (N=56)*	NCT03575819	Completed	Positive topline results reported in 2Q 2024
Phase 1b/2	FG-3246 combination with enzalutamide in patients with mCRPC (N=36)**	NCT05011188	Active, recruiting	Positive Phase 1b interim results reported in 2Q 2024 and presented at ASCO; Phase 2 topline results expected in 1H 2025
Phase 1	PET46 imaging development study (N=24)	NCT05245006	Active, recruiting	2024
Phase 2	An open label dose optimization study in patients with $\geq 2L$ mCRPC*** Initial imaging for CD46 expression with PET46 Retrospective analysis of correlation of PET positivity and efficacy	TBD	Pending	Anticipate initiation in 1Q 2025

FG-3246 Program Upcoming Catalysts

3Q 2024

Meet with the FDA to
discuss FG-3246
development plan

FG-3246 IND
submission

4Q 2024

PET46 IND
Submission

1H 2025

Initiate Phase 2
FG-3246 dose optimization
(monotherapy) trial with
PET46 screening in 1Q 2025

Topline results from the IST
Phase 2 trial of FG-3246 +
enzalutamide in 1H 2025

FG-3246 Presents a Unique Opportunity in mCRPC

1 Novel Mechanism of Action and Potential First-in-Class Opportunity

- ADC – antibody against novel target tethered to a validated chemotherapy payload
- Binds a unique epitope on CD46 present on cancer cells, including prostate/colorectal, but absent in most normal tissues

2 Investigating PET Biomarker Imaging Agent

- CD46 biomarker diagnostic, PET46, in development for screening, patient selection and enrichment

3 Phase 1 Efficacy Results

- **FG-3246 monotherapy activity in biomarker unselected patients in selected cohorts receiving ≥ 1.2 mg/kg:**
 - Median rPFS of 8.7 months
 - PSA decline by $>50\%$: 36%
 - ORR: 20%
- **Combination FG-3246 + Enzalutamide in biomarker unselected patients:**
 - Median rPFS: 10.2 months
 - PSA declines in 12/17 (71%) of evaluable patients

4 Consistent Safety Profile

- Adverse events consistent with those observed with other MMAE-based ADC therapies

5 Potential Opportunity in Multiple Cancer Types

- Multiple lines of mCRPC
- Colorectal and other solid tumors

Roxadustat

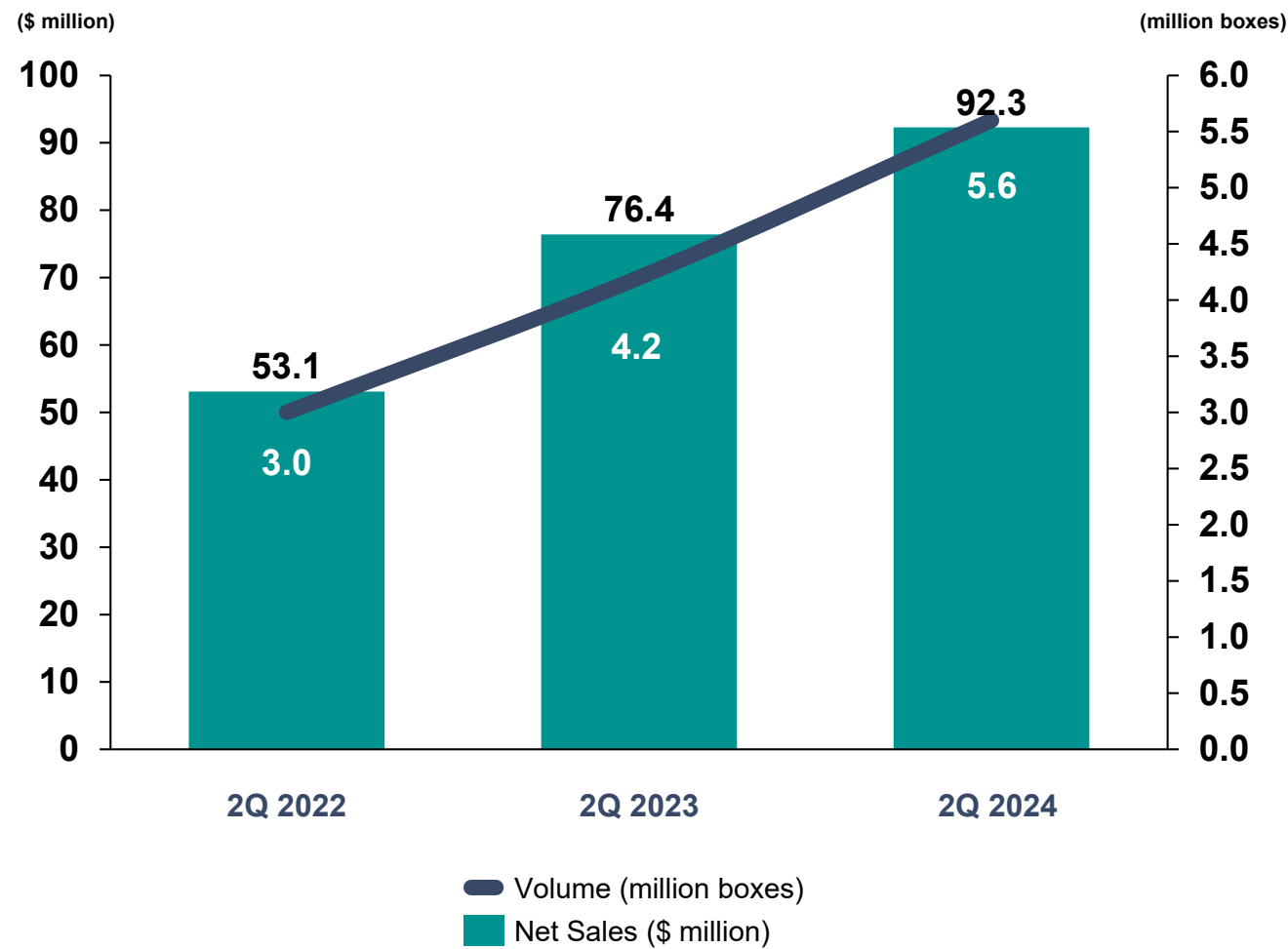
Oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor, **based on 2019 Nobel Prize-winning science**, for the treatment of anemia





China: Continued Strong Performance from Volume Growth

China Roxadustat Volumes & Net Sales



21% YEAR OVER YEAR GROWTH

Roxadustat net sales to distributors in China of \$92.3 million in second quarter of 2024 compared to \$76.4 million a year ago*

- Driven by an increase in volume of 33%

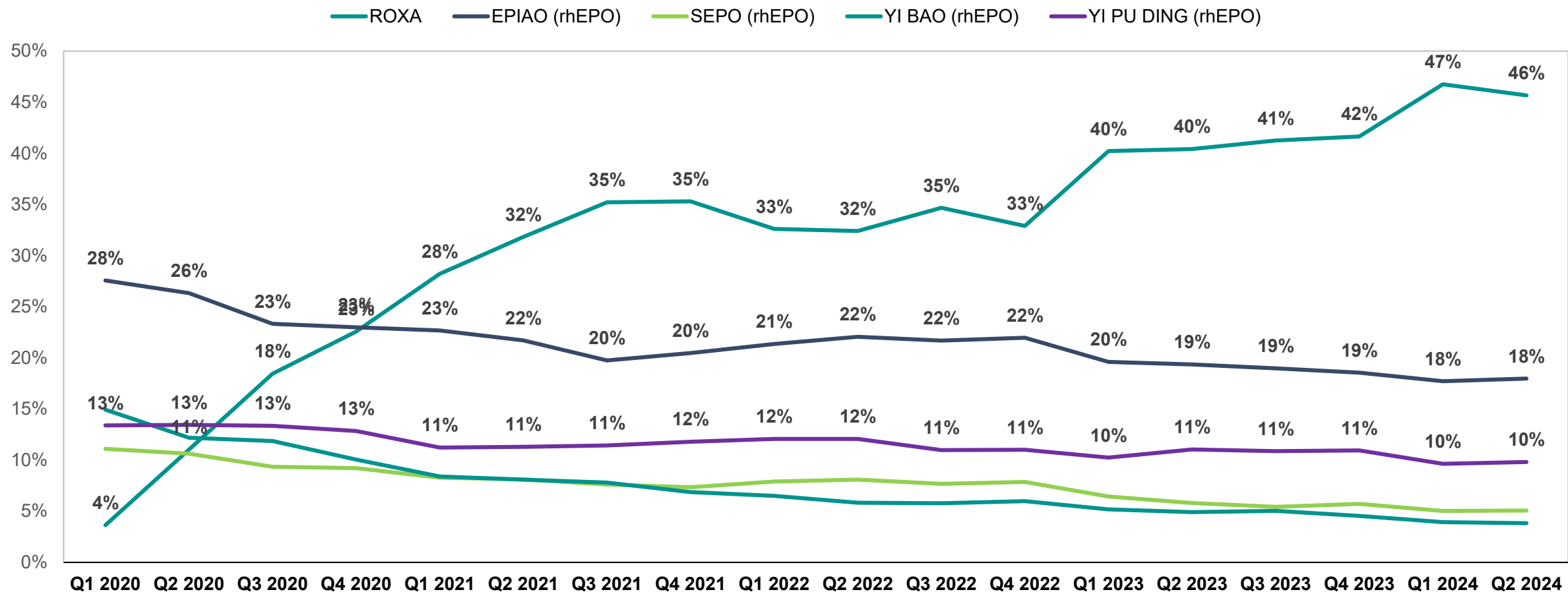
FibroGen net product revenue under U.S. GAAP of \$49.6 million in second quarter of 2024 compared to \$23.9 million a year ago, representing 108% year over year growth

*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.



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

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



April - May only

Source: IQVIA MIDAS; 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

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: China and South Korea

FibroGen: US 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 3Q 23. **Approval decision expected 2H 2024.**

Opportunity to partner roxadustat for MDS.

Financials



Thank You

For more information contact ir@fibrogen.com

NASDAQ: FGEN