



FibroGen Reports Third Quarter 2024 Financial Results

November 12, 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 potential for cash, cash equivalents and accounts receivable 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 September 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.

FibroGen Strategic Pillars and Investment Highlights

Focus on FG-3246 and FG-3180 - a First-in-Class, CD46 Targeting ADC and PET Imaging Agent

Compelling data from two 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 reiterated to **\$135-\$150 million**, representing full year roxadustat net sales in China of **\$330-\$350 million**, due to continued strong underlying demand

Approval decision for chemotherapy induced anemia (CIA) sNDA in China **expected in early 2025**

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 Lower 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

\$160.0M in cash, cash equivalents, investments, and accounts receivable as of September 30, 2024

Assuming additional repatriation of cash from our China operations, cash, cash equivalents, and accounts receivable expected to fund operating plans into 2026



FG-3246 and FG-3180 Program

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

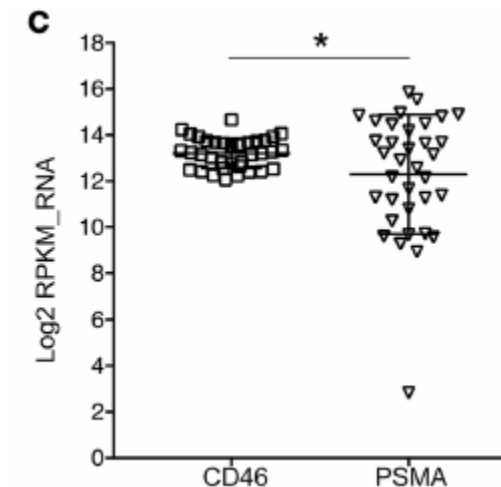
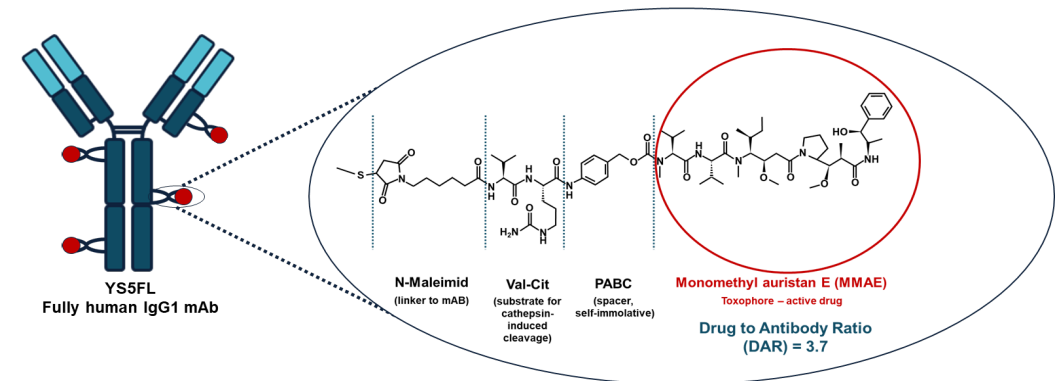
FG-3246 Therapeutic

- 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

Novel CD46 Epitope

- Transmembrane protein negatively regulates the complement system
 - Upregulated during tumorigenesis
 - Helps tumors evade complement-dependent cytotoxicity (CDC)
- Highly expressed in mCRPC tissues with lower interpatient variability and higher median expression compared with PSMA
- Expression up-regulated in the progression from localized castration-sensitive prostate cancer to mCRPC and further overexpressed following treatment with androgen signaling inhibitors
- Overexpressed in colorectal cancer, and other solid tumors vs. normal tissue

Su et al JCI Insight 2018



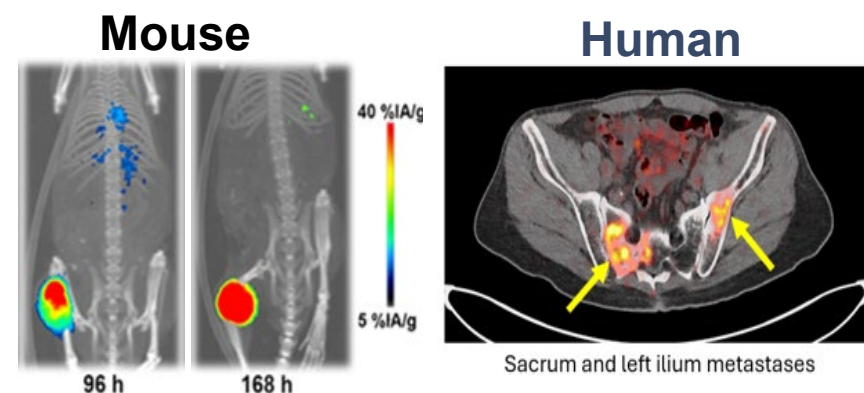
Su et al JCI Insight 2018

FG-3180, a PET Imaging Agent, is an Integral Part of the Development Strategy

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

- **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 biomarkers have demonstrated positive impact on patient outcomes

- **PET-based biomarker currently considered superior to CD46 IHC in prostate cancer** due to potential greater applicability to patients with bone-only disease who are not amenable for IHC testing (~50% of advanced mCRPC)
- Exploratory Phase 2 trial designed to assess utility of PET46 and CD46 IHC for patient selection and to determine best patient selection strategy prior to Phase 3 trial



FG-3246 is Clinically Active as Monotherapy and in Combination with Enzalutamide

Phase 1 monotherapy dose escalation and expansion results

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

Initiate Phase 2 monotherapy dose optimization study in 1Q 2025

Phase 1b portion of IST of FG-3246 in combination with enzalutamide results

Median rPFS: 10.2 months

PSA declines in 12/17 (71%) of evaluable patients

The MTD and recommended Phase 2 dose of FG-3246 (2.1mg/kg) was established in combination with enzalutamide 160 mg daily

Accrual is ongoing in Phase 2 with mandatory FG-3180 ([⁸⁹Zr]-YS5 PET imaging) during screening to determine its potential utility in patient selection

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

mCRPC Landscape Data: Enzalutamide/Abiraterone rPFS, 2nd line treatment, ≥1 ARSI

Trial Name	Sponsor	Therapeutic	Comparator	rPFS (months)												
				1	2	3	4	5	6	7	8	9	10	11		
TRITON3	pharmaand	Rucaparib	Enza/abi /docetaxel							6.4						
PSMAfore	Novartis	¹⁷⁷ Lu-PSMA-617	Enza/abi							5.6						
Splash	POINT Biopharma	¹⁷⁷ Lu- PNT2002	Enza/abi							6.0						
PROfound	AstraZeneca	Olaparib	Enza/abi				3.6									
CONTACT-02	Exelixis	Cabozantinib/ Atezolizumab	Enza/abi /prednisone				4.2									
Ph1 FG-3246 Monotherapy	Fortis	FOR46 / FG-3246	N/A										8.7			
Ph1 FG-3246 Combination	UCSF	FG-3246 / Enzalutamide	N/A												10.2	

Monotherapy Study: Heavily pre-treated patient population with median of 5 prior lines of therapy
Combination Study: Majority of 17 patients exposed to 2 prior ARSIs.

FG-3246 Phase 2 Design Highlights

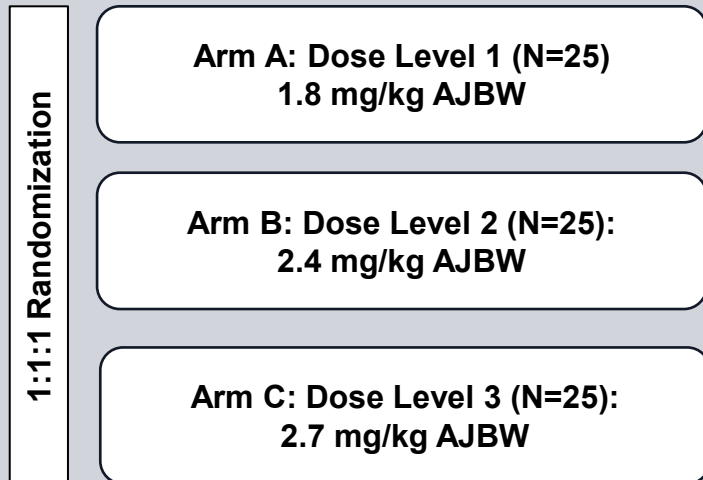
Dose Optimization in Post-ARSI, Pre-Chemo mCRPC, All Comers, US only

Phase 2 - FG-3246 Dose Optimization

Primary Endpoint: Optimal dose for Phase 3 based on efficacy, safety, and PK

Secondary Endpoints: rPFS, PSA50, PSA90

Exploratory Endpoint: FG-3180 (PET imaging agent) as a diagnostic radiopharmaceutical



All arms will use primary prophylaxis with G-CSF

Safety Review Committee

- Planned review when 10 patients in each arm complete cycle 1
- Planned review when 25 patients in each arm complete cycle 1
- Ad hoc as needed

Interim Analysis

- Futility evaluated by rPFS at 6 months
- Exposure/Response analysis
- Planned for 6 months post N=15 enrolled in each cohort

Final Analysis

- Planned for 12 months post N=25 enrolled in each cohort
- Benefit/Risk assessment (Recommended Phase 3 Dose)
- Decision on FG-3180 for patient pre-selection in Phase 3

FG-3246 and FG-3180 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=41)**	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	FG-3180 (PET46) imaging development study (N=~34)**	NCT05245006	Active, recruiting	1H 2025
Phase 2	An open label dose optimization study in patients with mCRPC Initial imaging for CD46 expression with FG-3180 PET biomarker Retrospective analysis of correlation of PET positivity and ADC efficacy	TBD	Pending	Anticipate initiation in 1Q 2025

FG-3246 Program Recent & Upcoming Catalysts

3Q 2024

- ☑ Productive meeting with the FDA to discuss development path

4Q 2024
+
1Q 2025

FG-3246 (4Q 2024) and
FG-3180 (1Q 2025)
IND Submissions

1H 2025

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

Topline results from the Phase 2
investigator sponsored study 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, FG-3180 (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

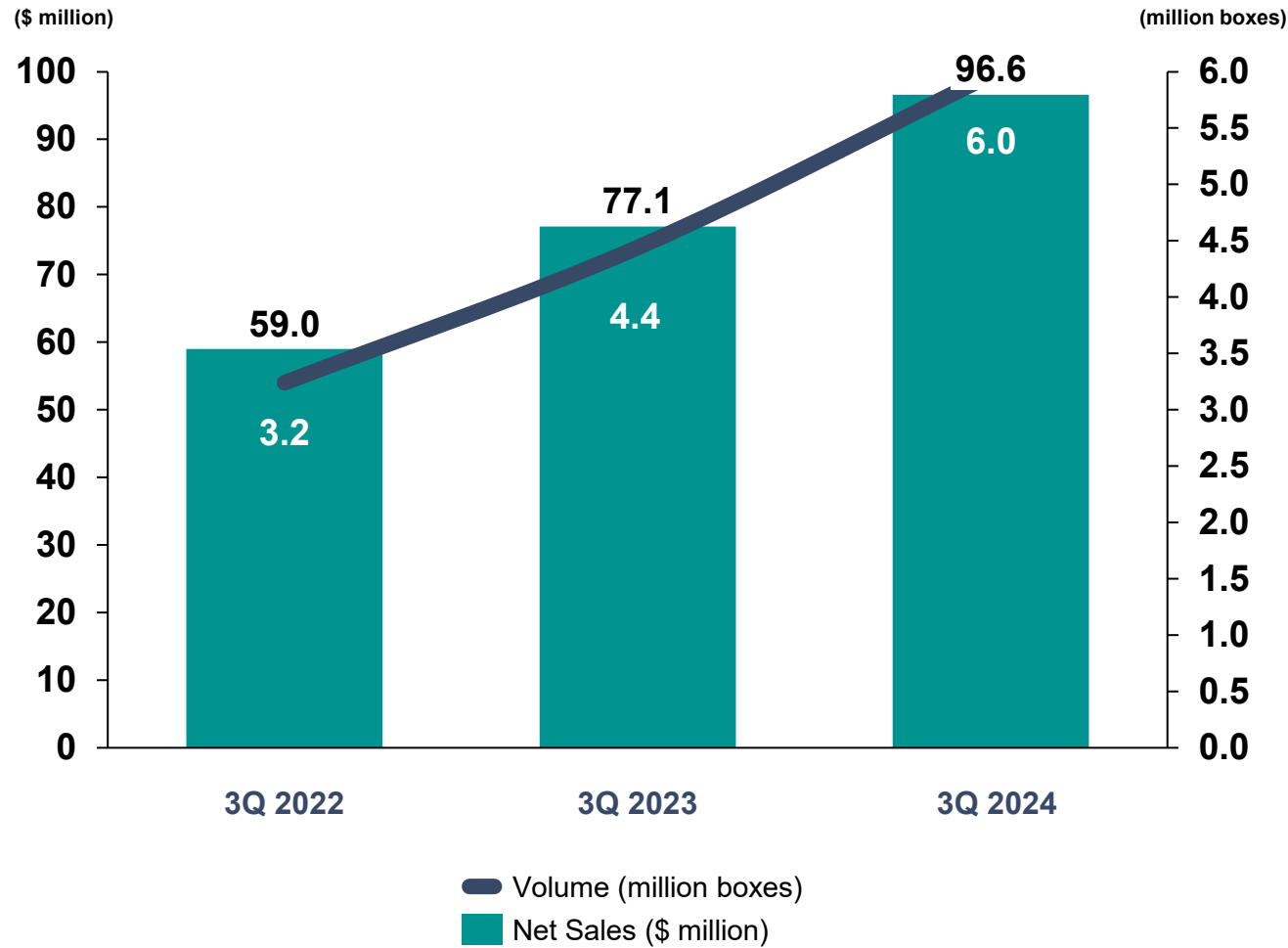
Oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor, **based on 2019 Nobel Prize-winning science**, for the treatment of anemia





China: Continued Strong Performance from Volume Growth

China Roxadustat Volumes & Net Sales



25% YEAR OVER YEAR GROWTH

Roxadustat net sales to distributors in China of \$96.6 million in third quarter of 2024 compared to \$77.1 million a year ago*

- Driven by an increase in volume of 34%

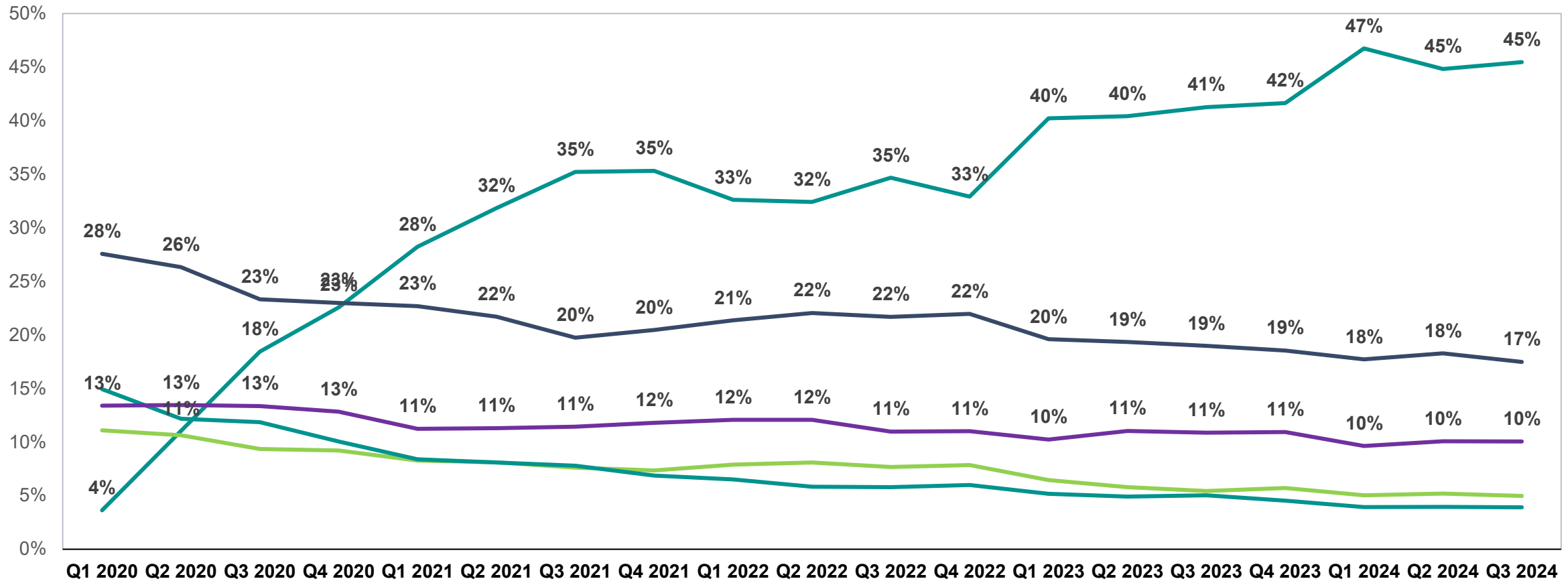
FibroGen net product revenue under U.S. GAAP of \$46.2 million in third quarter of 2024 compared to \$29.4 million a year ago, representing 57% year over year growth



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

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

ROXA EPIAO (rhEPO) SEPO (rhEPO) YI BAO (rhEPO) YI PU DING (rhEPO)



July - August 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 Approved in Multiple Countries Worldwide

Roxadustat (爱瑞卓®, EVRENZO™) is **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.

Additional Indications Under Evaluation

Anemia associated with chemotherapy-induced anemia (CIA) – sNDA accepted in China based on positive Phase 3 study. **Approval decision expected in early 2025.**

Opportunity to partner or develop roxadustat for anemia associated with Lower-Risk MDS.



Anemia from Lower-Risk MDS is a High Unmet Need Opportunity

High Unmet Need¹

~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 luspatercept)

Significant Opportunity

Targeted Phase 3 program could enable an approval in anemia from Lower-Risk MDS

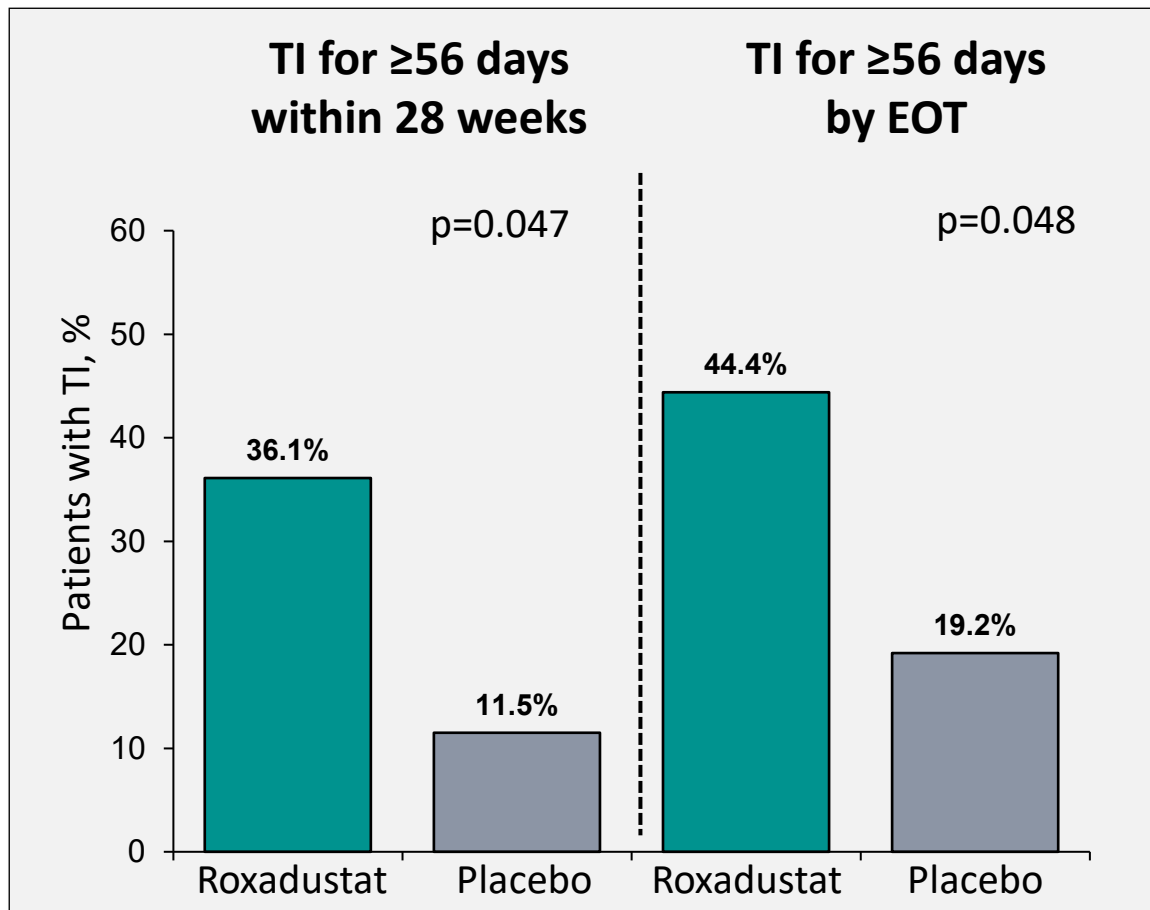
FDA Orphan designation would provide 7 years of data exclusivity in the U.S.*

Attractive pricing opportunity combined with efficient commercial model; potential for 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 LR-MDS: Phase 3 Development Opportunity Based on Subgroup Results from MATTERHORN Phase III Trial

More Patients With a Higher Transfusion Burden^a Receiving Roxadustat Achieved TI vs Placebo



% (95% CI)	Roxadustat (n=36)	Placebo (n=26)	Roxadustat vs placebo
TI for ≥56 days within 28 weeks ^b	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 ^b	44.4% (27.9–61.9)	19.2% (6.6–39.4)	OR: 3.369 (1.014–11.189); p=0.048

^aHigher transfusion burden defined as ≥2 pRBC units Q4W

Financials



Thank You

For more information contact ir@fibrogen.com

NASDAQ: FGEN