



# FibroGen Reports Fourth Quarter and Full Year 2024 Financial Results

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**March 17, 2025**



## 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”, the net cash portion of the purchase price and closing of the sale of FibroGen China as well as the payoff of the Morgan Stanley Tactical Value term loan, statements regarding cash, such as the expectation that cash, cash equivalents and accounts receivable will be sufficient to fund FibroGen’s operating plans into 2027, 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 most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, 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 presentation, and FibroGen undertakes no obligation to update any forward-looking statement in this presentation, except as required by law.

# Completing FibroGen Transformation: Delivering on 2025 Strategic Priorities

## Transformational Sale of FibroGen China for Approximately \$160 Million

- Simplifies FibroGen operations to focus on high-value assets in the U.S.
- Payoff Morgan Stanley Tactical Value term loan facility
- Most efficient way to access all FibroGen net cash held in China and extend cash runway into 2027

## FG-3246 and FG-3180: Attractive Assets in Prostate Cancer

- FG-3246, a potential first-in-class, CD46 targeting ADC, with clinically meaningful responses in pretreated mCRPC and a well-characterized safety profile
  - Phase 1 monotherapy study median rPFS of nearly 9 months (~5 prior lines of therapy) compares favorably with results of standard of care agents evaluated in contemporary mCRPC trials in the post-ARSI setting
- FG-3180, a PET imaging agent, in clinical development as potential novel patient selection biomarker
- Opportunity to pursue multiple registrational pathways sequentially or in parallel: multiple lines of therapy in prostate cancer, monotherapy or combination therapy, and all comers or CD46<sup>high</sup> selected patients

## Roxadustat: Meaningful Commercial and Late-Stage Development Opportunity

- Approved in > 40 countries and commercialized by AstraZeneca and Astellas
- Compelling wholly owned, late-stage, U.S. development opportunity in anemia due to LR-MDS

## Multiple Near-Term Catalysts

- Initiation of Phase 2 monotherapy trial of FG-3246 in mCRPC, post-ARSI / pre-chemo setting by mid-2025
- Planned meeting with the FDA for the development program of roxadustat in LR-MDS in 2Q 2025
- Topline results from Phase 2 portion of IST for FG-3246 in combination with enzalutamide in mCRPC in 2H 2025
- Interim results from Phase 2 monotherapy trial of FG-3246 expected in mid-2026



# FG-3246 and FG-3180 Program

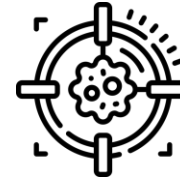
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Potential first-in-class anti-CD46 antibody drug conjugate (ADC) for metastatic castration-resistant prostate cancer and PET imaging agent

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



Prostate cancer is the **second most common** cancer type



~ **65,000 drug treatable mCRPC** cases in the U.S. annually



**13%** of men **will be diagnosed with prostate cancer** at some point during their lifetime



**5-year survival** in mCRPC is ~**30%**

## Highest Unmet Needs in mCRPC

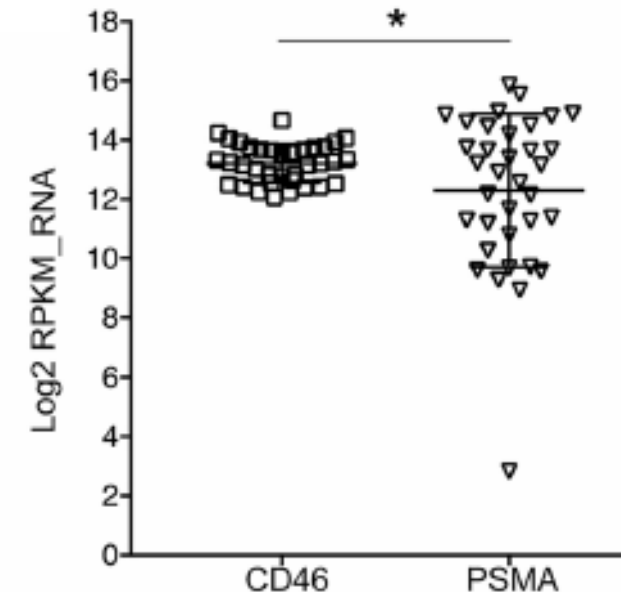
- Therapies that extend survival in patients who are ineligible for or progressed on ARSI and/or chemotherapy
- Novel MOAs that can treat patients who progressed on available treatment options (ex. non-PSMA)
- Predictive tools to inform patient selection
- Optimal combination and sequencing of therapies

# CD46 as a Novel Tumor Selective Target in Solid Tumors

CD46 negatively regulates the complement system and helps tumors evade complement-dependent cytotoxicity

- **CD46 is a multi-functional protein**
  - Negatively regulates the complement system and helps tumors evade complement-dependent cytotoxicity
  - A part of a protein complex mediating cytoskeletal dynamics, invasion, and metastasis
- **It is overexpressed in mCRPC, colorectal cancer, and other solid tumors vs normal tissues**
- **CD46 expression is up-regulated as prostate cancer progresses from localized castration-sensitive prostate cancer to mCRPC**
  - CD46 is then further overexpressed following treatment with androgen signaling inhibitors
- **50%-70% of mCRPC patients are estimated to have high expression of CD46 (CD46<sup>high</sup>)**

Gene expression in mCRPC<sup>1</sup>



**CD46 is overexpressed homogenously and at higher levels compared to PSMA**

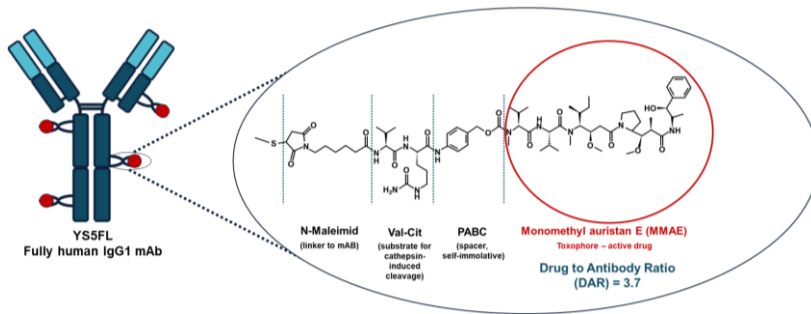
# Targeting a Novel Epitope of CD46 Has Therapeutic and Diagnostic Potential

## FG-3246 Therapeutic

Targeting antibody: YS5FL is a fully-human IgG1 mAb to tumor-selective epitope of CD46

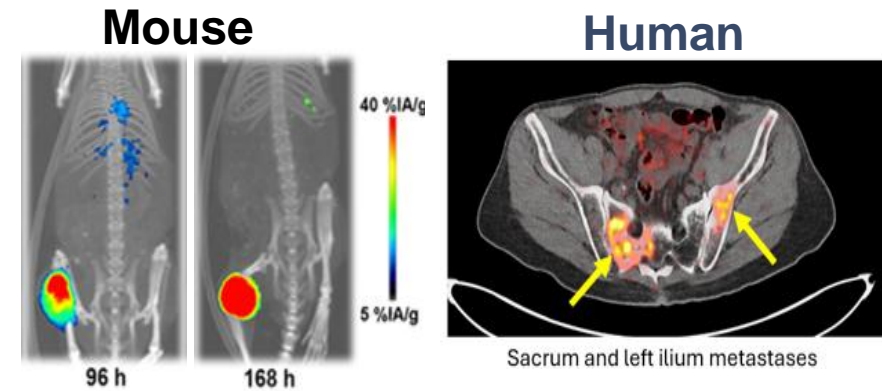
Payload: MMAE – a potent anti-microtubule agent (validated chemotherapy)

- Binds to an epitope that is not fully formed/less accessible on most normal cells
- Does not interfere with complement system regulation
- **Androgen receptor agnostic approach**



## FG-3180 PET Imaging Agent

- Utilizes same targeting antibody as FG-3246 with  $^{89}\text{Zr}$  biomarker demonstrating specific uptake in CD46 positive tumors
- Potential to inform patient selection
- PET-based biomarker currently considered superior to CD46 IHC in prostate cancer

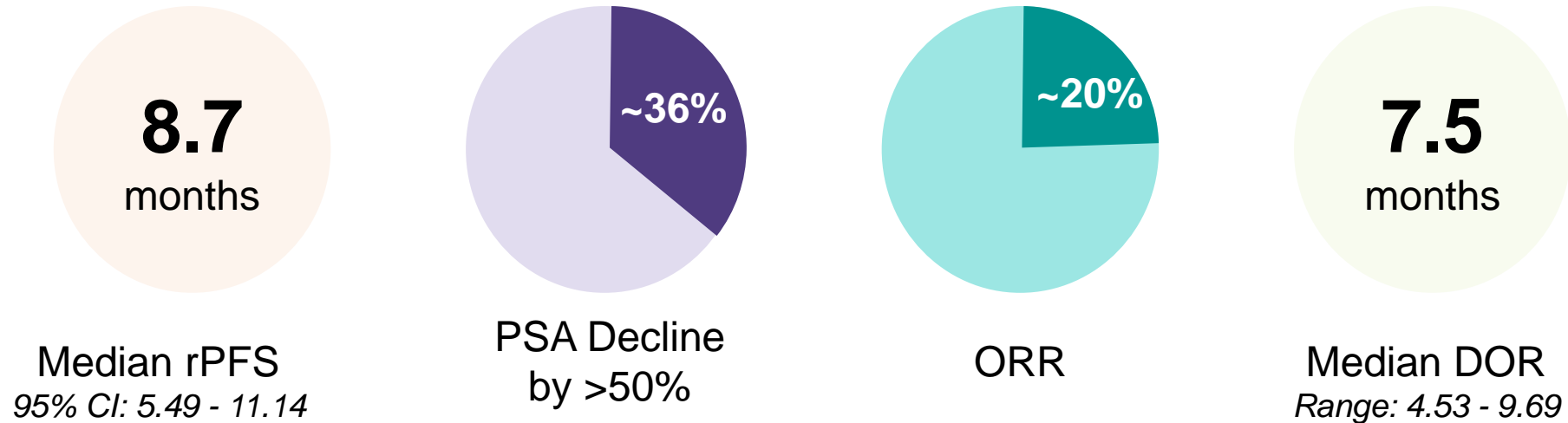


Development strategy aims to achieve **clinically differentiated profile** in competitive yet dissatisfied mCRPC market

# FG-3246 Demonstrated Meaningful Monotherapy Clinical Activity in 5L+ mCRPC Patients

Phase 1 dose escalation and expansion study results in biomarker unselected and heavily pre-treated patient population with median of 5 prior lines of therapy

Efficacy analysis included **40 patients** from the dose escalation cohorts-level  $\geq 1.2$  mg/kg and cohort 1 (adenocarcinoma) of the dose expansion cohort at 2.7 mg/kg AJBW



2.7 mg/kg AJBW declared as the MTD in the study



# FG-3246 Demonstrated Compelling Survival Benefit in a Significant Sample Size of Heavily Pre-Treated and Biomarker Unselected Patients vs Comparable Early-Stage Studies

Sponsor	Therapeutic	Median Treatment Line	rPFS Evaluable Patients	rPFS (months)										
				1	2	3	4	5	6	7	8	9	10	11
Amgen	Xaluritamig (AMG509)	4L	N=106								7.8			
Janux	JNAX007	5L	N=8								7.4			
Daiichi Sankyo	DS-7300	6L	N=54 (DOR only)				4.4 (DOR Only)							
ARX517	Ambrx (now J&J)	5L	Not Reported	Not Reported										

Fortis	FOR46 / FG-3246	5L+	N=40									8.7		
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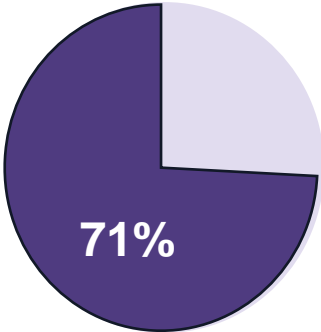
**Monotherapy Study: Heavily pre-treated patient population with median of 5 prior lines of therapy**

# Clinically Meaningful Efficacy Signals Observed in the Phase 1b Portion of the Ongoing Study Evaluating FG-3246 in Combination with Enzalutamide in mCRPC

Phase 1b interim results in biomarker unselected patients, majority of which **exposed to 2 prior ARSIs**



Preliminary Estimate of Median rPFS



% of evaluable patients with PSA declines

- The MTD and recommended Phase 2 dose of FG-3246 was established as 2.1 mg/kg AJBW with primary G-CSF prophylaxis in combination with enzalutamide 160 mg daily
- Phase 2 portion is currently ongoing 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 2H 2025

# FG-3246 5L+ Monotherapy and 2L+ Combination Therapy Demonstrated Compelling Survival Benefit in Biomarker Unselected Patient Population vs 2L Therapies in Late-Stage Trials

Phase 3 Trial	Sponsor	Patient Selection	Therapeutic   Comparator	rPFS (months)												
				1	2	3	4	5	6	7	8	9	10	11	12	
TRITON3 <sup>1,*</sup>	pharmaand	BRCA mutant	Rucaparib												11.2	
			Enza/abi/docetaxel						6.4							
PSMAfore <sup>2</sup>	Novartis	PSMA positive	<sup>177</sup> Lu-PSMA-617													12.0
			Enza/abi					5.6								
Splash <sup>3</sup>	POINT Biopharma	PSMA positive	<sup>177</sup> Lu- PNT2002											9.5		
			Enza/abi						6.0							
CONTACT-02 <sup>5</sup>	Exelixis	Visceral disease or extrapelvic adenopathy	Cabozantinib/ Atezolizumab							6.3						
			Enza/abi/prednisone				4.2									

## Contemporary Chemotherapy Data

KEYNOTE-921	Merck	All Comers	pembro + docetaxel											8.6		
			Docetaxel											8.3		

## Results in unselected patients:

Ph1 FG-3246 Monotherapy	Fortis	All Comers	FG-3246											8.7		
Ph1 FG-3246 Combination	UCSF		FG-3246 + Enzalutamide												10.2	

While we cannot make direct comparisons to other trials due to differences in study design, analysis methods, population sizes, controls and phases of development, we are encouraged there are opportunities for new treatments

\*in patients with BRCA mutation. \*\*In patients with BRCA, ATM or other prespecified mutations.

1. Fizazi K, et al. *NEJM*. 2023;388(8):719-732. 2. Morris MJ, et al. *Lancet*. 2024;404(10459):1227-1239. 3. POINT Biopharma PR. December 18, 2023. 4. de Bono J, et al. *NEJM*. 2020;382(22):2091-2102. 5. Agarwal N, et al. *ASCO* 2024.

# FG-3246 and FG-3180 Phase 2 Monotherapy Design Highlights

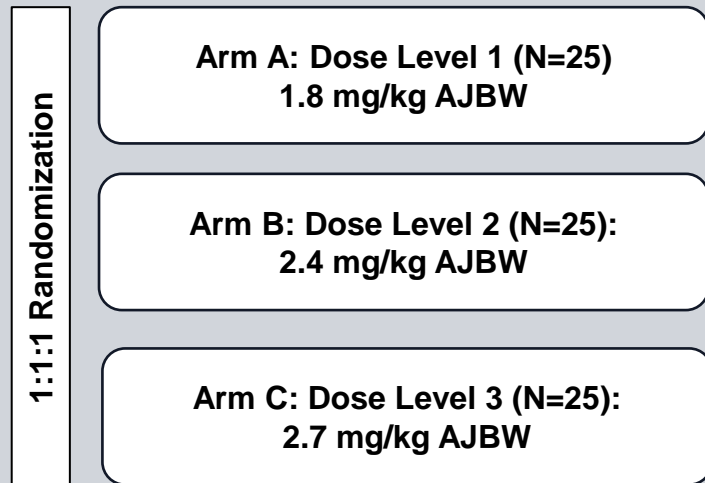
Phase 2 monotherapy trial initiation is expected by mid-2025

## Phase 2 - FG-3246 Dose Optimization in Post-ARSI, Pre-Chemo mCRPC, All Comers (US only)

**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

### Expected Mid-2026

#### Interim Analysis

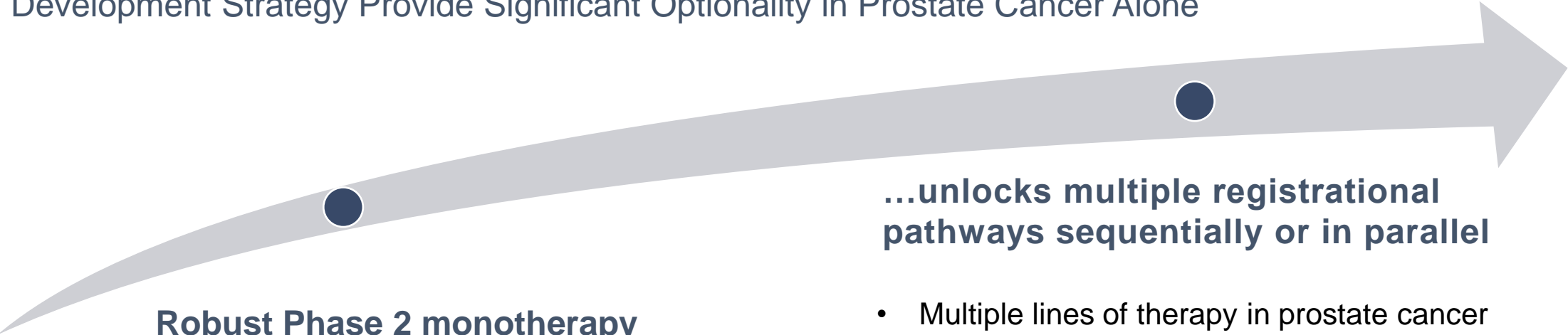
- Planned for 12 weeks after 12 patients in each arm are enrolled
- DMC recommendation based on futility analysis and review of other available efficacy, safety, PK and E-R data
- Futility evaluated by Composite Response Rate (PSA50/ORR)

#### 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 Near-Term Development Highlights

Development Strategy Provide Significant Optionality in Prostate Cancer Alone



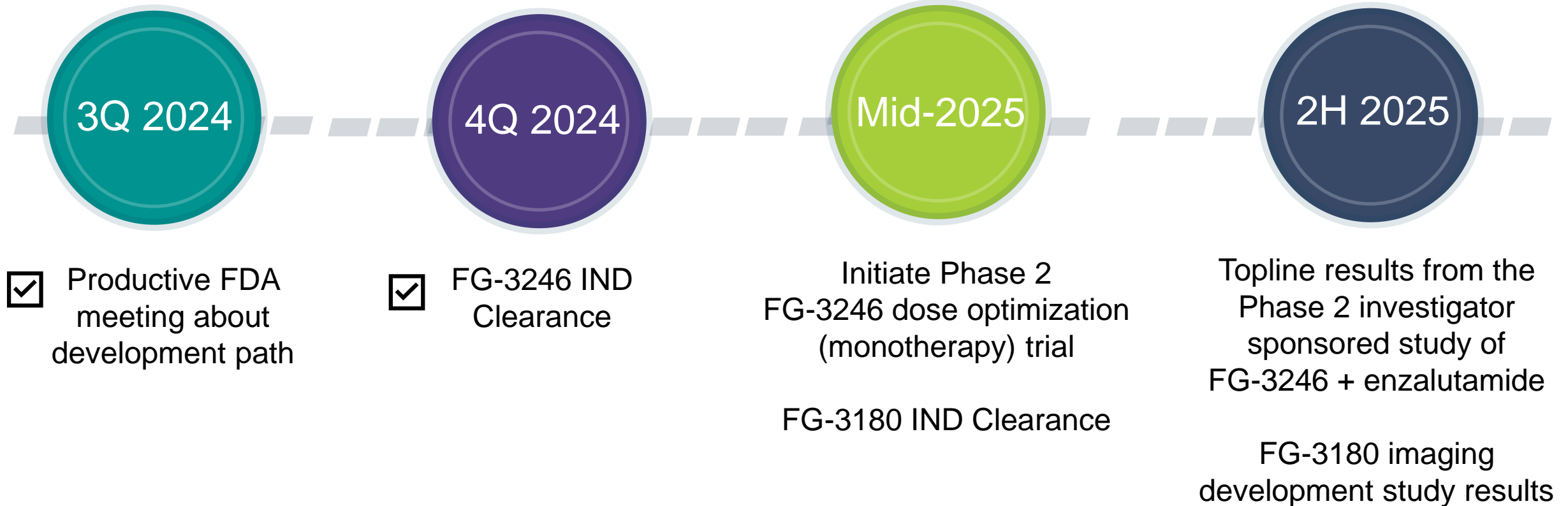
## Robust Phase 2 monotherapy trial in pre-chemo mCRPC...

- Designed to select dose for optimal benefit/risk profile
- 3 factors expected to drive rPFS in all-comers: Preliminary evidence of exposure-response relationship, primary prophylaxis with G-CSF, and enrolling patients in earlier lines of therapy
- Validation of FG-3180 as predictive patient selection biomarker

## ...unlocks multiple registrational pathways sequentially or in parallel

- Multiple lines of therapy in prostate cancer
- Monotherapy and/or combination therapy approaches
- All comers or CD46<sup>high</sup> selected patient populations

# FG-3246 Program Recent & Upcoming Catalysts

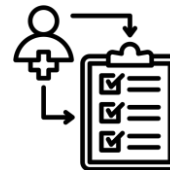


# FG-3246 and FG-3180 Present a Unique Opportunity in mCRPC



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

Binds to a unique epitope on CD46 present on cancer cells but absent in most normal tissues



## Compelling Results in Two Phase 1 Studies

FG-3246 was clinically active as monotherapy and in combination with enzalutamide



## Investigating FG-3180, a PET Biomarker Imaging Agent

Development of CD46 biomarker diagnostic for assessment of CD46 expression, with potential use as a patient selection tool in Phase 3 trial



## Consistent Safety Profile

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



## Significant Potential Opportunity

FG-3246 has potential in multiple lines of mCRPC as well as in other solid tumors such as colorectal cancer

# 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





# Anemia Associated with Lower-Risk MDS Represents a Significant Opportunity

Anemia is the hallmark symptom of MDS that gives rise to significant morbidity

**~70K**

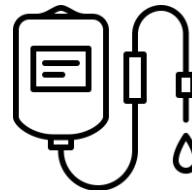
patients live with MDS in the US



**~90% suffering from anemia** and its **negative impact** on quality of life



Current 1L agents are **effective** in **<50% patients** with **limited treatment options** in 2L+

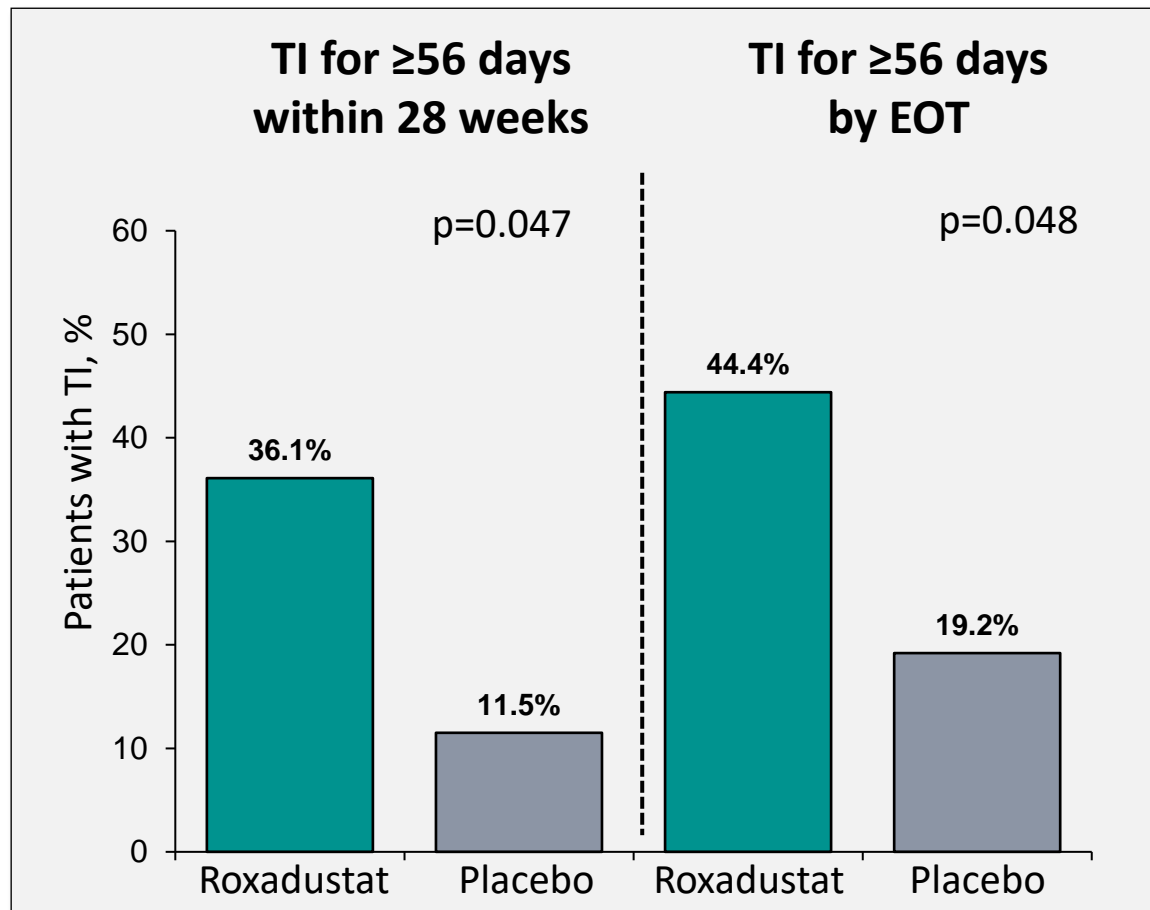


SOCs are challenging to dose-calibrate and can only be administered through IV infusion or subQ

There is a need for treatments that provide durable response and the convenience of oral administration vs. current treatments (intravenous for ESAs and imetelstat, SubQ for luspatercept)

# Anemia of LR-MDS: Phase 3 Development Opportunity Based on Subgroup 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

# Significant Opportunity for Roxadustat in Anemia Associated with LR-MDS

- ✓ Targeted Phase 3 program could enable an approval in anemia associated with Lower-Risk MDS
- ✓ FDA Orphan designation would provide 7 years of data exclusivity in the U.S.\*
- ✓ Differentiated profile with potentially superior tolerability with convenient dosing and administration
- ✓ Significant unmet need despite recent approvals
- ✓ No other oral treatments for anemia of LR-MDS commercially available or in late-stage development
- ✓ Attractive pricing opportunity combined with efficient commercial model
- ✓ Potential for multi-hundred million dollars in peak US sales

**FibroGen is currently exploring the opportunity to develop Roxadustat for anemia associated with LR-MDS internally or through a partner**

**FDA Meeting planned for 2Q 2025**

# Financials

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# FibroGen China Sale: Summary of Key Commercial Terms

## Purchase Price

- Enterprise value of **\$85 million**

## Value of FibroGen Cash Held in China

- Approximately **\$75 million** of FibroGen net cash held in China at closing
  - Defined as net cash at closing held by FibroGen China, including FibroGen's portion of Falikang net cash

## Transaction Close Timing and Other Details

- Transaction expected to close by mid-2025, pending customary closing conditions, including regulatory review in China
- Transaction scope **does not** include the Eluminex license agreement, whose rights will be retained by FibroGen

## Significant Balance Sheet Transformation

- Payoff of MSTV term loan facility at closing, simplifying the company's capital structure
- Provides FibroGen full access to all cash in China
- Extends cash runway into 2027

# Thank You

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

**NASDAQ: FGEN**