



# FibroGen Reports Second Quarter 2025 Financial Results

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August 11, 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, convenience, and potential clinical or commercial success of FibroGen products and product candidates, statements under the caption “Upcoming Milestones”, the estimated 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, upon closing of the FibroGen China sale, cash, cash equivalents and accounts receivable will be sufficient to fund FibroGen’s operating plans into 2028, 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.

# Continuous Execution on 2025 Strategic Priorities

## Transformational Sale of FibroGen China for ~\$210 Million

- Total consideration for the sale of FibroGen China to AstraZeneca now expected to be approximately \$210 million, **a \$50 million increase from initial guidance**
- Enables access to all net cash held in China (~\$125M at close) extending **cash runway into 2028**
- Simplifies operations to drive focus on high-value assets in the U.S.
- Payoff Morgan Stanley Tactical Value term loan facility

## FG-3246 & FG-3180: Phase 2 Ready, 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 showed median rPFS of nearly 9 months (~5 prior lines of therapy) and compares favorably with SOC 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
  - Received IND clearance, to be used alongside FG-3246 in upcoming Phase 2 study

## Roxadustat: A 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
- Reached agreement with the FDA on important design elements for a pivotal Phase 3 trial for roxadustat for the treatment of anemia in patients with LR-MDS and high red blood cell transfusion burden
  - Phase 3 protocol submission expected in 4Q 2025

## Multiple Near-Term Catalysts

- **Initiation of Phase 2 monotherapy** trial of FG-3246, including FG-3180, in mCRPC, post-ARSI / pre-chemo setting expected in **3Q 2025** with **interim results expected in 2H 2026**
- Topline results from Phase 2 portion of IST for **FG-3246 in combination with enzalutamide** in mCRPC in **4Q 2025**

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# FG-3246 and FG-3180 Program

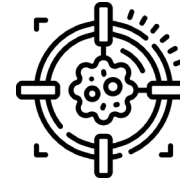
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Potential first-in-class anti-CD46 antibody drug conjugate (ADC) for metastatic castration-resistant prostate cancer and PET imaging agent

# 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



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

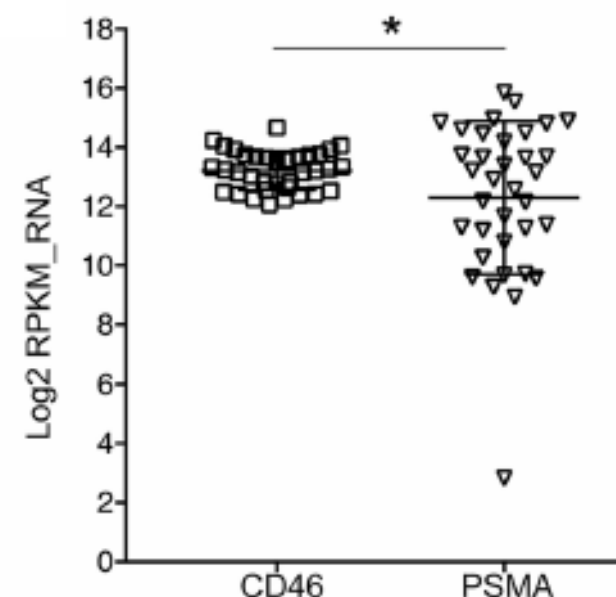
- Therapies that extend survival in patients who are ineligible for or progressed on ARSI and/or chemotherapy
- Novel MOAs that can treat patients who progressed on available treatment options (ex. non-PSMA)
- Predictive tools to inform patient selection
- Optimal combination and sequencing of therapies

# 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**

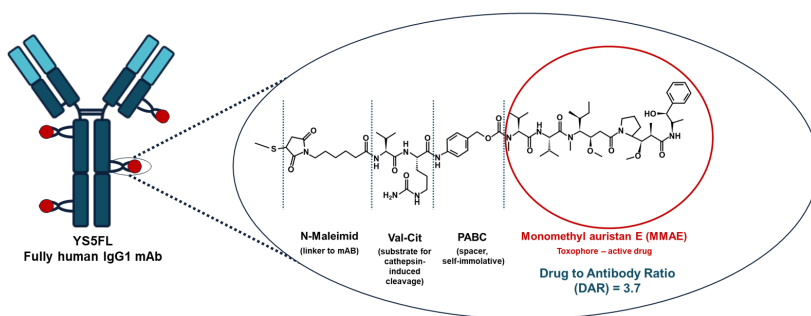
# Targeting a Novel Epitope of CD46 Has Therapeutic and Diagnostic Potential

## FG-3246 Therapeutic

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

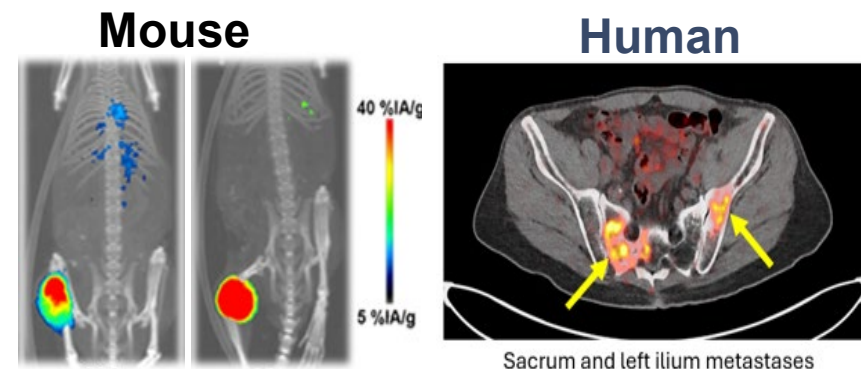
Payload: MMAE – a potent anti-microtubule agent (validated chemotherapy)

- 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

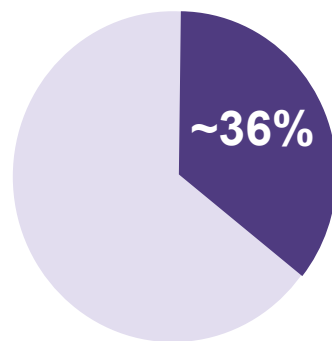
# FG-3246 Demonstrated Meaningful Monotherapy Clinical Activity in 5L+ mCRPC Patients

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

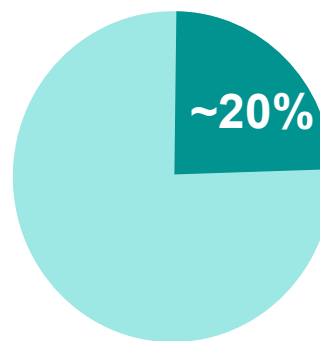
Efficacy analysis included **40 patients** from the dose escalation cohorts-level  $\geq 1.2$  mg/kg and cohort 1 (adenocarcinoma) of the dose expansion cohort at 2.7 mg/kg AJBW



Median rPFS  
95% CI: 5.49 - 11.14



PSA Decline  
by >50%



ORR



Median DOR  
Range: 4.53 - 9.69

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



# FG-3246 Demonstrated Competitive Survival Benefit in a Phase 1 Study of Heavily Pre-Treated and Biomarker Unselected Patients vs Select 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=16								7.5			
Daiichi Sankyo	DS-7300	6L	N=54 (DOR only)				4.4 (DOR Only)							
ARX517	Ambrex (now J&J)	5L	Not Reported	Not Reported										

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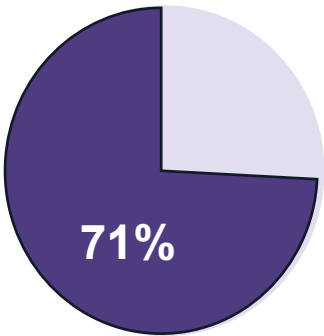
Monotherapy Study: Heavily pre-treated patient population with median of 5 prior lines of therapy

# 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 4Q 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									9.3			
			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

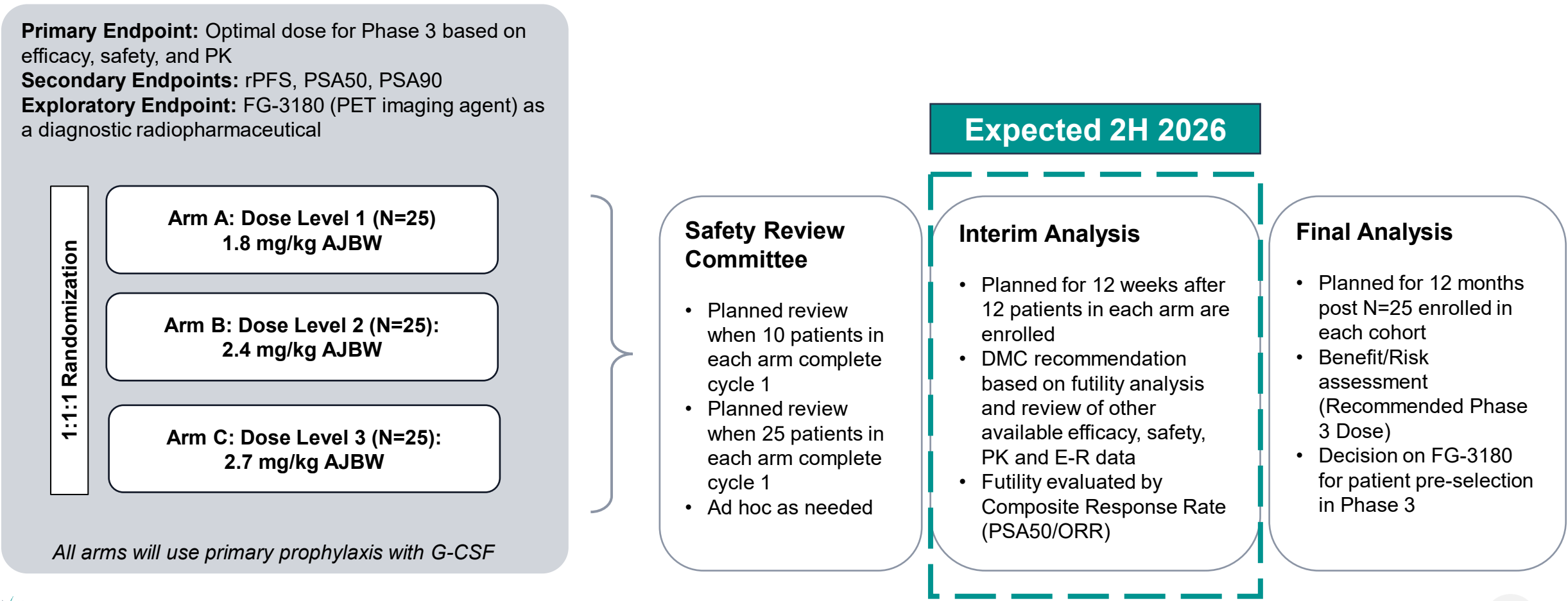
*\*in patients with BRCA mutation. \*\*In patients with BRCA, ATM or other prespecified mutations.*

1. Fizazi K, et al. *NEJM*. 2023;388(8):719-732. 2. Pluvicto Prescribing Information. 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](#).

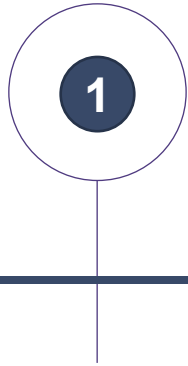
# FG-3246 and FG-3180 Phase 2 Monotherapy Design Highlights

Phase 2 monotherapy trial initiation is expected in 3Q 2025

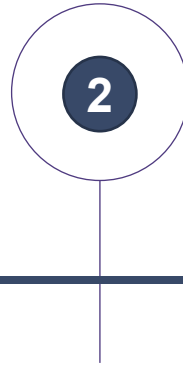
## Phase 2 - FG-3246 Dose Optimization in Post-ARSI, Pre-Chemo mCRPC, All Comers (US only)



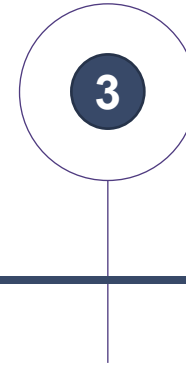
# FG-3246 Phase 2 Monotherapy Trial: Three Main Factors Driving the Potential for Increasing rPFS versus the Phase 1 Study (>8.7 months)



**Use of three of the highest tolerated doses (1.8mg/kg; 2.4mg/kg; 2.7mg/kg), given the exposure response established during the Phase 1 dose escalation and expansion trial**



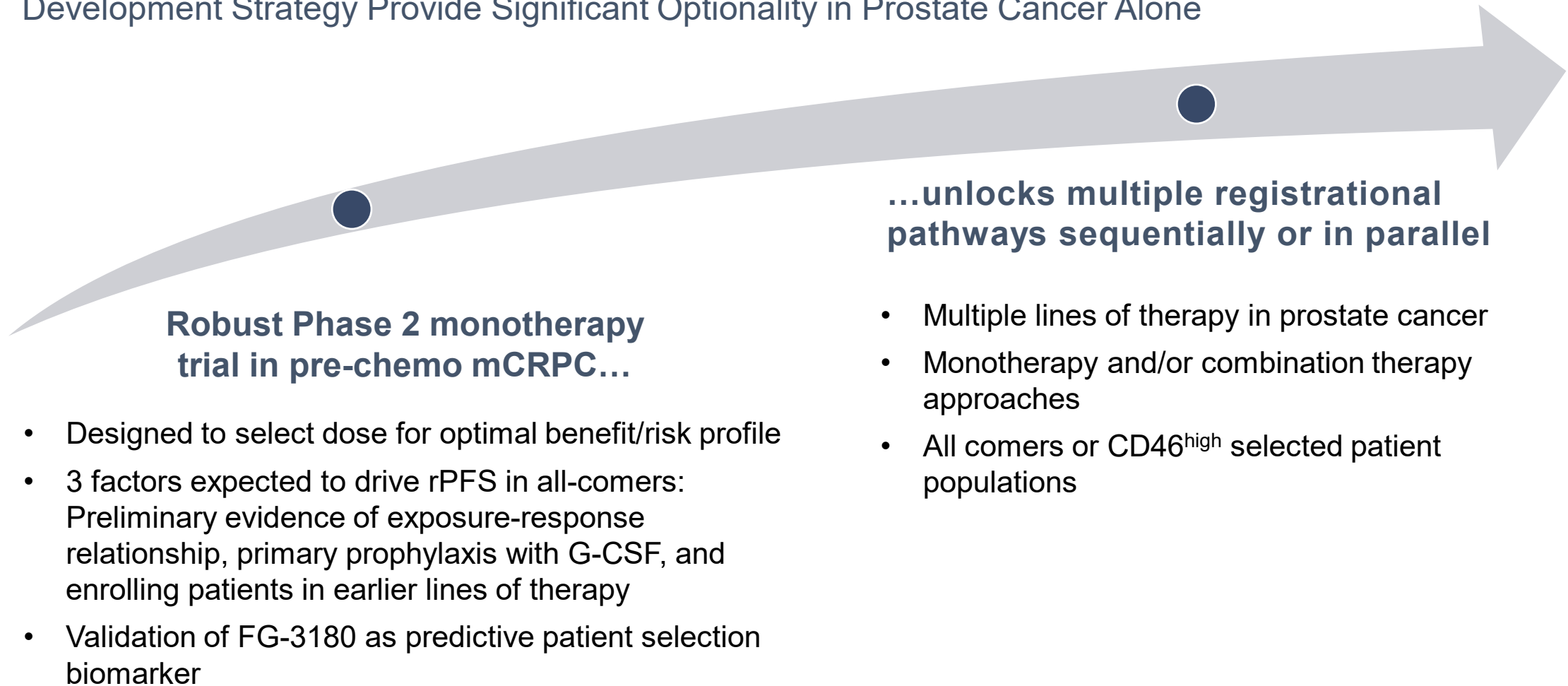
**Use of primary prophylaxis G-CSF to help mitigate MMAE-associated adverse events like neutropenia, and maintain patients on their drug regimen longer**



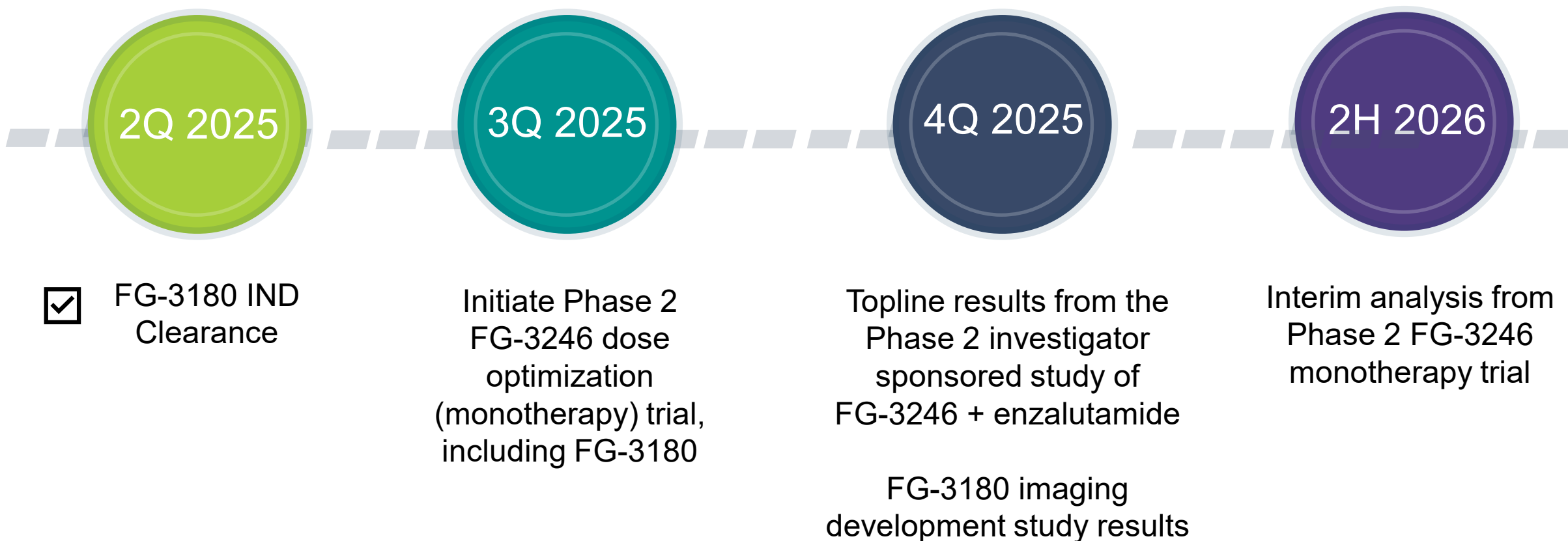
**Moving upline to healthier patients in 1L or 2L mCRPC treatment as opposed to 5L+ in the Phase 1 trial**

# FG-3246 and FG-3180 Near-Term Development Highlights

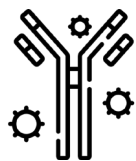
Development Strategy Provide Significant Optionality in Prostate Cancer Alone



## FG-3246 Program Recent & Upcoming Catalysts

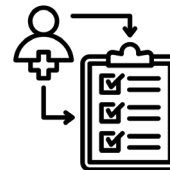


# FG-3246 and FG-3180 Present a Unique Opportunity in mCRPC



## 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**

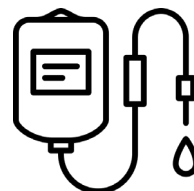
patients live with MDS in the US



**~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 injection

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

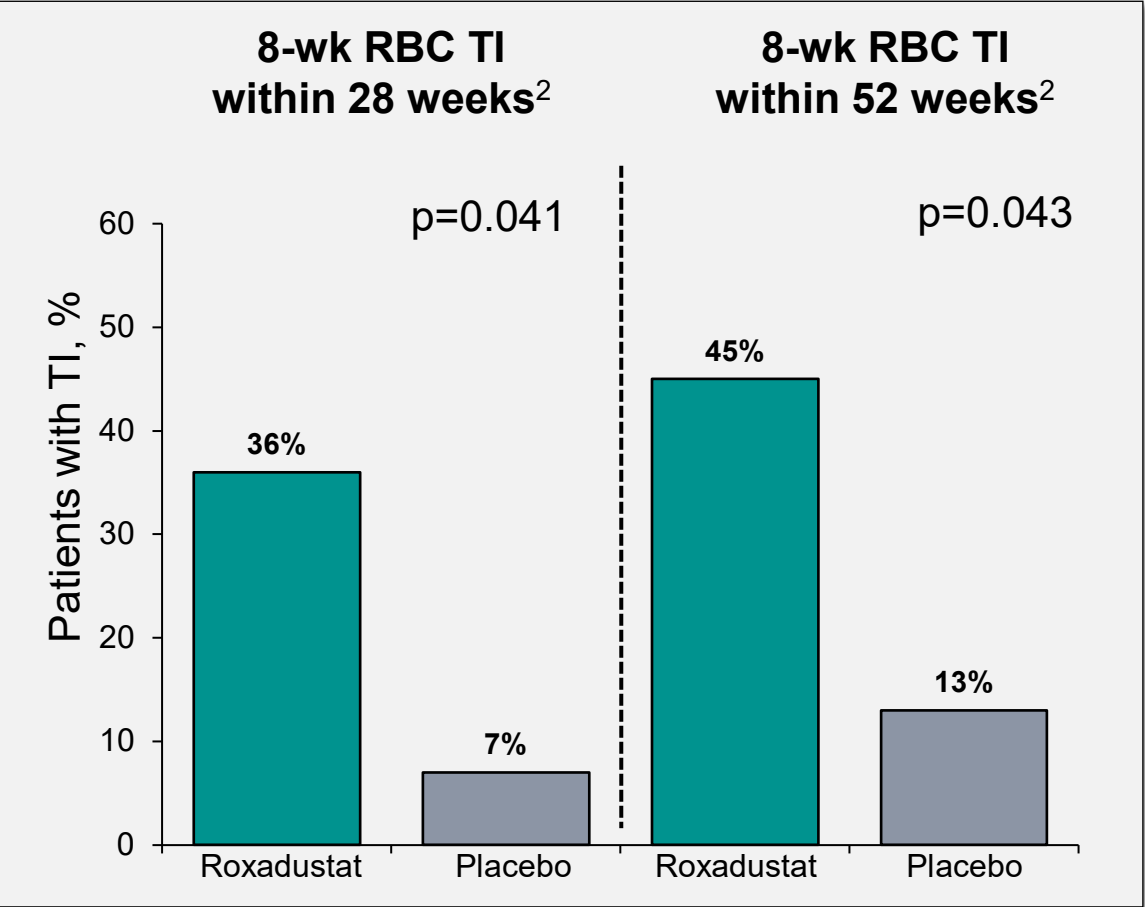


# Significant Opportunity for Roxadustat in Anemia Associated with LR-MDS

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

# Anemia of LR-MDS: Phase 3 Development Opportunity Based on Post Hoc Subgroup Results from MATTERHORN Phase 3 Trial

In patients with high transfusion burden<sup>1</sup>, roxadustat demonstrated TI benefits compared to placebo



No. of patients with response (% [95% CI])	Roxadustat (n=22)	Placebo (n=15)
8-wk RBC TI within 28 weeks <sup>2</sup>	8 (36% [17-59])	1 (7% [0-32])
8-wk RBC TI within 52 weeks <sup>2</sup>	10 (45% [24-68])	2 (13% [2-40])

Final analysis data cut-off date: Aug 2, 2023

Full analysis population (all randomized patients who received ≥1 dose of study drug and had ≥1 corresponding on-treatment Hb assessment)

<sup>1</sup>High transfusion burden at baseline defined by IWG2018: ≥4 pRBC units in two consecutive 8-week periods prior to randomization

<sup>2</sup>Post-hoc analysis with nominal p-values

CI, confidence interval; pRBC, packed red blood cells; TI, transfusion independence

# Planned Pivotal Phase 3 Trial Overview

Currently exploring the opportunity to develop internally or through a partner



## Patient Population

- High transfusion burden: Patients requiring  $\geq 4$  pRBC units in two consecutive 8-week periods prior to randomization
- Refractory to, intolerant to, or ineligible for prior ESAs



## Safety

Management of potential thrombotic risk through:

- Eligibility criteria
- Dose modification criteria
- Discontinuation criteria



## Efficacy

- Primary endpoint: either  $\geq 8$ -week or  $\geq 16$ -week RBC-TI response rate
- Final analysis will be performed when all participants have completed  $\sim 12$  months of treatment or discontinued



## Dose Regimen

- Oral route of administration, three times per week
- Starting dose of 2.5 mg/kg with potential for stepwise dose titration to a maximum of 3.5 mg/kg

**Final protocol submission anticipated in 4Q 2025**



# Financials

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# FibroGen China Sale: Updated Summary of Key Commercial Terms

Purchase Price	■ Enterprise value of <b><u>\$85 million</u></b>
Value of FibroGen Cash Held in China	■ Approximately <b><u>\$125 million</u></b> of FibroGen net cash held in China at closing <ul style="list-style-type: none"><li>○ Defined as net cash at closing held by FibroGen China, including FibroGen's portion of Falikang net cash</li></ul>
Transaction Close Timing and Other Details	■ Transaction expected to close in 3Q 2025, pending customary closing conditions, including regulatory review in China ■ Transaction scope <b><u>does not</u></b> 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 2028



# Thank You

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

**NASDAQ: FGEN**