## FibroGen Reports First Quarter 2025 Financial Results

May 12, 2025



## **Forward-Looking Statements**

This presentation contains 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 forwardlooking 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 the second half of 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 \$185 Million	<ul> <li>Total consideration for the sale of FibroGen China to AstraZeneca now expected to be approximately \$185 million, a \$25 million increase from initial guidance</li> <li>Most efficient way to access all net cash held in China (~\$100M at close) and extends cash runway into 2H 2027</li> <li>Simplifies FibroGen operations to focus on high-value assets in the U.S.</li> <li>Payoff Morgan Stanley Tactical Value term loan facility</li> </ul>
FG-3246 and FG-3180: Phase 2 Ready, Attractive Assets in Prostate Cancer	<ul> <li>FG-3246, a potential first-in-class, CD46 targeting ADC, with clinically meaningful responses in pretreated mCRPC and a well-characterized safety profile         <ul> <li>Phase 1 monotherapy study recently published in the Journal of Clinical Oncology: 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</li> </ul> </li> <li>FG-3180, a PET imaging agent, in clinical development as potential novel patient selection biomarker         <ul> <li>Recently received IND clearance, paving the way to be used alongside FG-3246 in upcoming Phase 2 study</li> </ul> </li> </ul>
Roxadustat: A Late-Stage Development Opportunity	<ul> <li>Approved in &gt; 40 countries and commercialized by AstraZeneca and Astellas</li> <li>Compelling wholly owned, late-stage, U.S. development opportunity in anemia due to LR-MDS</li> <li>Filed Type-C meeting request with FDA for roxadustat in anemia associated LR-MDS <ul> <li>Expect feedback on potential path forward in 3Q 2025</li> </ul> </li> </ul>
Multiple Near-Term Catalysts	<ul> <li>Initiation of Phase 2 monotherapy trial of FG-3246, including FG-3180, in mCRPC, post-ARSI / pre-chemo setting in 3Q 2025</li> <li>Topline results from Phase 2 portion of IST for FG-3246 in combination with enzalutamide in mCRPC in 4Q 2025</li> <li>Interim results from Phase 2 monotherapy trial of FG-3246 expected in 2H 2026</li> </ul>



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



 $\sim$  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

# 0

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

<u>Targeting antibody</u>: YS5FL is a fully-human IgG1 mAb to tumor-selective epitope of CD46 <u>Payload</u>: 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 <sup>89</sup>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 Competitive Survival Benefit in a Phase 1 Study of Heavily Pre-Treated and Biomarker Unselected Patients vs Select Comparable Early-Stage Studies

<b>0 1 1 1 1</b>	Theremoutin	Median	rPFS Evaluable					rPF	S (mon	ths)				
Sponsor	Therapeutic	Treatment Line	Patients	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)				<b>4.4</b> (DOR On	ly)						
ARX517	Ambrx (now J&J)	5L	Not Reported	Not Re	eported									





# 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



- 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

	<b>6</b>	Patient	Therapeutic					r	PFS (n	nonths	;)				
Phase 3 Trial	Sponsor	Selection	Comparator	1	2	3	4	5	6	7	8	9	10	11	12
TRITON3 <sup>1,*</sup>		BRCA mutant	Rucaparib											11.2	
	pharmaand		Enza/abi/docetaxel						6.	4					
DSMAforo <sup>2</sup>	PSMAfore <sup>2</sup> Novartis	DSMA positivo	<sup>177</sup> Lu-PSMA-617									9.3	3		
PSIMAIOIe		PSMA positive	Enza/abi						5.6						
Coloob <sup>3</sup>		PSMA positive	<sup>177</sup> Lu- PNT2002									ę	9.5		
Spiash	Splash <sup>3</sup> POINT Biopharma		Enza/abi						6.0						
	_	Visceral disease	Cabozantinib/ Atezolizumab						6.3	3					
CONTACT-02 <sup>5</sup> Exelixis	Exelixis	or extrapelvic adenopathy	Enza/abi/prednisone				4.2								

#### **Contemporary Chemotherapy Data**

KEYNOTE-921	Morok	All Comoro	pembro + docetaxel				8.6	
KETNOTE-921	YNOTE-921 Merck All Come	All Comers	Docetaxel				8.3	

#### **Results in unselected patients:**

Ph1 FG-3246 Monotherapy	Fortis	All Comers	FG-3246					8.7		
Ph1 FG-3246 Combination	UCSF	All Comers	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 MMAEassociated 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

#### 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**



(monotherapy) trial,

including FG-3180

sponsored study of FG-3246 + enzalutamide

FG-3180 imaging development study results



## 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

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



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 dosecalibrate 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





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). *bAd-hoc* analysis with nominal p-values. CI, confidence interval; EOT, end of treatment; Hb, hemoglobin; OR, odds ratio; pRBC, packed red blood cells; Q4W, every 4 weeks; TI, transfusion independence.

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

- Targeted Phase 3 program could enable an approval in anemia associated with LR-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 feedback expected in 3Q 2025



# **Financials**

## FibroGen China Sale: <u>Updated</u> Summary of Key Commercial Terms

Purchase Price	■ Enterprise value of <u>\$85 million</u>
Value of FibroGen Cash Held in China	<ul> <li>Approximately <u>\$100 million</u> of FibroGen net cash held in China at closing</li> <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	<ul> <li>Transaction expected to close in 3Q 2025, pending customary closing conditions, including regulatory review in China</li> <li>Transaction scope <u>does not</u> include the Eluminex license agreement, whose rights will be retained by FibroGen</li> </ul>
Significant Balance Sheet Transformation	<ul> <li>Payoff of MSTV term loan facility at closing, simplifying the company's capital structure</li> <li>Provides FibroGen full access to all cash in China</li> <li>Extends cash runway into the second half of 2027</li> </ul>



# **Thank You**

For more information contact ir@fibrogen.com

NASDAQ: FGEN