UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 26, 2024

FIBROGEN, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36740**	**77-0357827**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
409 Illinois Street **San Francisco, California**		**94158**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 415 978-1200

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value	FGEN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On June 26, 2024, FibroGen, Inc. ("FibroGen") and Rahul Aggarwal, M.D., of University of California, San Francisco, gave an investor presentation discussing the unmet need and evolving treatment landscape for prostate cancer and the clinical development program for FG-3246.

A copy of such investor presentation is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	Investor Presentation titled "Virtual KOL Investor Event Series Part II: Review FG-3246 Development Program in Metastatic Castration-Resistant Prostate Center" dated June 26, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FIBROGEN, INC.

Date: June 26, 2024

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Officer

Virtual KOL Investor Event Series Part II:

Review FG-3246 Development Program in Metastatic Castration-Resistant Prostate Cancer

Hosted by FibroGen Inc.

Wednesday, June 26, 2024

FibroGen

Forward-Looking Statements

This presentation contains “forward-looking” statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, business strategy, and plans, and objectives of management for future operations, are forward looking statements. These forward-looking statements can generally be identified by terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “contemplate,” “intend,” “target,” “project,” “should,” “plan,” “expect,” “predict,” “could,” “or potentially,” or by the negative of these terms or other similar expressions. Forward-looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses, or current expectations concerning, among other things, ongoing and planned development and clinical trials, the potential safety, efficacy, reimbursement, convenience, or clinical and pharmaco-economic benefits of our product candidates, and the potential markets for any of our product candidates.

Forward-looking statements involve known and unknown risks, uncertainties, assumptions, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements, including the other risks and uncertainties that are described in the Risk Factors section of our most recent annual report on Form 10-K or quarterly report on Form 10-Q filed with the Securities and Exchange Commission. Forward-looking statements represent our management’s beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

FibroGen Strategic Pillars and Investment Highlights

Pamrevlumab Pivotal Clinical Trial Readouts	Pamrevlumab readouts for pancreatic cancer, targeting a significant unmet medical need and representing a multi-billion-dollar revenue opportunity: • **Precision Promise^{SM} Phase 2/3 topline expected mid-2024** • **LAPIS Phase 3 topline expected 3Q 2024**
Growing Roxadustat Revenue and Cash Flow	**Growing revenue and cash flow stream** from roxadustat; **approved in > 40 countries** and commercialized by AstraZeneca and Astellas. sNDA accepted in China for chemotherapy induced anemia, **approval decision expected in 2H 2024.** 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 LR-MDS**.
Early-Stage Oncology Pipeline	FG-3246 (CD46-targeting ADC) for mCRPC: **Data from multiple Phase 1 studies in 2024. Initiation of Phase 2 monotherapy dose optimization study in 2H 2024.** FG-3165 (Galectin-9 targeting mAb) for solid tumors: **IND clearance in 2Q 2024.** FG-3175 (CCR8 targeting mAb) for solid tumors: **IND in 2025.**
Strong Balance Sheet	**$214.7M** in cash, cash equivalents, investments, and accounts receivable as of March 31, 2024. Expected to fund operating plans into 2026.

ADC=antibody drug conjugate; CIA=chemotherapy-induced anemia; IND=investigational new drug; mAb=monoclonal antibody; mCPRC=metastatic castration-resistant prostate cancer.

Review FG-3246 Development Program in Metastatic Castration-Resistant Prostate Cancer

Rahul Aggarwal, MD

Associate Director for Clinical Sciences, UCSF Helen Diller Family Comprehensive Cancer Center

Professor of Medicine

UCSF Division of Hematology/Oncology

FG-3246 is an investigational drug and not approved for marketing by any regulatory authority.

Prostate Cancer Deep Dive

Rahul Aggarwal, MD

Prostate Cancer is the Most Common Cancer in Men and Has a High Unmet Need for Treatment Options That Extend Survival in Late-Stage Disease

Prostate Cancer Facts

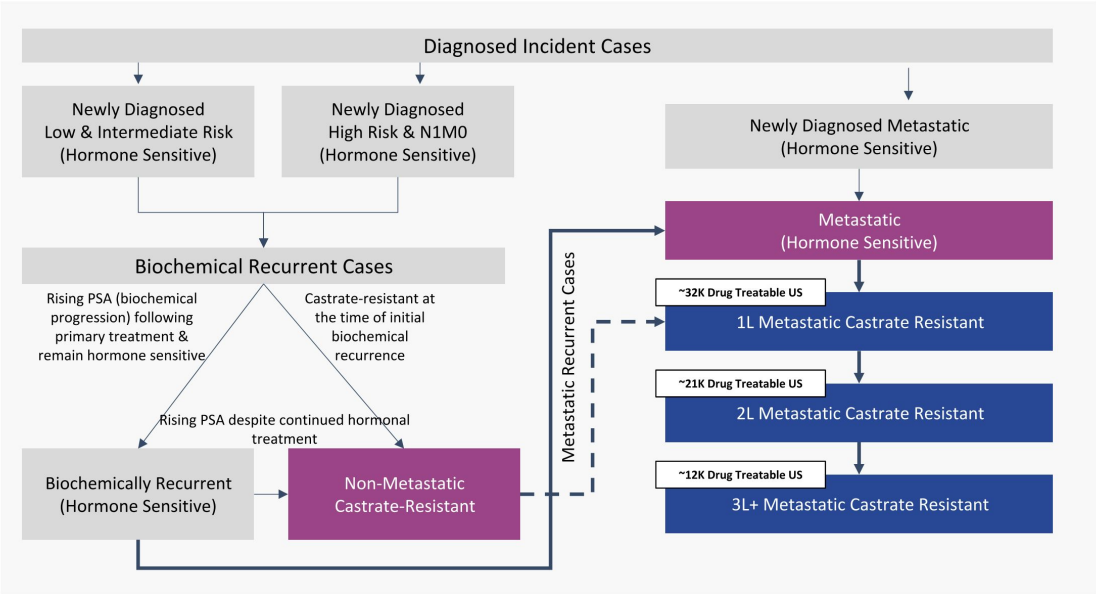
- 3.4 million men live with prostate cancer in the US
- It is the second most common cancer type after breast cancer. ~13% of men will be diagnosed with prostate cancer at some point during their lifetime
- While most men diagnosed with prostate cancer can still live long lives, there are ~ 65K drug 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

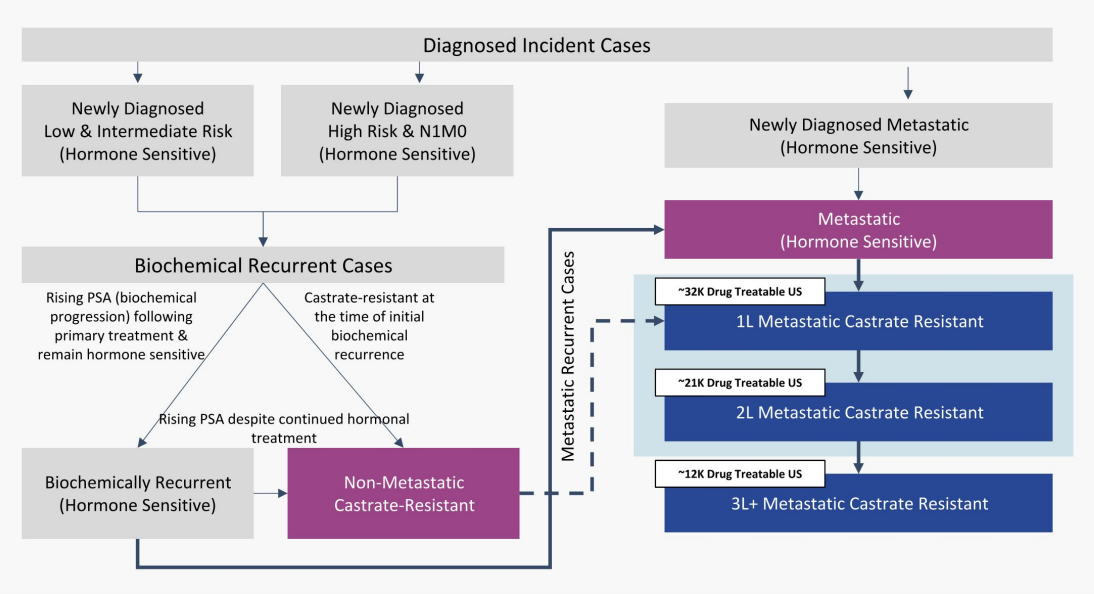
1. SEER, 2024. https://seer.cancer.gov/statfacts/html/prost.html. 2. DRG, 2024. 3. Bernal A, et al. *Pharmaceuticals* (Basel). 2024;17(3):351. 4. American Cancer Society 2024. 5. NIH 2024.

Prostate Cancer Diagnosis and Progression Overview



Source: DRG, 2024

Prostate Cancer Diagnosis and Progression Overview



Potential placement of FG-3246 within treatment paradigm:

For treatment of $CD46^{high}$ patients in 1L or 2L mCRPC as monotherapy or in combination

For 1L mCRPC patients who progressed on ARSI in mHSPC or nmCRPC

For 2L mCRPC patients who progressed on no more than 1 ARSI and have not received chemo in mCRPC

Source: DRG, 2024

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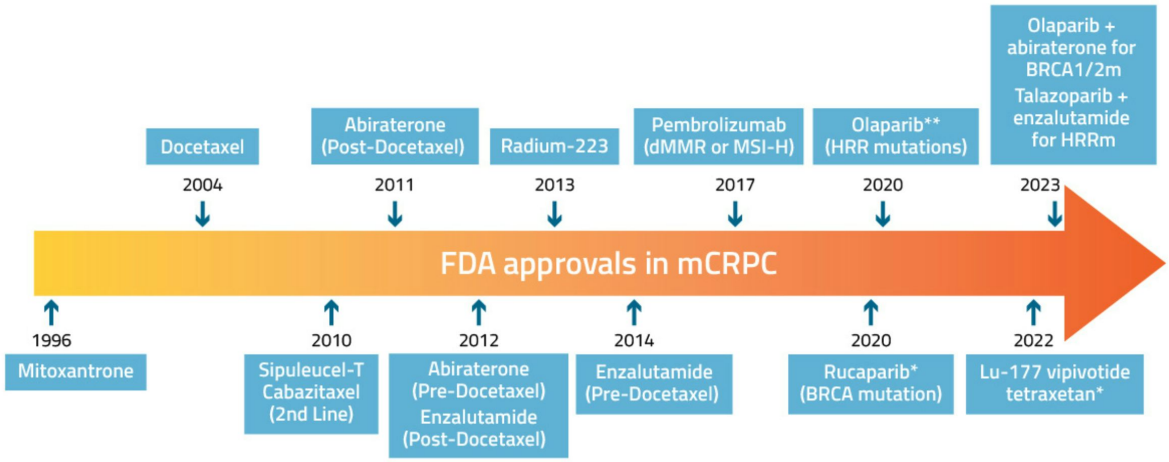
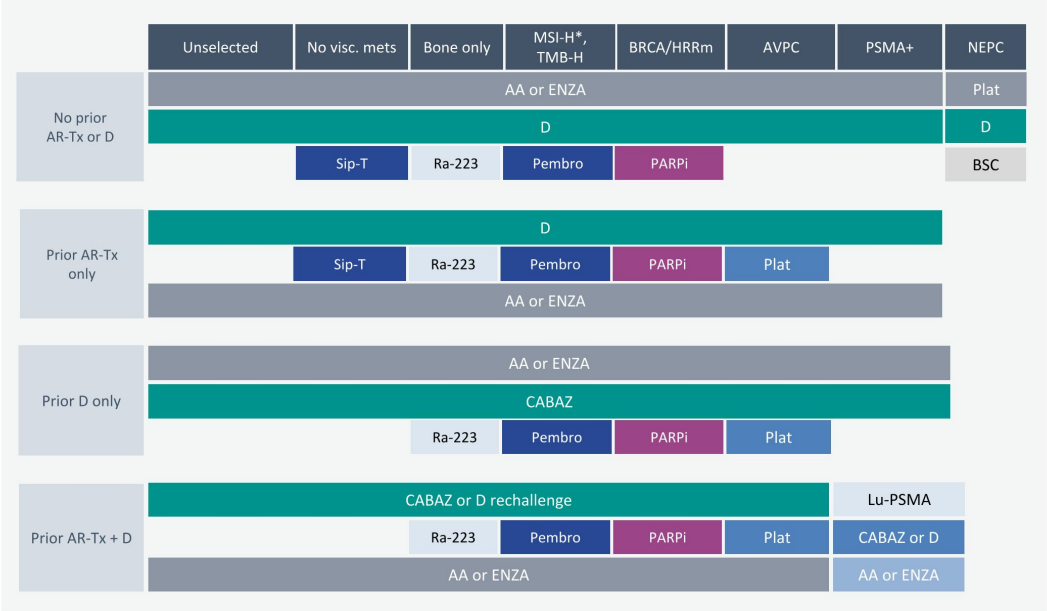
mCRPC Treatment Landscape

Timeline of FDA Approvals in Metastatic CRPC



*Progressed following androgen-axis targeted treatment and taxane-based chemotherapy
**Progressed following treatment with enzalutamide or abiraterone

mCRPC Treatment Algorithm based on NCCN Guidelines Version 3.2024



Color Key

- AR-targeted therapy
- Chemotherapy
- Immunotherapy
- Targeted therapy
- Radiotherapy

Abbreviations:

AR-Tx = AR-targeted therapy
AA = abiraterone
ENZA = enzalutamide
APA = apalutamide
DARO = darolutamide
D = docetaxel
CABAZ = cabazitaxel
AVPC = aggressive variant PCa
NEPC = neuroendocrine PCa
Lu-PSMA = 177Lu-PSMA-617
Plat = Platinum

***MSI-H/dMMR**

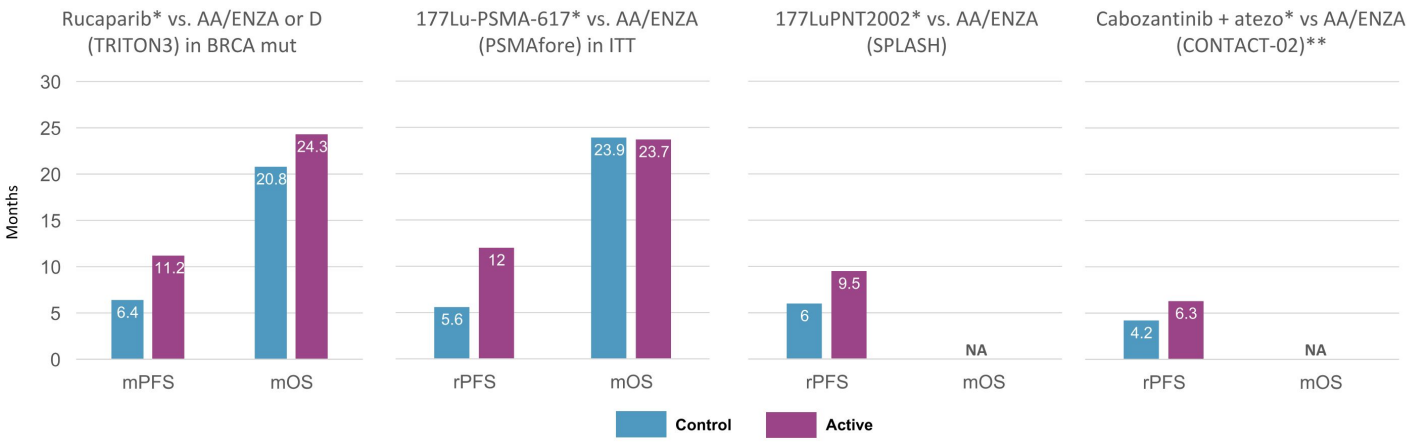
Algorithm based on NCCN Guidelines Version 3.2024

Note: ADT continued with all combinations

Evolving Treatment Landscape in Post-AR, Chemo-Naïve mCRPC

Non-Targeted Efficacy Benchmarks (US, 2024): ARSI Switch rPFS: 5.5m-6.5m, Chemo rPFS: 8.0m-8.5m

Targeted Efficacy Benchmarks (US, 2024): Post ARSI/ Pre Chemo rPFS: 9.5m-12m



*Trial met primary endpoint, FDA approval pending
**Included patients with visceral disease or measurable extrapelvic adenopathy.

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

Intermediate Endpoints in Metastatic CRPC

Radiographic Progression-Free Survival	PSA50 and PSA90 response rates	Objective response rate
The only surrogate endpoint that has been accepted for regulatory approval BICR and use of standard criteria (PCWG3 + modified RECIST 1.1)	Useful for gauging preliminary anti-tumor activity May not be as applicable for all agents (e.g. radium-223)	Useful for gauging preliminary anti-tumor activity Requires measurable disease by RECIST 1.1 (only ~ 30-40% of mCRPC)

Recently reported results for Investigational treatments in development for mCRPC

Drug Name/Company	Target/MOA	Population	PSA50	ORR (%)	rPFS (median) or duration of tx	Safety
ARX517 *Ambrx (now JNJ)*	ADC (amberstatin) targeting PSMA	Metastatic CRPC, no biomarker selection, ≥ 2 prior systemic tx	52% (dose levels ≥ 2.0 mg/kg)	50% (2/4 patients)	Not reported	AE discontinuation rate 3% Grade 3 TRAEs 9.2%
AMG 509 *Amgen*	BiTE targeting STEAP1	Metastatic CRPC, no biomarker selection, at least one ARSI, 1-2 prior taxanes	59% (at higher dose levels)	41% (at higher dose levels)	Not reported	Cytokine release, myalgia/arthalgia, fatigue, anemia
DS-7300 *Daiichi Sankyo*	ADC (deruxtecan) targeting B7-H3	Metastatic CRPC, no biomarker selection, median 6 prior lines of therapy	21% (4/19 pts)	25% (15/59 evaluable pts)	4.8 months (3.9 – 5.9)	Grade ≥ 3 TRAEs include anemia, neutropenia, diarrhea, nausea/vomiting
JANX007 *Janux*	BiTE targeting PSMA	Metastatic CRPC, no biomarker selection	83% (starting step ≥ 0.2 mg, 5/6 patients)	Not reported	Not reported	Cytokine release, other safety data no yet reported

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.

FG-3246 Product Characteristics and Mechanism of Action

FG-3246 is an investigational drug and not approved for marketing by any regulatory authority.

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

FG-3246 Therapeutic

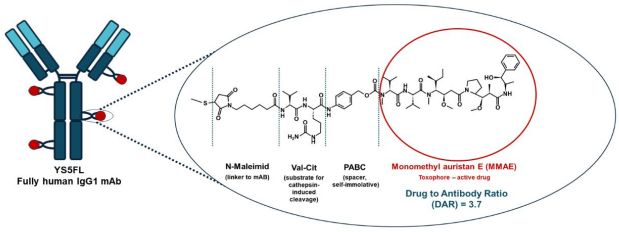
- Novel antibody-drug conjugate (ADC)
- Targeting antibody: YS5FL is a fully-human IgG1 monoclonal antibody to tumor-selective epitope of CD46
- Payload: MMAE - Potent anti-microtubule agent

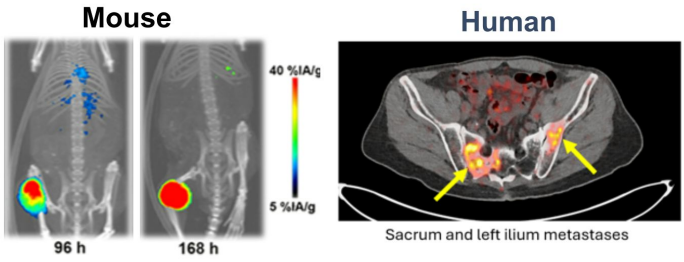
CD46

- 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





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FG-3246 Clinical Data Overview

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FOR46-001

Phase I monotherapy study of FG-3246 administered Q3W in patients with metastatic castration resistant prostate cancer (mCRPC)

Study sponsored and conducted by FORTIS

NCT03575819

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Study Overview

Phase 1 Study Design

- Phase 1, first-in-human, dose-escalation with expansion study of FG-3246 in patients with mCRPC
  - Dose escalation, n = 33
  - Dose expansion, n = 23
    - *Adenocarcinoma, n=18*
    - *Neuroendocrine, n=5*
- Initial accelerated titration for FG-3246 doses < 1.0 mg/kg (expanded to 3 if ≥ 1 Grade 2 treatment-related AE or a DLT), transitioning to standard 3 + 3 escalation
- FG-3246 starting dose level 0.1 mg/kg every 21 days, administered IV on Day 1 of each 21-day cycle
- Primary prophylaxis with G-CSF not mandated; secondary prophylaxis required for Grade ≥ 3 neutropenia

Study Endpoints

- Primary Endpoints: Evaluate the safety and tolerability of FG-3246 in mCRPC patients, Determine the MTD and/or recommended Phase 2 dose in mCRPC patients
- Secondary Endpoints: Characterize the PK of FG-3246, YS5FL, and MMAE, Efficacy including rPFS, PSA50, and objective response rate
- Exploratory Endpoint: Evaluate potential relationships between CD46 expression and measures of antitumor activity

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Phase 1 monotherapy

Study Overview

Eligibility Criteria

- Progressive metastatic castration resistant prostate cancer (CRPC) by PCWG3 criteria
- Prior treatment with at least one androgen signaling inhibitor (e.g., abiraterone, enzalutamide)
- No prior taxane for the treatment of metastatic CRPC
  - Prior taxane for castration-sensitive disease allowed
- Dose expansion only
  - Availability of CRPC tissue from newly acquired or archival tumor sample
  - No histologic evidence of small cell neuroendocrine prostate cancer
- CD46 expression by IHC not required for eligibility
  - Assessed retrospectively using a commercially-available monoclonal Ab (clone 3F1, different epitope from YS5FL) when archival CRPC tissue available

Phase 1 monotherapy

FG-3246 - FOR46-001 Baseline Characteristics

Adenocarcinoma Study Cohort (N = 51)

Median age, years (range)	69 (42 – 81)
Race, n White/Black/Asian/Native American	43 / 5 / 2 / 1
Median PSA, ng/mL (range)	41 (0.2 – 1627)
Measurable disease (RECIST 1.1), n (%)	31 (60.8)
Type of disease progression at study entry, n (%)	
PSA	36 (70.6)
Node only (no bone disease)	5 (9.8)
Bone (± nodal disease)	26 (51.0)
Visceral ± other sites	13 (25.5)
Symptomatic progression	1 (2.0)
No. of prior therapy lines, median (range)	5 (2 – 14)

Prior Systemic Therapies, n (%)	
Androgen deprivation	
Medical	47 (92.2)
Leuprolide	46 (90.2)
Other LHRH/GnRH	10 (19.6)
Surgical	4 (7.8)
Androgen signaling inhibitor	51 (100)
Bicalutamide	31 (60.8)
Enzalutamide	35 (68.6)
Abiraterone	36 (70.6)
Other	9 (17.6)
Sipuleucel-T	16 (31.4)
Immune checkpoint inhibitors	11 (21.6)
Docetaxel (CSPC setting)	12 (23.5)
Other/Investigational	13 (25.5)

Phase 1 monotherapy

FG-3246 Phase 1 Safety Summary

- Safe and generally well tolerated
- Adverse events consistent with other MMAE based antibody-drug conjugate (ADC) therapies
  - Peripheral Neuropathy
    - All Grades – 34.1%, Grade 3 or higher – 2.3%
  - Neutropenia
    - All Grades – 45.5%, Grade 3 or higher – 36.4%
  - Infusion-Related Reactions
    - All Grades - 47.7%, Grade 3 or higher – 2.3%
  - No ocular toxicities
- 2.7 mg/kg ajbw declared as the MTD in the study; number and severity of AEs were dose-exposure related
  - Dose optimization in the phase 2 trial will encompass 2 dose levels 2.4 mg/kg ajbw and 1.8 mg/kg ajbw

Phase 1 monotherapy

FG-3246 Safety Profile Consistent with Other MMAE-ADCs

Selected Cohorts: Dose escalation cohorts-level ≥ 1.2 mg/kg, combined with cohort 1 (adenocarcinoma) of the Expansion cohort

Selected Cohorts - Safety (N=44)

All Grades by Patient (≥ 10%)	All Grades N (%)	≥ Grade 3 N (%)
Fatigue	25 (56.8)	3 (6.8)
Weight decreased	23 (52.3)	1 (2.3)
Infusion related reaction	21 (47.7)	1 (2.3)
Nausea	20 (45.5)	0
Neutropenia	20 (45.5)	16 (36.4)
Constipation	19 (43.2)	0
Decreased appetite	16 (36.4)	1 (2.3)
Diarrhoea	16 (36.4)	0
Neutrophil count decreased	16 (36.4)	13 (29.5)
White blood cell count decreased	16 (36.4)	12 (27.3)
Neuropathy peripheral	15 (34.1)	1 (2.3)
Anaemia	14 (31.8)	3 (6.8)
Arthralgia	14 (31.8)	0
Alopecia	13 (29.5)	0
Hypoalbuminaemia	11 (25.0)	1 (2.3)
Vomiting	11 (25.0)	0
Alanine aminotransferase increased	10 (22.7)	0
Aspartate aminotransferase increased	10 (22.7)	0
Back pain	10 (22.7)	1 (2.3)
Lymphocyte count decreased	10 (22.7)	3 (6.8)

All Grades by Patient (≥ 10%)	All Grades N (%)	≥ Grade 3 N (%)
Blood alkaline phosphatase increased	9 (20.5)	1 (2.3)
Oedema peripheral	9 (20.5)	0
Abdominal pain	8 (18.2)	0
Blood creatinine increased	8 (18.2)	0
Dyspnoea	8 (18.2)	0
Hypocalcaemia	8 (18.2)	2 (4.5)
Hypokalaemia	8 (18.2)	1 (2.3)
Hypophosphotaemia	8 (18.2)	0
Pain in extremity	8 (18.2)	1 (2.3)
Headache	7 (15.9)	0
Hyponatraemia	7 (15.9)	3 (6.8)
Peripheral sensory neuropathy	7 (15.9)	0
Pyrexia	7 (15.9)	0
Blood lactate dehydrogenase increased	6 (13.6)	0
Hypomagnesaemia	6 (13.6)	0
Lymphopenia	6 (13.6)	1 (2.3)
Tachycardia	6 (13.6)	0
Fall	5 (11.4)	0
Insomnia	5 (11.4)	0

Number and severity of AEs were dose-exposure related;
No new safety signals; All AEs were managed by institutional standard of care.

Sources:
Table 14.3.1.3.7 Summary of Grade ≥ 3 TEAE by Preferred Term Decreasing Frequency
Table 14.3.1.3.9 Summary of All Grade TEAE by Preferred Term Decreasing Frequency

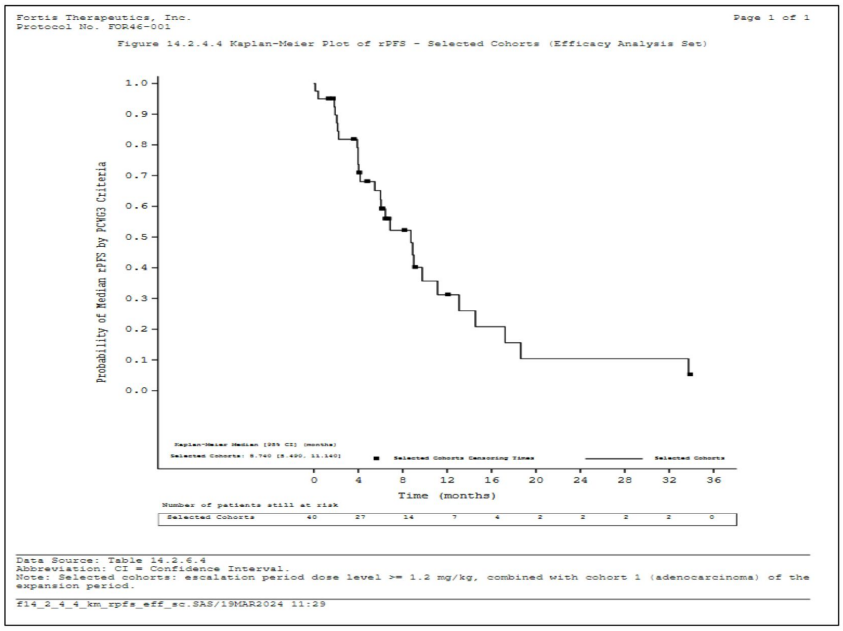
Phase 1 monotherapy

8.7 Month rPFS - Potentially Clinically Meaningful Efficacy

Median rPFS (months) Selected Cohorts (N=40):

8.7 months
(n=27: 26 PD; & 1 Death Event)

Selected Cohorts: Dose escalation cohorts-level ≥ 1.2 mg/kg, combined with cohort 1 (adenocarcinoma) of the Expansion cohort



Phase 1 monotherapy

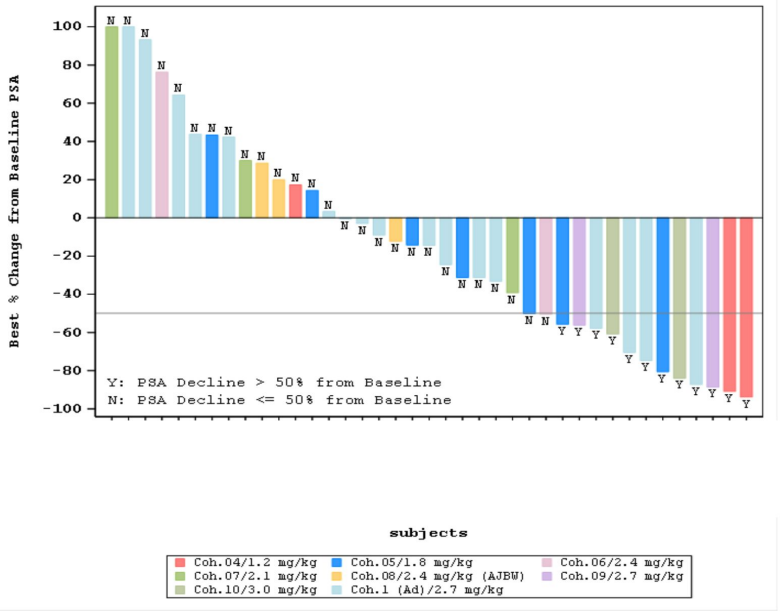
Meaningful PSA50 Response Observed in Selected Cohorts, Represents Compelling Indication of Clinical Activity

PSA Decline Selected Cohorts (N=39):

PSA Decline by >50%: 14 (35.9%)

PSA Decline by >50% confirmed at least 2 weeks later: 12 (30.8%)x

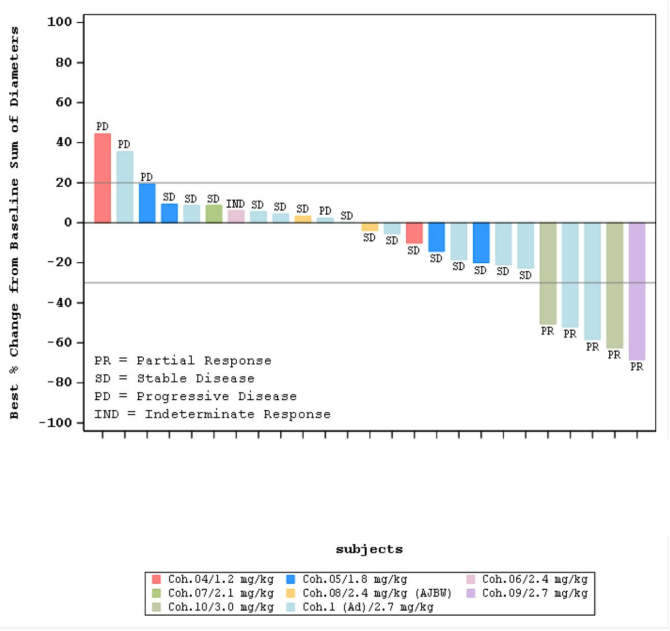
Selected Cohorts: Dose escalation cohorts-level ≥ 1.2 mg/kg, combined with cohort 1 (adenocarcinoma) of the Expansion cohort



Confirmed Objective Response Rate RECIST Evaluable Set (Selected Cohorts)

	Selected Cohorts (N=25)
Confirmed ORR	5 (20%)
Complete Response	0
Partial Response	5 (20%)
Stable Disease	15 (60%)
Prog. Dis	4 (16%)
Indeterminate	1 (4%)

Selected Cohorts:
Dose escalation cohorts-level ≥ 1.2 mg/kg, combined with cohort 1 (adenocarcinoma) of the Expansion cohort

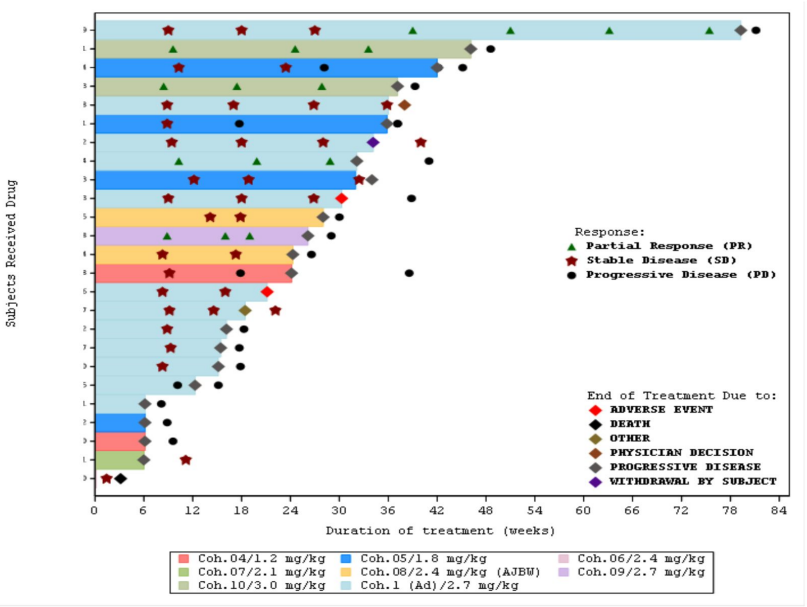


Duration of Response (DOR) in Selected Cohorts

Median Tumor DOR (months) Selected Cohorts (N=25):

7.5 (N=5; 5 with ORR)

Selected Cohorts: Dose escalation cohorts-level ≥ 1.2 mg/kg, combined with cohort 1 (adenocarcinoma) of the Expansion cohort



FG-3246 Phase 1 Monotherapy Summary

Single agent activity in heavily pretreated mCRPC (median 5 prior lines of therapy)

- 8.7 months rPFS
- Objective Response Rate (ORR) 20%
- Duration Of Response (DoR) 7.5 months
- PSA50 = 36%
- Safe and well tolerated to date

Doses selected for Phase 2/3 registrational trial: 1.8 and 2.4 mg/kg

- 2.4 mg/kg and/or 1.8 mg/kg with secondary G-CSF prophylaxis to provide best risk/benefit profile
- Dose Optimization in the phase 2 component of the registration trial

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Investigator Sponsored Study by Dr Rahul Aggarwal

FG-3246 + Enza Phase 1b

ASCO 2024 Interim Data

Phase 1b Dose Escalation Study of FG-3246, a Novel Antibody-Drug Conjugate Targeting a Tumor Specific Epitope of CD46, in Combination with Enzalutamide (Enza) in Patients with mCRPC

NCT05011188

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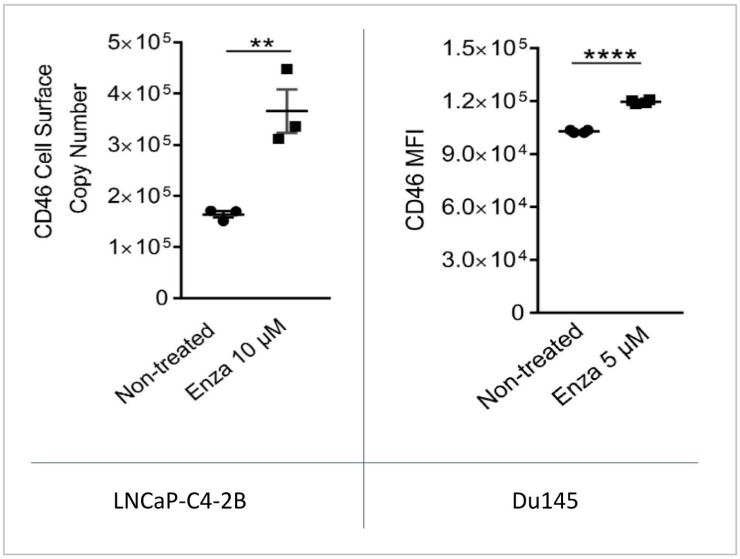
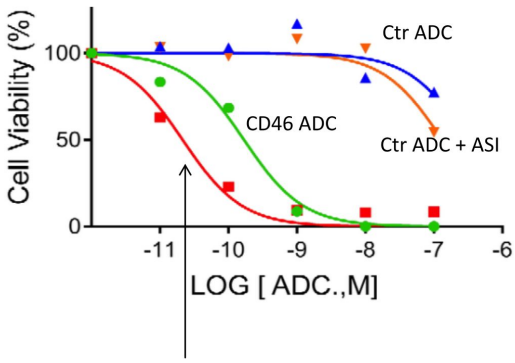
ARSIs Up-regulate CD46 in mCRPC and Sensitizes to FG-3246 Tx

Provides rationale for combination therapy





ASI + CD46 ADC shows enhanced killing
(EC50 on LNCaP-C4-2B: 13 pM vs. 226 pM)

Su et al., JCI Insight 2018

Phase 1b combination

Study Design: Primary, Secondary and Exploratory Endpoints

Eligible patients must have progressive mCRPC per PCWG3 criteria, at least 1 prior androgen-signaling inhibitor (ASI); no prior taxane for CRPC and an ECOG performance status ≤1.

Phase 1b Primary Endpoint

- Maximum tolerated dose (MTD) and recommended phase 2 dose (RP2D) of FG-3246 in combination w/ enzalutamide

Secondary Endpoints

- PSA50 Response Rate
- Objective Response Rate by RECIST 1.1 criteria
- Median radiographic progression-free survival (rPFS)
- Overall Survival
- Frequency and severity of adverse events by CTCAE version 5.0

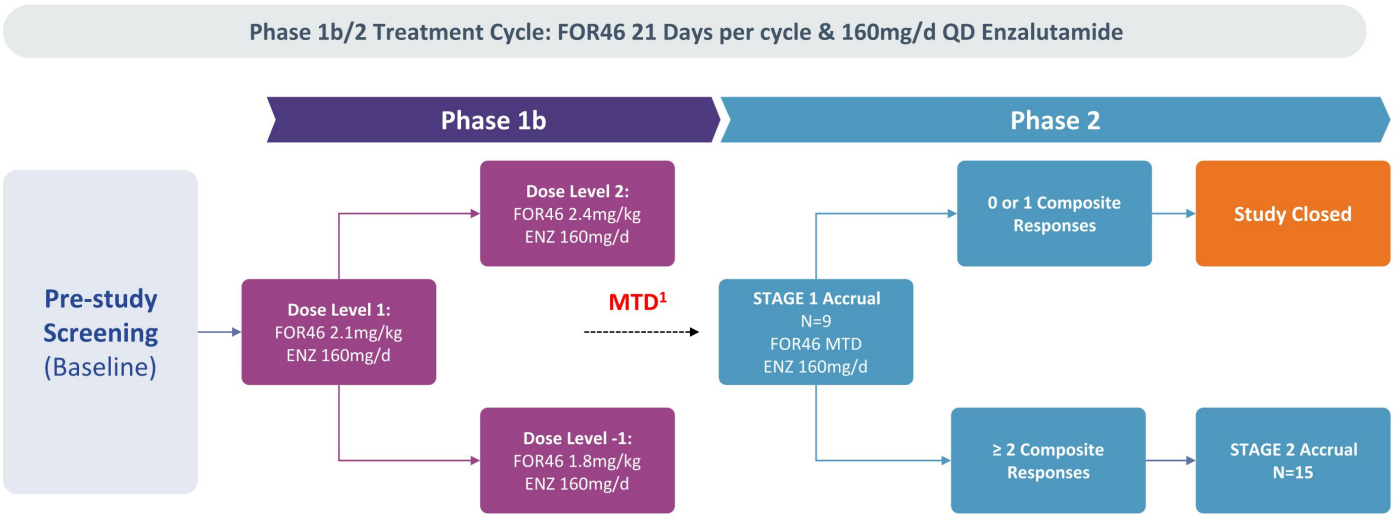
Exploratory Endpoints: *Evaluating the association between…*

- Tumor characteristics & AR transcriptional signature score with clinical outcomes.
- CD46 expression by immunohistochemistry with clinical outcomes
- Uptake on 89Zr-DFO-YS5 PET with clinical outcomes: 1-3 mCi 89Zr-DFO-YS5 was administered, and PET/CT imaging was performed 5-7 days post-injection on a Siemens Biograph Vision PET/CT scanner

Presented at ASCO June 2024

Study Design: Trial Schematic

Phase 1b/2 study evaluating FOR46 in combination with enzalutamide in patients with mCRPC after prior progression on abiraterone. Dose Escalation with Expansion (3+3) dependent on DLTs.



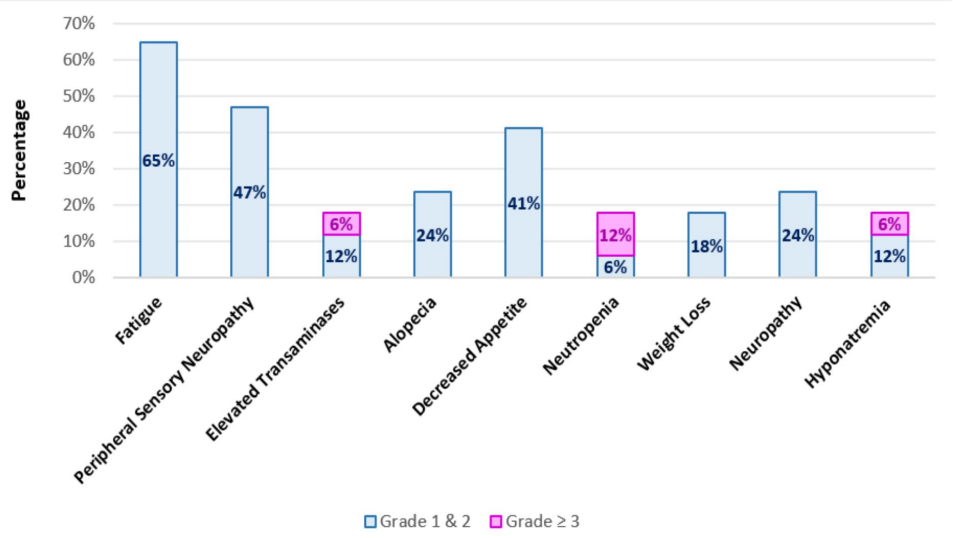
[1]Maximum Tolerated Dose (MTD) = 2.1 mg/kg, AJBW dosing with primary G-CSF prophylaxis, in combination with enza 160 mg/day

Presented at ASCO June 2024

Phase 1b combination

Treatment-related Adverse Events

Treatment-related AEs that lead to treatment discontinuation included increased LFTs (transaminases) (n=1), Neuropathy, Grade 2 (n=3), and Hyponatremia (n =1)



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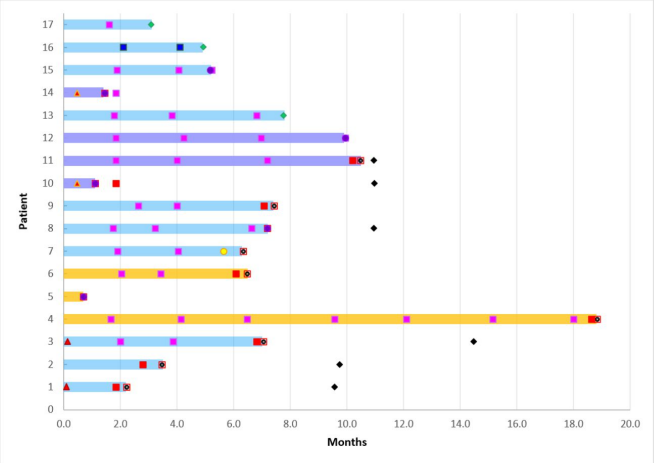
Phase 1b combination

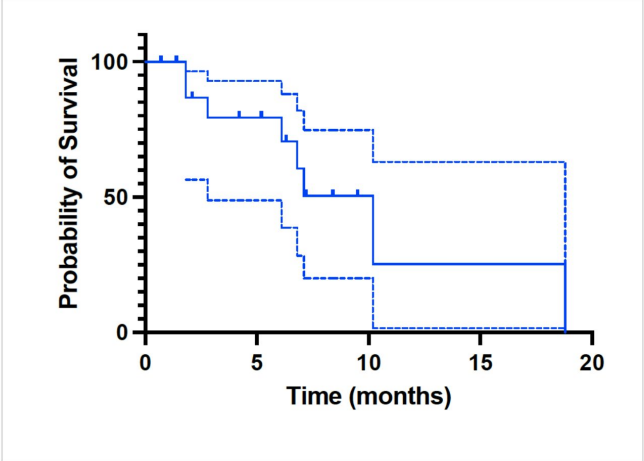
Clinical Outcomes: DoT, rPFS

- Median time on treatment for patients in all dose levels (N = 17) was **6 months** (range: 1 – 18) with 3 patients still on treatment.
- The preliminary estimate of median radiographic progression-free survival was **10.2 months.**

Duration of Treatment



Radiographic Progression-free Survival



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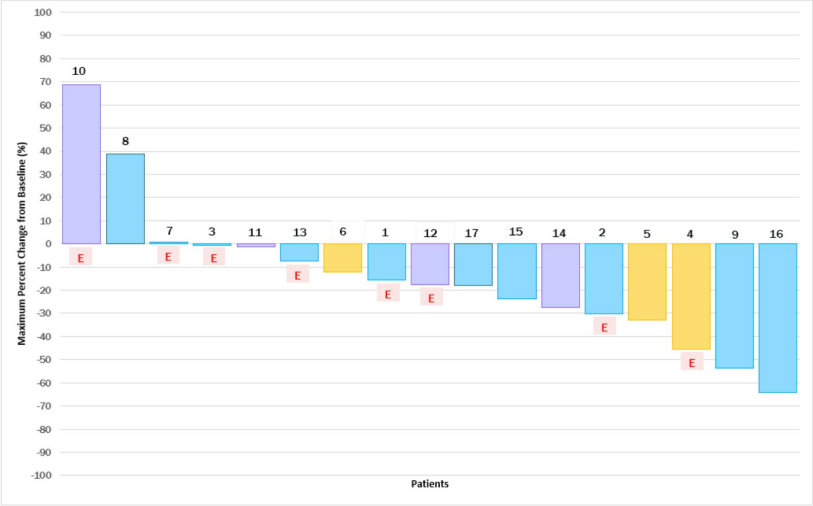
Phase 1b combination

Clinical Outcomes: PSA



The majority of patients (12/17 evaluable, 71%) experienced a decline in PSA levels post-treatment

5 of the 12 patients (42%) that experienced PSA decline had previous progression on enzalutamide

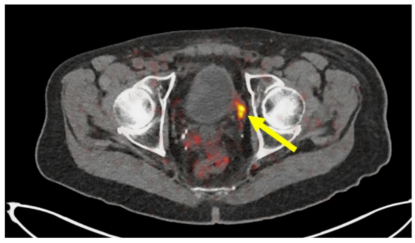
There were two patients who experienced ≥ 50% decline from baseline in PSA

Presented at ASCO June 2024

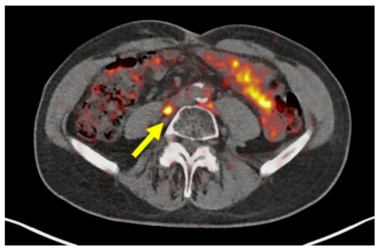
Phase 1b combination

Zr-89 labeled YS5 Demonstrates Tumor Specific Uptake

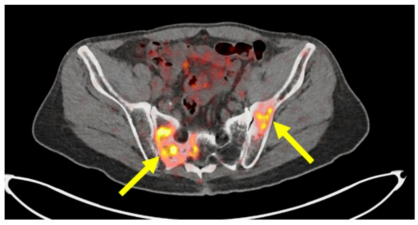
Axial PET/CT fusion images obtained 5 days following administration of ^{89}Zr-DFO-YS5 in a 72 year old man with history of prostate adenocarcinoma, with prior treatments of Lupron, abiraterone, and enzalutamide, and a PSA of 53.5. PET/CT revealed multiple small lymph node metastases in the pelvis, retroperitoneum, and supraclavicular regions, and bone metastases in the pelvis.



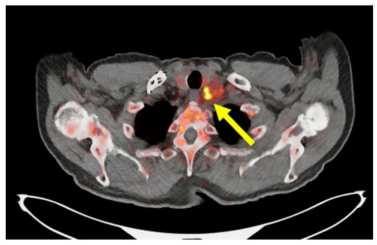
L pelvic sidewall lymph node



Retroperitoneal lymph nodes



Sacrum and left ilium metastases



L supraclavicular lymph node

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Phase 1b Conclusions: FG-3246 + Enzalutamide

1. The MTD and recommended phase 2 dose of FOR46 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 with **PSA declines in 12/17 (71%**) of evaluable pts, and a preliminary estimate of **median rPFS of 10.2 months**

3. Accrual is ongoing in Phase 2 with mandatory [^{89}Zr]-YS5 PET imaging performed during screening to determine its potential utility in patient selection

Presented at ASCO June 2024

FG-3246 is an investigational drug and not approved for marketing by any regulatory authority.

Opportunity
mCRPC and Lifecycle Management

Deyaa Adib, MD
FibroGen Chief Medical Officer

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 Diagnostic

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

3 Phase 1 Monotherapy Efficacy Results

- Adenocarcinoma selected cohorts receiving ≥ 1.2 mg/kg:
  - Median rPFS of 8.7 months
  - PSA decline by >50%: 36%
  - ORR: 20%

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

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

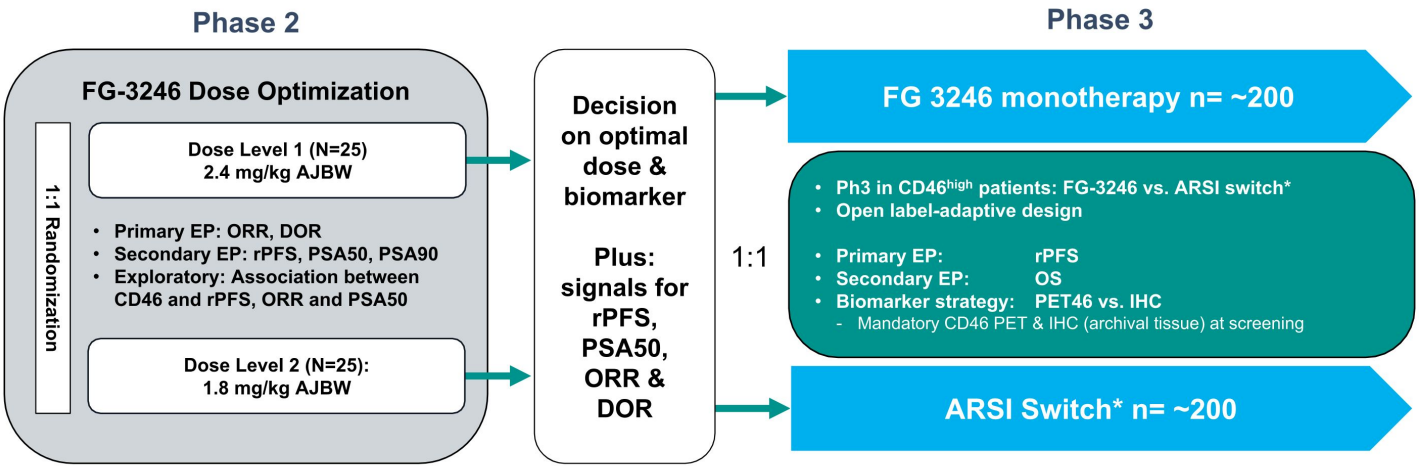
- **Likely that patient selection biomarker is required** to achieve clinically differentiated profile in prostate cancer, based on early clinical data and highly competitive mCRPC market
- Estimate that 50%-70% of mCRPC patients will be CD46^{high}
- PSMA PET biomarker have demonstrated positive impact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

Planning for Seamless Phase 2/3 RCT > 2L Pre-Chemo mCRPC

Randomized, dose optimization, biomarker-driven, adaptive phase 2/3 design: FG-3246 vs. ARSI switch*



*Pending upon consultation with FDA summer 2024

Treatment Option Landscape for Pre-chemo mCRPC and Target FG3246 Product Profile

	FG-3246 Target Product Profile	ARSI switch	Chemo	PSMA targeted radioligands
Patient population	CD46-high selected	Unselected	Unselected	PSMA-high selected
rPFS (months)	>10m	5.6m-6.4m	8.3m	9.5 - 12.0m
OS (months)	28.6m	~20m (not yet mature)	19.0m	~19m (not yet mature)
Safety & Tolerability: Adverse Events	In line with other MMAE containing ADCs	Comparable to FG-3246	FG-3246 compares favorably	FG-3246 compares favorably
Dosing & Administration	IV every 3 weeks	PO twice daily	IV	IV, every 6 weeks for up to 6 doses
Patient Cost per Course of Therapy	NA	~$186K (2024) (Xtandi)	~$62k (2024) (6.2k x 10 cycles, branded)	~273k (2024)
REFERENCES	Internal Estimates	PSMAfore, SPLASH	KEYNOTE-921	PSMAfore, SPLASH

FibroGen

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

FG-3246 & PET46 Biomarker - Vision and Strategy

Horizon 1: Establish

- Pursue accelerated registrational path to pre-chemo mCRPC
- Establish FG-3246 in pre-chemo mCRPC in CD46^{high} patients (monotherapy & combination therapy)
- Establish PET46 biomarker as standard of care diagnostic

Horizon 2: Expand

Expand footprint in prostate cancer by moving into earlier stages of disease

Launch in other solid tumor type (e.g., R/R mCRC)

Horizon 3: Explore

Explore novel combinations and additional solid tumors

Q&A Session

Thank You