FibroGen Initiates Phase 2 Monotherapy Trial of FG-3246, a First-in-Class CD46 Targeting ADC, in Metastatic Castration-Resistant Prostate Cancer

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- *FG-3246 Phase 2 dose optimization trial to enroll 75 patients with metastatic castration-resistant prostate cancer (mCRPC) in the post-androgen receptor signaling inhibitor (ASRI) and pre-chemotherapy setting*
- *FG-3180 to be evaluated in the Phase 2 trial as a companion PET imaging agent and a potential predictive patient selection biomarker*
- *Interim analysis expected in 2H 2026*

SAN FRANCISCO, Sept. 24, 2025 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today announced the initiation of the Phase 2 monotherapy, dose-optimization trial of FG-3246, a potential first-in-class antibody-drug conjugate (ADC) targeting CD46-expressing cancer lesions in patients with metastatic castration-resistant prostate cancer (mCRPC). The trial will also assess the diagnostic and predictive performance of FG-3180, a companion PET imaging agent, which shares the same CD46-targeted antibody used in FG-3246. The ability of FG-3180 to identify mCRPC lesions and predict response to FG-3246 will be evaluated.

"With the transformation of FibroGen to a U.S.-focused organization now complete and a robust cash runway into 2028, we are excited to advance our FG-3246 program and initiate the Phase 2 monotherapy trial with the activation of the University of California San Francisco (UCSF) site," said Thane Wettig, Chief Executive Officer of FibroGen. "FG-3246 demonstrated compelling clinical activity in patients that were heavily pre-treated, with a competitive radiographic progression free survival benefit in the Phase 1 monotherapy study. We are confident that the dosing regimen of FG-3246, use of prophylactic G-CSF, and the enrollment of patients in earlier lines of treatment of mCRPC set us up to further demonstrate the potential of this program. We anticipate results from the interim analysis of our Phase 2 study in the second half of 2026. We also look forward to reporting the results from the ongoing investigator-sponsored study of FG-3246 in combination with enzalutamide in the fourth quarter of this year."

The Phase 2 monotherapy trial (NCT06842498) is a randomized, open label, dose optimization trial designed to evaluate the safety, efficacy, tolerability, and pharmacokinetics (PK) of FG-3246 for the treatment of patients with mCRPC who have progressed following ARSI treatment and who have not received chemotherapy for their mCRPC. The trial is scheduled to enroll 75 patients who will be randomized 1:1:1 to receive either 1.8, 2.4 or 2.7 mg/kg AJBW of FG-3246. The primary endpoint of the trial is the determination of the optimal dose for the Phase 3 trial based on efficacy, safety, and PK parameters. Secondary endpoints include radiographic progression free survival (rPFS), prostate-specific antigen (PSA) 50 response, and PSA90 response. An interim analysis is planned once 12 patients enrolled in each of the three dose arms have completed 12 weeks on study or discontinued and is anticipated in the second half of 2026. An exploratory sub-study will evaluate FG-3180, a companion PET imaging agent, as a diagnostic radiopharmaceutical. All patients deemed eligible for participation in the Phase 2 trial will participate in the sub-study evaluating FG-3180 prior to randomization.

In addition, topline results from the ongoing investigator-sponsored study of FG-3246 in combination with enzalutamide in patients with mCRPC are expected in the fourth quarter of 2025.

About FG-3246
FG-3246 (FOR46) is a potential first-in-class fully human antibody-drug conjugate (ADC), exclusively in-licensed from Fortis Therapeutics, and is being developed by FibroGen for metastatic castration-resistant prostate cancer and potentially other tumor types. FG-3246 binds to an epitope of CD46, a cell receptor target, that induces internalization upon antibody binding, is present at high levels in prostate cancer and other tumor types and demonstrates very limited expression in most normal tissues. FG-3246 is comprised of an anti-CD46 antibody, YS5, linked to the anti-mitotic agent, MMAE, which is a clinically and commercially validated ADC payload. FG-3246 has demonstrated anti-tumor activity in both preclinical and clinical studies.

FG-3246 is currently in an ongoing Phase 1b/2 study being conducted at UCSF as an investigator-sponsored trial to evaluate FG-3246 in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC). An additional investigator-sponsored radiopharmaceutical marker trial using a zirconium-89 positron emission tomography (PET) tracer for CD46 that utilizes the YS5 antibody is also underway at UCSF. The Phase 2 monotherapy dose optimization trial for FG-3246 in mCRPC was initiated in the third quarter of 2025, with interim results expected in the second half of 2026. FG-3246 is an investigational drug and not approved for marketing by any regulatory authority.

About Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Prostate cancer is the second most common malignancy in men, contributing significantly to male mortality rates. Approximately 13% of men will be diagnosed with prostate cancer at some point during their lifetime. There are about 65,000 drug treatable mCRPC cases in the U.S. annually and 5-year survival in mCRPC is approximately 30%.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company focused on development of novel therapies at the frontiers of cancer biology and anemia. Roxadustat (爱瑞卓®, EVRENZOTM) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease (CKD) patients on dialysis and not on dialysis. The Company continues to evaluate a development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndrome (LR-MDS) in the U.S. FG-3246 (also known as FOR46), a first-in-class antibody-drug conjugate (ADC) targeting CD46 is in development for the treatment of metastatic castration-resistant prostate cancer. This program also includes the development of FG-3180, an associated CD46-targeted PET biomarker. For more information, please visit www.fibrogen.com.

Forward-Looking Statements
This release 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 regarding FibroGen's cash runway, 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 release, and FibroGen undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

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Source: FibroGen, Inc.