Kyntra Bio Announces Positive Data from the Investigator-Sponsored Phase 1b/2 Study of FG-3246 in Combination with Enzalutamide in Patients with Metastatic Castration Resistant Prostate Cancer to Be Presented at ASCO GU 2026

February 23, 2026

- *FG-3246 and enzalutamide combination therapy, in biomarker unselected patients with androgen receptor pathway inhibitor (ARPI)-treated, taxane-naïve metastatic castration-resistant prostate cancer (mCRPC), led to a median radiographic progression free survival (rPFS) of 7.0 months in the overall study cohort, with median rPFS of 10.1 months observed in patients who progressed on only one prior ARPI*
- *Higher tumor uptake of FG-3180, a CD46 directed PET imaging agent, demonstrated a trend towards higher probability of PSA50 response, highlighting its potential for patient selection*
- *Combination therapy had a similar safety and exposure profile to the previous FG-3246 Phase 1 monotherapy trial*
- *Results further validate key FG-3246 Phase 2 monotherapy design elements, most importantly the inclusion of patients who have progressed on only one prior ARPI and integration of baseline FG-3180 PET for all enrolled patients*
- *FG-3246 Phase 2 monotherapy trial on track for interim analysis in 2H 2026*

SAN FRANCISCO, Feb. 23, 2026 (GLOBE NEWSWIRE) -- Kyntra Bio (Nasdaq: KYNB), formerly FibroGen (Nasdaq: FGEN), today announced that the data on anti-tumor activity of FG-3246 in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC) from the investigator-sponsored Phase 1b/2 study will be presented at the 2026 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), taking place February 26-28, 2026 in San Francisco, CA.

“The results from this Phase 1b/2 investigator-initiated study demonstrate encouraging preliminary anti-tumor activity of FG-3246 in combination with enzalutamide in patients with mCRPC. Notably, the 10.1 months of rPFS in patients with only one prior ARPI underscores the potential of FG-3246 in earlier lines of therapy,” commented Dr. Rahul Aggarwal, Professor of Medicine at the University of California San Francisco, and Principal Investigator of the study. “The positive trend observed in the association between tumor uptake of FG-3180 (CD46-targeting PET) and PSA50 response, though from a small number of patients, is especially intriguing and I’m excited to see the potential utility of this biomarker further explored in the Phase 2 monotherapy study.”

“These data from the investigator sponsored trial expand on the clinically meaningful results previously observed with FG-3246,” said Thane Wettig, Chief Executive Officer of Kyntra Bio. “The 10.1 months of median rPFS observed in patients progressing on only one prior ARPI, and the mitigation of neutropenia related adverse events with prophylactic G-CSF are especially encouraging as they further validate our Phase 2 monotherapy trial design. We look forward to sharing the interim analysis of the Phase 2 monotherapy trial in the second half of 2026 as well as further characterizing the potential utility of FG-3180 as a patient selection biomarker.”

The presentation includes data from 44 biomarker unselected patients with progressive metastatic castration-resistant prostate cancer, 17 of which were enrolled in the Phase 1b dose escalation portion of the study. Eligibility criteria for the trial included patients who progressed on at least one prior ARPI while patients who were treated with prior chemotherapy in the castration-resistant setting were excluded. Over 60% of the patients progressed on two or more prior ARPIs, which included prior enzalutamide treatment. The primary endpoint of the escalation phase was assessment of dose-limiting toxicities (DLT) and determination of the maximum tolerated dose and recommended dose for the Phase 2 portion of the study – which was determined to be 2.1 mg/kg of FG-3246 and 160 mg/day of enzalutamide. The primary endpoint of the Phase 2 expansion portion of the study was composite response rate (PSA50 response and/or objective response per RECIST v1.1). Secondary endpoints were PSA50 response rate, objective response rate, radiographic progression free survival (rPFS), overall survival, and treatment-related adverse events (TRAEs).

FG-3246 combined with enzalutamide demonstrated anti-tumor activity with a composite response rate of 21% in the overall cohort and 40% in patients who had progressed on only one prior ARPI. Median rPFS of 7.0 months was observed in the overall cohort. Notably, median rPFS of 10.1 months was observed in patients who had progressed on only one prior ARPI, a result which was consistent across the different prior ARPIs administered. Additionally, higher tumor uptake of FG-3180 demonstrated a trend towards higher probability of PSA50 response ($p=0.053$), highlighting the potential of FG-3180 as a biomarker for patient selection.

Combination therapy of FG-3246 and enzalutamide demonstrated a similar safety profile as was observed in the previous Phase 1

monotherapy trial of FG-3246. Neutropenia risk was successfully mitigated with use of G-CSF prophylaxis. The most frequent TRAEs with the combination therapy included fatigue, peripheral neuropathy, anorexia, and dysgeusia. Cumulative toxicities, including peripheral neuropathy, led to treatment discontinuation for some patients.

The poster presentation, titled "A phase 1b/2 study of FOR46 (FG-3246) in combination with enzalutamide (enza) in patients with metastatic castration resistant prostate cancer (mCRPC)", is scheduled for the poster session taking place on February 26, 2026 from 11:30 AM to 12:45 PM PT.

FG-3246 is currently being evaluated in a Phase 2 monotherapy trial with interim data expected in the second half of 2026. The trial also includes treatment with FG-3180, a CD46-directed PET imaging agent, which will measure expression levels of CD46 positive lesions. This will enable further assessment of the correlation between CD46 expression and response to FG-3246 and the potential of FG-3180 to serve as a biomarker to aid in patient selection in future trials of FG-3246.

About FG-3246 and FG-3180
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 Kyntra Bio 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-3180 is a companion diagnostic PET imaging agent, using the same CD46-targeting antibody together with an ^{89}Zr tracker. To date, FG-3180 demonstrated specific uptake in CD46 positive tumors and is currently being evaluated as a biomarker for its potential to inform patient selection.

About the Phase 1b/2 Study of FG-3246 in Combination with Enzalutamide
This Phase 1b/2 study is an investigator-sponsored trial being conducted at the University of California San Francisco to evaluate FG-3246 (FOR46) in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC) after prior progression on at least one androgen receptor pathway inhibitor. The primary objective for the Phase 1b portion of the study is to determine the maximally tolerated dose (MTD) and recommended Phase 2 dose of FG-3246 in combination with enzalutamide in patients with mCRPC. The objectives of the Phase 2 portion of the study are to determine the composite response rate (CRR), proportion of participants with a greater than or equal to 50% change in prostate specific antigen (PSA50), objective response rate (ORR), median duration of response, median radiographic progression free survival (rPFS), and median overall survival (OS) of patients treated with FG-3246 in combination with enzalutamide. For more information about this study, which is currently enrolling, please visit www.clinicaltrials.gov (NCT05011188).

About Kyntra Bio
Kyntra Bio is a biopharmaceutical company focused on development of novel therapies in oncology and rare disease. Roxadustat (爱瑞卓®, EVRENZO™) is currently approved in 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 the development plan for the Phase 3 trial of roxadustat in anemia associated with lower-risk myelodysplastic syndromes (LR-MDS) in the U.S. FG-3246 (also known as FOR46), a first-in-class antibody-drug conjugate (ADC) targeting CD46, is in Phase 2 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.kyntrabio.com.

Forward-Looking Statements
This release contains forward-looking statements regarding Kyntra Bio's strategy, future plans and prospects, including statements regarding its commercial products and clinical programs and those of its 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 Kyntra Bio products and product candidates, statements regarding the potential effectiveness of FG-3180 as a biomarker or predictor of response rate, and any forward looking statements regarding the design, efficacy or safety results of our ongoing Phase 2 monotherapy trial of FG-3246. 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. Kyntra Bio'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 Kyntra Bio'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 Kyntra Bio undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

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Source: Kyntra Bio