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Sutro Biopharma Announces Initiation of REFRαME-L1 Phase 2 Trial with Luvelta for Patients with Non-Small Cell Lung Cancer

SOUTH SAN FRANCISCO, Calif., Aug. 22, 2024 (GLOBE NEWSWIRE) -- Sutro Biopharma, Inc. (Sutro or the Company) (NASDAQ: STRO), a clinical-stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs), today announced that REFRαME-L1, the global Phase 2 study of luveltamab tazevibulin (luvelta) for patients with non-small cell lung cancer (NSCLC) whose tumor expresses Folate Receptor-α (FRα), has been initiated and is open for enrollment. Initial data from this study is expected in the first half of 2025.

“The initiation of REFRαME-L1 is an important milestone in our efforts to expand the application of luvelta to a broad range of patients with FRα expressing cancers. We have generated compelling preclinical evidence that luvelta can provide an important new treatment option for NSCLC, driven by its precise design, wide therapeutic window, and ability to treat patients with lower FRα expression profiles,” said Anne Borgman, M.D., Sutro’s Chief Medical Officer.

Lung cancer is the leading cause of cancer-related deaths worldwide[1]. More than half of patients have metastatic disease at diagnosis, which has a 5-year survival rate as low as 8%[2]. Despite a variety of treatment strategies, most patients with advanced NSCLC eventually become resistant to treatment and have less treatment options as their disease progresses to later lines of treatment.

FRα has been found in multiple cancer types including NSCLC, but exhibits limited expression in normal tissue[3,4,5]. Approximately 30% of patients with adenocarcinoma NSCLC have FRα expression, making FRα an attractive therapeutic target for treatment of advanced NSCLC and providing patients an opportunity for a targeted therapy.

REFRαME-L1 is a Phase 2 trial evaluating the safety and efficacy of luvelta in adult patients with previously treated advanced or metastatic NSCLC with FRα expression ≥25% Tumor Proportion Score (TPS). Patients are expected to be dosed with 4.3 mg/kg of luvelta every three weeks.

*1: Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. Cancer J Clin. 2021;71(3):209.
*2: National Cancer Institute (NCI). Surveillance, Epidemiology, and End Results program. SEER*Stat Database. Bethesda, MD: National Cancer Institute; 2021. https://seer.cancer.gov/statfacts/html/lungb.html.
*3: Cheung A, Bax HJ, Josephs DH, Smith J, Jones A, Lewis K, et al. Targeting folate

receptor alpha for cancer treatment. Oncotarget. 2016;7(32):52553-52574.
*4: Nunez MI, Behrens C, Woods DM, Lin H, Suraokar M, Kadara H, et al. High expression of folate receptor alpha in lung cancer correlates with adenocarcinoma histology and EGFR [corrected] mutation. J Thorac Oncol. 2012;7(5):833-40. Erratum in: J Thorac Oncol. 2012 Jun;7(6):1065.
*5: O'Shannessy DJ, Yu G, Smale R, Fu YS, Singhal S, Thiel RP, et al. Folate receptor alpha expression in lung cancer: diagnostic and prognostic significance. Oncotarget. 2012;3(4):414 425.

About Luveltamab Tazevibulin
Luveltamab tazevibulin, abbreviated as “luvelta” and formerly known as STRO-002, is a FRα-targeting antibody-drug conjugate (ADC) designed to treat a broad range of patients with ovarian cancer, including those with lower FRα-expression who are not eligible for approved treatment options targeting FRα. Developed and manufactured with Sutro’s cell-free XpressCF® platform, luvelta is a homogeneous ADC with four hemiasterlin cytotoxins per antibody, precisely positioned to efficiently deliver to the tumor while ensuring systemic stability after dosing. REFRαME-O1, a Phase 2/3 registration-directed study for patients with platinum-resistant ovarian cancer is ongoing. The Company has additional ongoing trials in patients with endometrial cancer, non-small cell lung cancer, and in combination with bevacizumab in patients with ovarian cancer. The Company expects to initiate REFRαME-P1, a Phase 2/3 registration-directed study for patients with CBF/GLIS2 acute myeloid leukemia, a rare subtype of pediatric cancer, in the second half of 2024. The U.S. Food and Drug Administration (FDA) has granted luvelta a Fast Track designation for Ovarian Cancer, as well as Orphan and Rare Pediatric Disease designations for CBF/GLIS2 Pediatric AML.

About Sutro Biopharma
Sutro Biopharma, Inc., is a clinical-stage company relentlessly focused on the discovery and development of precisely designed cancer therapeutics, to transform what science can do for patients. Sutro’s fit-for-purpose technology, including cell-free XpressCF®, provides the opportunity for broader patient benefit and an improved patient experience. Sutro has multiple clinical stage candidates, including luveltamab tazevibulin, or luvelta, a registrational-stage folate receptor alpha (FolRα)-targeting ADC in clinical studies. A robust pipeline, coupled with high-value collaborations and industry partnerships, validates Sutro’s continuous product innovation. Sutro is headquartered in South San Francisco. For more information, follow Sutro on social media @Sutrobio, or visit www.sutrobio.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated preclinical and clinical development activities, including enrollment and site activation; timing of announcements of clinical results, trial initiation, and regulatory filings; potential benefits of luvelta and the Company’s other product candidates and platform; potential market opportunities for luvelta and the Company’s other product candidates; and the Company’s expected cash runway. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject

to risks and uncertainties that may cause the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the Company's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates and the Company's ability to successfully leverage Fast Track designation, the market size for the Company's product candidates to be smaller than anticipated, clinical trial sites, supply chain and manufacturing facilities, the Company's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, the Company's ability to fund development activities and achieve development goals, the Company's ability to protect intellectual property, the value of the Company's holdings of Vaxcyte common stock, and the Company's commercial collaborations with third parties and other risks and uncertainties described under the heading "Risk Factors" in documents the Company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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