November 1, 2024

Sutro Biopharma Announces Initiation of the Registration-enabling REFRαME-P1 Trial with Luvelta for Pediatric Patients with CBF/GLIS AML

SOUTH SAN FRANCISCO, Calif., Nov. 01, 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-P1, the registration-directed study of luveltamab tazevibulin (luvelta) for pediatric patients with CBFA2T3::GLIS2 (CBF/GLIS; RAM phenotype) acute myeloid leukemia (AML), has been initiated and is open for enrollment.

“We are excited to announce the initiation of our second pivotal trial, the registration-enabling clinical trial of luvelta in infants and toddlers with a rare and aggressive form of leukemia,” said Anne Borgman, M.D., Sutro’s Chief Medical Officer. “We look forward to bringing this promising targeted therapy to a pediatric patient group with limited effective treatment options.”

“Beginning this trial is an important next step in the clinical development pathway for luvelta, as it has the opportunity to address the unmet in many types of cancer that express Folate Receptor-α (FRα) beyond ovarian,” said Soheil Meshinchi, M.D., Ph.D. “With my focus on the biology of AML, I am honored to have been a part of making this medicine available to patients in dire need via a compassionate use mechanism sponsored by Sutro, through which we have seen encouraging results in this devastating disease.”

In December 2023, Dr. Meshinchi presented data on anti-leukemic activity from the compassionate use of luvelta in 25 pediatric patients with relapsed/refractory CBFA2T3-GLIS2 (CBF/GLIS) acute myeloid leukemia (AML) at the American Society of Hematology Annual Meeting and Exposition. Data demonstrated that treatment with luvelta produced meaningful clinical responses, including complete remission in 42% of patients with ≥5% blasts, and prolonged overall survival, enabling some patients to receive hematopoietic stem cell transplant, a potentially curative therapy.

CBF/GLIS subtype AML is a rare and highly lethal form of leukemia found exclusively in infants and young children, with the average age of onset at 18 months[1]. There are no therapies specifically approved to target this form of leukemia and it is resistant to conventional chemotherapy, with an induction failure rate of over 80%[2]. Due to a lack of effective treatment, children diagnosed with the disease have a dismal two-year survival rate[3]. Recent studies have shown that FOLR1, which encodes for FRα, is silent in normal hematopoiesis, but is uniquely induced by the CBF/GLIS gene fusion[4].

REFRaME-P1 is a registration-enabling study evaluating the efficacy and safety of luvelta in infants and children under 12 years of age with CBF/GLIS AML. This will be a global study, with the majority of sites planned to be open by the end of the year.

*1: National Institutes of Health [NIH], 2022; Quessada et al 2021; Masseti et al 2019
*2: Smith JL, et al. Comprehensive Transcriptome Profiling of Cryptic CBFA2T3-GLIS2 Fusion-Positive AML Defines Novel Therapeutic Options: A COG and TARGET Pediatric AML Study. Clin Cancer Res. 2020 Feb 1;26(3):726-737. doi: 10.1158/1078-0432.CCR-19-1800. Epub 2019 Nov 12. PMID: 31719049; PMCID: PMC7002196.
*3: Tang T, et al. Targeting FOLR1 in high-risk CBF2AT3-GLIS2 pediatric AML with STRO-002 FOLR1-antibody-drug conjugate, Blood Adv. 2022 Nov 22;6(22):5933-5937. doi: 10.1182/bloodadvances.2022008503. PMID: 36149945; PMCID: PMC9701621.
*4: Le Q, et al. Targeting FOLR1 in High-Risk CBFA2T3-GLIS2 AML with Stro-002 FOLR1-Directed Antibody-Drug Conjugate, Blood, Volume 138, Supplement 1, 2021, Page 209, ISSN 0006-4971, https://doi.org/10.1182/blood-2021-153076.

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 another ongoing registration-directed trial, REFRαME-P1, for patients with CBF/GLIS acute myeloid leukemia, a rare subtype of pediatric cancer, as well as additional ongoing trials in patients with endometrial cancer, non-small cell lung cancer, and in combination with bevacizumab in patients with ovarian cancer. 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/GLIS 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; outcome of regulatory decisions; potential benefits of luvelta and the Company’s

other product candidates and platform; timing of payments under our collaboration agreements; potential expansion into other indications and combinations, including the timing and development activities related to such expansion; 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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