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Sutro Biopharma Announces New Positive Data from the Compassionate Use of Luveltamab Tazevibulin (luvelta) in Pediatric Patients with Relapsed/Refractory CBF/GLIS Presented at ASH 2023

– Complete remission seen in 42% of patients with CBF/GLIS AML with ≥5% blasts and 75% of pediatric patients with CBF/GLIS AML with <5% blasts; treatment with luvelta was either alone or in combination –

– Luvelta was generally well-tolerated –

– Data supports potential further development in CBF/GLIS AML –

SOUTH SAN FRANCISCO, Calif., Dec. 11, 2023 (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 its research collaborators presented data on anti-leukemic activity from the compassionate use of luveltamab tazevibulin (luvelta), a novel folate receptor-α (FR-α) targeting ADC, in pediatric patients with relapsed/refractory CBFA2T3-GLIS2 (CBF/GLIS) acute myeloid leukemia (AML), commonly known as RAM phenotype AML. Data demonstrated that treatment with luvelta produced meaningful clinical responses, including complete remission (CR); and prolongs overall survival (OS) enabling some patients to receive potentially curative therapies such as hematopoietic stem cell transplant. These patients were treated under the single patient IND mechanism. These data were featured in a poster presentation at the 65th American Society of Hematology Annual Meeting and Exposition (ASH 2023) in San Diego, CA.

“Treatment with luvelta led to notable response in a significant subset of patients who had exhausted all therapeutic options,” said Soheil Meshinchi, M.D., Ph.D., presenter and primary author. “Response varied from deep remissions to disease stabilization with minimal toxicity – mostly in outpatient setting. Luvelta was well tolerated as long-term maintenance therapy with little to no hematopoietic toxicity.”

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

of 15%[3]. Recent studies have shown that FOLR1, which encodes for FolRα, is silent in normal hematopoiesis, but is uniquely induced by the CBF/GLIS fusion[4].

Under compassionate use, 25 pediatric patients with relapsed/refractory CBF/GLIS subtype AML were treated with luvelta at doses up to 4.3 or 5.2mg/kg every two to four weeks for a median duration of 15.9 weeks (3-73.1), with the majority of patients receiving at least five doses (68%). Of the 25 treated patients, 19 had ≥5% blasts (morphologic disease, or MD) and 8 had <5% blasts (sub-morphologic disease, or SMD)[5]. Collective results show that treatment with luvelta produced clinically meaningful and durable responses across a broad range of patients in various settings including in patients with or without prior stem cell transplant and in monotherapy or in combination with cytotoxic therapy. These data were generated by the treating physicians and collected and enabled for presentation by Sutro.

“It is clear from these data that luvelta is providing an ongoing and promising impact on the lives of infants and young children with this rare leukemia,” said Bill Newell, Sutro’s Chief Executive Officer. “These results add to the growing body of research supporting the development of luvelta, which has now seen positive clinical results across three different tumor types, including those with potentially low or variable folate receptor-α expression.”

ASH Presentation Highlights:

- Overall, anti-leukemic activity was seen with luvelta either as a single agent or in combination.
    - 19 patients had ≥5% blasts and 8 patients had <5% blasts[5].
        - A CR/CRh was observed in 8 out of 19 (42%) patients with ≥5% blasts treated with luvelta, with 5 out of 8 CR/CRh patients reaching a minimal residual disease (MRD)-negative CR (63%).
        - 6 out of 8 patients with <5% blasts experienced an MRD-negative CR (75%).
- Patients whose leukemia experienced an MRD-negative CR had an improved outcome over those who did not experience an MRD-negative CR.
- Treatment with luvelta also enabled some children to bridge to stem cell transplant, which is potentially curative therapy.
- Luvelta was well-tolerated as a monotherapy agent and in combination with standard of care therapies with minimal hematopoietic toxicity and can be delivered as outpatient therapy.
- As of September 17, 2023, 8 patients remain on treatment, with 5 of the 8 (63%) in continued remission and on luvelta maintenance.

The poster titled, “Anti-leukemic Activity of Luveltamab Tazevibulin (LT, STRO-002), a Novel Folate Receptor-α (FR-α)-targeting Antibody Drug Conjugate (ADC) in Relapsed/Refractory CBFA2T3::GLIS2 AML,” will be accessible through the News & Events page of the Investor Relations section of the company’s website at www.sutrobio.com.

*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.
*5: Two patients initially presented with <5% blasts, received luvelta and proceeded to BMT. Both relapsed post-transplant with ≥5% blasts and re-started luvelta.

About Luveltamab Tazevibulin
Luveltamab tazevibulin, abbreviated as “luvelta” and formerly known as STRO-002, is a FolRα-targeting antibody-drug conjugate (ADC) designed to treat a broad range of patients with ovarian cancer, including those with lower FolRα-expression who are not eligible for approved treatment options targeting FolRα. 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. Sutro recently initiated REFRaME, a Phase 2/3 registration-directed study for patients with platinum-resistant ovarian cancer. The company has ongoing trials in patients with endometrial cancer and in combination with bevacizumab in patients with ovarian cancer. The company is also assessing the clinical path forward for CBF/GLIS2 acute myeloid leukemia, a rare subtype of pediatric cancer, as well as non-small cell lung 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/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, transforming 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, 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 future milestone and royalty payments, the Company’s expectations about its cash runway, and potential market opportunities for luvelta and the Company’s other product candidates. 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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