December 10, 2022

Sutro Biopharma Announces Presentation of STRO-002 Data from the Compassionate Use Program in Pediatric Patients with Relapsed/Refractory CBF/GLIS AML at ASH 2022

- A total of 17 pediatric patients were treated with STRO-002 on a compassionate use basis; eight patients achieved complete remission, of which seven patients were MRD negative -

- Safety and efficacy profile in this patient population provides added confidence to advance clinical development of STRO-002, which is currently being studied in patients with advanced ovarian and endometrial cancers -

- FDA recently granted Orphan Drug Designation to STRO-002 in this patient population -

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2022 (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 at Fred Hutchinson Cancer Research Center presented data from the Compassionate Use Program on anti-leukemic activity of STRO-002, 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, in an oral presentation at the 64th American Society of Hematology Annual Meeting and Exposition (ASH 2022) in New Orleans, LA.

STRO-002 was provided to 17 pediatric patients with CBF/GLIS subtype AML on a compassionate use basis. Clinical results from these patients were compiled by Sutro and presented as an oral presentation by Soheil Meshinchi, M.D., Ph.D., Professor, Clinical Research Division, at Fred Hutchinson Cancer Research Center; Professor, Division of Pediatric Hematology-Oncology, at the University of Washington School of Medicine; and Principal Investigator for the program, titled, “Anti-Leukemic Activity of STRO-002 a Novel Folate Receptor-α (FR-α)-Targeting ADC in Relapsed/Refractory CBFA2T3-GLIS2 AML.”

“I am heartened to observe such encouraging results in children with this rare disease who have a dismal prognosis with conventional therapies and no treatment options,” commented Dr. Meshinchi. “The clinical responses to STRO-002 in this group of patients who have relapsed or are refractory to standard of care treatments, suggest that this drug is particularly promising and provides hope for patients and families impacted by this devastating disease.”

CBF/GLIS subtype AML is a rare, serious and life-threatening disease affecting pediatric

patients with a median age of 1.5 years[1] and the prevalence of CBF/GLIS in childhood is approximately 1 to 3% of pediatric AML cases[1]. These high-risk children with AML have an extremely poor prognosis with a 5-year overall survival of approximately 20%[2]. Patients are highly refractory to standard of care therapies and there are currently no approved therapies specifically targeting CBF/GLIS subtype AML.

Recent studies have shown that FOLR1, which encodes for FolRα, is silent in normal hematopoiesis, but is uniquely induced by the CBF/GLIS fusion[3]. Preclinical data presented last year at ASH 2021 demonstrated that patients with CBF/GLIS AML may benefit from STRO-002.

“We are encouraged by the positive results of our compassionate use program in children with a rare form of AML with STRO-002, which was recently granted Orphan Drug Designation by FDA in this patient population,” said Bill Newell, Sutro’s Chief Executive Officer. “These results underscore our confidence in the efficacy and tolerability for STRO-002, in addition to the development path forward for patients with ovarian and endometrial cancers.”

ASH 2022 Data Highlights:

- 17 pediatric patients were treated with STRO-002 on a compassionate use basis.
- All 17 patients were relapsed/refractory to standard of care AML treatments. The median age of the patients is two years old and the median number of prior therapies is two. Eight of the patients had previously undergone a stem cell transplant (SCT).
- STRO-002 was well-tolerated as a monotherapy agent and in combination with standard of care therapies.
- In the 17 patients treated, Best Overall Response (BOR) includes eight patients with complete remission (CR), of which seven patients were minimal residual disease (MRD) negative.
- 47% of the patients achieved complete remission and 53% of the patients achieved partial response or stable disease.
- Responders were seen in various settings including in patients with or without prior stem cell transplant and in monotherapy or in combination with cytotoxic therapy.

The presentation will be made available today in the “Clinical/Scientific Presentation and Publication Highlights” section of Sutro Biopharma’s website at www.sutrobio.com and a whitepaper with details about this rare indication and Sutro’s compassionate use program is available on the Company’s website here.

*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: 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 STRO-002

STRO-002 is an optimized FolRα-targeting antibody-drug conjugate (ADC) with a drug-antibody ratio (DAR) of 4, which is precisely conjugated using non-natural amino acids attached to stable protease-cleavable linkers and hemiasterlin-derivative warheads. STRO-002 potentially has a dual mechanism of action against the tumor through cytotoxic killing and through inducing immunogenic cell death. STRO-002 was designed with Sutro's proprietary cell-free protein synthesis and site-specific conjugation platform, which enables precise design, rapid empirical optimization, and manufacture of site-specific homogenous ADCs.

About Sutro Biopharma

Sutro Biopharma, Inc., headquartered in South San Francisco, is a clinical-stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs). Sutro has two wholly owned ADCs in the clinic—STRO-002, a folate receptor alpha (FolRα)-targeting ADC, in clinical studies for ovarian and endometrial cancers; and STRO-001, a CD74-targeting ADC, in clinical studies for B-cell malignancies. Additionally, Sutro is collaborating with Bristol Myers Squibb (BMS) on CC-99712, a BCMA-targeting ADC in the clinic for patients with multiple myeloma; with Merck KGaA, Darmstadt, Germany, known as EMD Serono in the U.S. and Canada (EMD Serono), on M1231, a MUC1-EGFR bispecific ADC in clinical studies for patients with solid tumors, particularly non-small cell lung cancer (NSCLC) and esophageal squamous cell carcinoma; with Merck, known as MSD outside of the United States and Canada, on MK-1484, a selective IL-2 agonist in clinical studies as a monotherapy and in combination with pembrolizumab for the treatment of solid tumors; and with Astellas Pharma (Astellas) on novel modality, immunostimulatory antibody-drug conjugates (iADCs). Sutro’s platform technology also enabled the spin out of Vaxcyte and the creation of VAX-24, a 24-valent pneumococcal conjugate vaccine in clinical studies for the prevention of invasive pneumococcal disease. Sutro’s rational design and precise protein engineering has enabled six product candidates in the clinic. Follow Sutro on Twitter, @Sutrobio, and at www.sutrobio.com to learn more about our passion for changing the future of oncology.

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 and regulatory filings, potential benefits of STRO-002 and the Company’s other product candidates and platform, potential future milestone and royalty payments, and potential market opportunities for STRO-002 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, the impact of the COVID-19 pandemic on the Company's business, 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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