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Sutro Biopharma Announces Oral Presentation at ASCO 2023 Featuring Data for Luveltamab Tazevibulin from the Phase 1 Dose-Expansion Study in Ovarian Cancer and the Initiation of the Phase 2/3 Pivotal Study REFRaME-O1

- Consistent with data shared in January 2023, the presentation at ASCO 2023 highlights data from the Phase 1 dose-expansion study for luveltamab tazevibulin, or luvelta, in ovarian cancer, demonstrating that FolRα-selected patients, who represent 80% of the patient population, experienced substantial clinical benefit -

- REFRaME-O1, the Phase 2/3 pivotal study of luvelta for patients with platinum-resistant ovarian cancer has been initiated and is open for enrollment -

SOUTH SAN FRANCISCO, Calif., June 03, 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 results from a Phase 1 dose-expansion study of luveltamab tazevibulin (luvelta), a novel Folate receptor alpha (FolRα)-targeting ADC, in patients with advanced ovarian cancer were featured in an oral presentation at the 2023 American Society of Clinical Oncology (ASCO 2023) Annual Meeting in Chicago, IL. In parallel, the Company continues to advance the clinical development of luvelta and announced that sites are now open for enrollment in REFRaME-O1, the pivotal Phase 2/3 study for patients with platinum-resistant ovarian cancer.

Data from the Phase 1 dose-expansion study of luvelta were presented by co-Principal Investigator, Ana Oaknin, M.D., Ph.D., Head of the Gynecological Tumor Unit and Attending Physician at the Vall d'Hebron University Hospital in Barcelona and Principal Clinical Investigator of the Gynecological Malignancies Group at the Vall d'Hebron Institute of Oncology. Consistent with data reported in January 2023, luvelta demonstrated substantial clinical benefit in FolRα-selected patients, defined by Tumor Proportion Score (TPS) of >25%, irrespective of staining intensity, which represents approximately 80% of the advanced ovarian cancer patient population.

When focusing on patients with a FolRα expression level above 25% (Tumor Proportion Score, or TPS >25% and regardless of staining intensity), the efficacy outcomes exhibited a 37.5% ORR, a median DOR of 5.5 months, and a median PFS of 6.1 months. Notably, at the higher starting dose level of 5.2 mg/kg, these patients experienced even higher response rates, with a 43.8% ORR, a median DOR of 5.4 months, and a median PFS of 6.6 months.

Responses were seen in FolRα expressing patients with TPS >25%, addressing patients who may not be eligible for other approved therapies targeting FolRα.

“I am encouraged by the preliminary efficacy, durability, and favorable safety profile observed in this study, which signify the potential of luveltamab tazevibulin as a promising therapeutic option for patients with ovarian cancer who are not well supported by current standard of care,” commented Dr. Oaknin. “The population of ovarian cancer patients that may benefit from treatment with luveltamab tazevibulin represents a significant unmet medical need globally.”

“We are excited to share these promising data in an oral presentation at ASCO, a globally respected oncology conference, which demonstrate the meaningful clinical benefit that luvelta may offer to ovarian cancer patients across a broad range of heterogeneity in FolRα-expression,” said Anne Borgman, M.D., Sutro’s Chief Medical Officer. “On the heels of these positive results, we are thrilled that REFRaME, our pivotal Phase 2/3 trial, is officially underway. From the clinical and nonclinical data gathered, we maintain our positive outlook that luvelta could potentially serve multiple additional indications where patients express FolRα.”

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.

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—luveltamab tazevibulin (STRO-002 or luvelta), 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, 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 formation of Vaxcyte and the innovation 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, trial initiation, and regulatory filings, potential benefits of luvelta and the Company’s other product candidates and platform, potential future milestone and royalty payments, 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, 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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