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Sutro Biopharma Announces First Patient Dosed in the Dose-Expansion Study of STRO-002 in Patients with Ovarian Cancer

SOUTH SAN FRANCISCO, Calif., Jan. 21, 2021 /PRNewswire/ -- Sutro Biopharma, Inc. (NASDAQ: STRO), a clinical-stage drug discovery, development and manufacturing company focused on the application of precise protein engineering and rational design to create next-generation cancer and autoimmune therapeutics, today announced the dosing of the first patient in the dose-expansion cohort of the Phase 1 STRO-002 study. STRO-002 is an internally developed, folate receptor alpha (FolRα) targeting antibody-drug conjugate (ADC) for the potential treatment of ovarian cancer. The dose-expansion cohort will assess the efficacy, safety and tolerability of STRO-002 at 4.3 and 5.2 mg/kg, given every 3 weeks in patients with ovarian cancer. The dose-expansion cohort for FolRα-selected endometrial cancer is planned for later this year.

"We are pleased to advance the clinical development of STRO-002 into dose-expansion studies. Results from our STRO-002 dose escalation in a heavily pre-treated ovarian cancer patient population demonstrated improved outcomes in RECIST response and duration of response," said Dr. Arturo Molina, Chief Medical Officer of Sutro Biopharma. "Sutro plans to expand the study to approximately 35 clinical sites in the U.S. and Europe. We are hopeful that the dose-expansion study will validate the preliminary signs of efficacy we have seen in dose-escalation and provide valuable data on the treatment paradigm and patient population that will benefit from treatment, bringing us one step closer to offering an important new potential treatment option to ovarian cancer patients."

Dr. Lainie Martin, Leader of Gynecology/Oncology Program at Hospital of the University of Pennsylvania and an investigator on the STRO-002-GM1 study, said, "STRO-002 continues to be well-tolerated and we have observed encouraging preliminary activity in patients with advanced platinum-resistant and refractory ovarian cancer. We are excited to be part of the STRO-002-GM1 dose-expansion study and to provide additional clinical data to show the potential of this therapeutic for ovarian patients with limited treatment options."

The dose-expansion study includes two patient cohorts, advanced epithelial ovarian cancer and endometrial cancer. The ovarian cancer cohort currently enrolling includes patients with platinum resistant disease and have received 1-3 prior regimens or platinum sensitive patients that have received 2-3 prior treatment regimens. Patients in the dose-expansion cohort of the STRO-002-GM1 Phase 1 study will be randomized 1:1 and treated with either 4.3 or 5.2 mg/kg STRO-002 intravenously once every three-weeks. Patients will not be pre-selected for FolRα expression and fresh or archival tumor tissue sample is required for immunohistochemistry (IHC) analysis of FolRα expression.

Additional information on the study can be found at:
https://clinicaltrials.gov/ct2/show/NCT03748186

About the Phase 1 Trial of STRO-002 in Ovarian Cancer
STRO-002-GM1, the Phase 1 open-label, multicenter, dose escalation trial with dose expansion of STRO–002, has completed enrollment. Follow-up is ongoing and will continue to evaluate the safety, tolerability, and preliminary anti-tumor activity of STRO-002 in adults with advanced epithelial ovarian cancer, including fallopian and primary peritoneal cancer. The trial is registered with clinicaltrials.gov identifier NCT03748186. Sutro discovered, developed and manufactures STRO-002 using its proprietary XpressCF® cell-free protein synthesis and XpressCF+™ site-specific conjugation technologies.

About Sutro Biopharma
Sutro Biopharma, Inc., located in South San Francisco, is a clinical-stage drug discovery, development and manufacturing company. Using precise protein engineering and rational design, Sutro is advancing next-generation oncology therapeutics.

Sutro's proprietary and integrated cell-free protein synthesis platform XpressCF® and site-specific conjugation platform XpressCF+™ led to the discovery of STRO-001 and STRO-002, Sutro's first two internally-developed ADCs. STRO-001 is a CD74-targeting ADC currently being investigated in a Phase 1 clinical trial of patients with advanced B-cell malignancies, including multiple myeloma and non-Hodgkin lymphoma. STRO-001 was granted Orphan Drug Designation by the FDA for multiple myeloma in October 2018. STRO-002 is a folate receptor alpha (FolRα)-targeting ADC, currently being investigated in a Phase 1 clinical trial of patients with ovarian and endometrial cancers. This is the second product candidate to be evaluated in clinical trials resulting from Sutro's XpressCF® and XpressCF+™ technology platforms. A third program, CC-99712 (BCMA-targeting ADC), which is part of Sutro's collaboration with Bristol Myers Squibb (formerly Celgene Corporation), is enrolling patients for its Phase 1 clinical trial of patients with multiple myeloma. Sutro's proprietary technology was responsible for the discovery and manufacturing of CC-99712, for which Bristol Myers Squibb has worldwide development and commercialization rights. Sutro is entitled to development and regulatory milestone payments and tiered royalties from Bristol Myers Squibb for this BCMA ADC. Sutro is dedicated to transforming the lives of cancer patients by creating medicines with improved therapeutic profiles for areas of unmet need.

To date, Sutro's platform has led to cytokine-based immuno-oncology therapies, ADCs, vaccines and bispecific antibodies directed at precedented targets in clinical indications where the current standard of care is suboptimal.

The platform allows it to accelerate discovery and development of potential first-in-class and best-in-class molecules through rapid and systematic evaluation of protein structure-activity relationships to create optimized homogeneous product candidates.

In addition to developing its own oncology pipeline, Sutro is collaborating with select pharmaceutical and biotech companies to discover and develop novel, next-generation therapeutics. As the pace of clinical development accelerates, Sutro and its partners are developing therapeutics designed to more efficiently kill tumors without harming healthy cells.

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, statements the Company makes regarding anticipated preclinical and clinical development activities, timing of clinical trials and announcements of clinical results, potential benefits of the Company's product candidates and platform and potential market opportunities for the Company's 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, 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, 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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