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Sutro Biopharma Announces STRO-002 FDA Fast Track Designation for Patients with Advanced Ovarian Cancer

SOUTH SAN FRANCISCO, Calif., Aug. 18, 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for STRO-002, a folate receptor alpha (FolRα)-targeting antibody-drug conjugate (ADC), for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy.

"We are pleased with the FDA's decision to grant Fast Track designation for STRO-002 and welcome the opportunity to have more frequent interactions with the agency," said Dr. Arturo Molina, Chief Medical Officer of Sutro Biopharma. "We continue to be enthused by the potential of the STRO-002 program, which has shown encouraging preliminary activity and tolerability in our Phase 1 dose-escalation study in ovarian cancer, and plan to continue to work with the FDA to potentially accelerate our clinical and regulatory efforts."

Bill Newell, Chief Executive Officer of Sutro Biopharma added, "Receiving Fast Track designation is an important recognition for STRO-002 as a potentially best-in-class FolRα ADC for women with ovarian cancer. We look forward to further collaboration with the FDA to bring this potentially important therapeutic option to women in advanced stages of their disease with limited treatment options."

About Fast Track Designation

The FDA's Fast Track designation is intended to facilitate the development and review of drug candidates that treat serious conditions or life-threatening conditions and demonstrate the potential to address an unmet medical need. A drug candidate that receives Fast Track designation can expect more frequent interaction with the FDA to discuss the drug candidate's development plan, the potential for accelerated approval, and the possibility of priority review, if relevant criteria are met at the time of submission of a Biologic Licensing Application (BLA).

About STRO-002 Clinical Development

STRO-001-GM1 is a Phase 1 trial for STRO-002 for patients with advanced ovarian cancer that have progressed or relapsed after standard of care treatments, to assess efficacy, safety, and tolerability. The dose-escalation cohort has been completed and the dose-expansion cohort has enrolled patients from sites in the U.S. and in Spain, with enrollment ongoing. Patients are not pre-selected for FolRα expression but are required to provide a

tissue sample for FolRα analysis prior to study treatment. Patients are randomized 1:1 and treated with STRO-002 at either 4.3 or 5.2 mg/kg every three weeks.

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 under investigation in a Phase 1 clinical trial for patients with advanced B-cell malignancies, and was granted Orphan Drug Designation by the FDA for multiple myeloma. STRO-002, a folate receptor alpha (FolRα)-targeting ADC, is currently being investigated in a Phase 1 clinical trial for patients with ovarian and endometrial cancers and was granted Fast Track designation by the FDA for ovarian cancer. A third product candidate, CC-99712, a 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 and has received Orphan Drug Designation from the FDA. A fourth product candidate, M1231, a MUC1-EGFR, first-in-class bispecific ADC, which is part of Sutro's collaboration with Merck KGaA, Darmstadt, Germany, known as EMD Serono in the U.S. and Canada (EMD Serono), is enrolling patients for its Phase 1 clinical trial of patients with metastatic solid tumors, non-small cell lung cancer (NSCLC) and esophageal squamous cell carcinoma. These four product candidates above being evaluated in clinical trials resulted from Sutro's XpressCF® and XpressCF+™ technology platforms. Bristol Myers Squibb and EMD Serono have worldwide development and commercialization rights for CC-99712 and M1231, respectively, for which Sutro is entitled to milestone or contingent payments and tiered royalties.

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 ADCs, bispecific antibodies, cytokine-based immuno-oncology therapies, and vaccines 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.

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 clinical development activities and timelines, the pace of the FDA's review of STRO-002, and potential benefits of the company's product candidates and

platform. 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, 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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