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Sutro Biopharma Announces Additional Data for Dose-Escalation Phase 1 Study of STRO-002 to be Presented at ASCO 2021

- Maturing data from the Phase 1 dose-escalation cohort for STRO-002 showed a median progression-free survival of 7.2 months**
- One patient achieved a CR and nine patients achieved a PR, of which four were confirmed PRs. Median duration of response on the five confirmed responders was 5.8 months**
- Data on STRO-002 from the dose-escalation cohort to be presented as a poster at ASCO and available as part of the Company Corporate Presentation has a cut-off date of April 23, 2021**

SOUTH SAN FRANCISCO, Calif., May 19, 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 additional data from the Company's dose-escalation cohort of the Phase 1 study of STRO-002, a folate receptor alpha (FolR α) targeting antibody-drug conjugate (ADC) for patients with advanced, progressive ovarian cancer; the data will also be presented as a poster at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting to be held on June 4-8, 2021.

"We are pleased to share today the maturing dose-escalation data on STRO-002 that will be presented by principal investigator Dr. R. Wendel Naumann during the 2021 ASCO Annual Meeting," said Bill Newell, Chief Executive Officer of Sutro Biopharma. "The 39 patients with advanced, progressive ovarian cancer on the study achieved a median progression-free survival of 7.2 months. Median duration of response was 5.8 months in the five confirmed responders. The dose-escalation data positions STRO-002 as a potentially important treatment option providing durable clinical benefit, especially when compared to standard of care and other agents in clinical development."

Summary of STRO-002-GM1 Phase 1 Dose-Escalation Cohort Update

The dose-escalation cohort enrolled patients with advanced, progressive epithelial ovarian cancer, not pre-selected based on FolR α -expression levels. Patient enrolled were heavily pre-treated and had received a median of six prior lines of therapy – including at least one platinum-based regimen in 100% of patients, and at least three prior lines of platinum regimens in 46%, bevacizumab in 82%, PARP inhibitors in 59%, checkpoint inhibitors in 21%, and other investigational agents in 36% of patients.

The cohort enrolled 39 patients and included 34 patients treated with clinically active dose levels at 2.9 mg/kg or higher, of which 31 patients had at least one post-baseline scan and were evaluable for RECIST responses. The cohort completed enrollment in August 2020 and the data in the ASCO 2021 abstract was based on an earlier cut-off date of January 30, 2021. The data that will be presented in a poster at ASCO 2021 had a cut-off date of April 23, 2021 and is summarized below.

- Of the 31 patients evaluable for RECIST, 10 patients met criteria for response. One patient achieved a complete response (CR) and nine patients achieved a partial response (PR). Of the nine PRs, four were confirmed PRs (cPRs) and five were unconfirmed PRs (uPRs).
- For the five confirmed responders (1 CR and 4 cPRs), the median duration of response (DOR) was 5.8 months (95% CI: 2.0, not evaluable).
- Median study follow-up was 8.4 months and median progression-free survival (PFS) was 7.2 months (95% CI: 4.5, 10.8).
- 86% of treatment-emergent adverse events (AEs) were Grade 1 or 2. The most common Grade 3 and 4 AEs were neutropenia (64%), arthralgia (13%), fatigue (10%), neuropathy (8%), and abdominal pain (8%), all of which were managed with standard medical treatment, dose reductions, or dose delays.
- Dose limiting toxicities (DLTs) were observed at higher dose levels in two patients – at 6.0 mg/kg (Grade 2 neuropathy/Grade 3 arthralgia) and at 6.4 mg/kg (Grade 3 bone pain).

Tissue samples for FolR α -expression analysis were provided by clinical sites retrospectively and were available in 18 patients treated at \geq 2.9 mg/kg in the dose-escalation cohort. Antitumor activity was observed across a broad range of FolR α -expression levels.

Dr. Arturo Molina, Chief Medical Officer of Sutro commented, "It is encouraging to see the durable clinical benefit in our dose-escalation cohort, including in patients with lower levels of FolR α -expression who are being excluded from other ovarian cancer clinical trials. The need for new treatment options for this community drives our efforts to potentially bring STRO-002 to the broadest patient population that may benefit from the therapy. In consideration of a potential FolR α biomarker enrichment strategy, we plan to take a data-driven approach through balancing an efficient path forward, while serving the high unmet medical needs for ovarian cancer patients."

The Phase 1 dose-escalation data with a data cut-off date of April 23, 2021 will be available today as part of the Company's Corporate Presentation, which can be accessed through the Company's website at www.sutro.bio. Additionally, the data will be presented virtually as a poster at the 2021 ASCO Annual Meeting from June 4-8, 2021, with details as follows:

Abstract: #5550
Session: Gynecologic Cancer
Time: Friday, June 4, 2021 at 9 a.m. ET
Title: Phase 1 Dose-Escalation Study of STRO-002, an anti-Folate Receptor alpha (FR α) Antibody Drug Conjugate (ADC), in Patients with Advanced, Progressive Platinum-Resistant/Refractory Epithelial Ovarian Cancer (EOC)
Presenter: R. Wendel Naumann, M.D., Professor & Director of Gynecologic Oncology Research at Levine Cancer Institute, Atrium Health

About the STRO-002-GM1 Phase 1 Study

STRO-002-GM1 is an open-label, multi-center, and two-part single-arm monotherapy Phase 1 study for STRO-002 in patients with advanced, progressive epithelial ovarian cancer, not pre-selected based on FolR α -expression levels. The Phase 1 is intended to study the safety, pharmacokinetics and preliminary efficacy of STRO-002, a folate receptor alpha (FolR α)-targeting ADC. The dose-escalation cohort has enrolled 39 patients and completed enrollment as of August 2020. The dose-expansion cohort is open for enrollment and requires tissue from patients for biomarker analysis prior to enrollment.

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 $\text{\textcircled{R}}$ and site-specific conjugation platform XpressCF+ TM 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 (FolR α)-targeting ADC, currently being investigated in a Phase 1 clinical trial of patients with ovarian and endometrial cancers. A third product candidate, 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 and has received Orphan Drug Designation from the FDA for multiple myeloma. A fourth product candidate, M1231, (MUC1-EGFR, first-in-class bispecific ADC), which is part of Sutro's collaboration with Merck KGaA, EMD Serono (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. The four product candidates above being evaluated in clinical trials resulted from Sutro's XpressCF $\text{\textcircled{R}}$ and XpressCF+ TM 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 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.

Follow Sutro on Twitter, [@SutroBio](#), and at www.sutro.bio.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, potential benefits of the company's product candidates and platform, potential future milestone and royalty payments, 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, 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.

Investor Contacts

Annie J. Chang
Sutro Biopharma
(650) 801-5728
ajchang@sutro.bio.com

Media Contacts

Maggie Beller
Russo Partners
(646) 942-5631
Maggie.beller@russopartnersllc.com

📄 View original content: <http://www.prnewswire.com/news-releases/sutro-biopharma-announces-additional-data-for-dose-escalation-phase-1-study-of-stro-002-to-be-presented-at-asco-2021-301295319.html>

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