December 3, 2020

Sutro Biopharma Announces Encouraging Interim Data on STRO-002 Phase 1 Dose-Escalation Study for Patients with Ovarian Cancer

- Responses observed in 32% (10/31) of evaluable patients treated at clinically active dose levels-including 1 CR, 3 cPRs and 6 uPRs -

- Disease control rate at 12 weeks is 74% (23/31) and 10 patients remained on treatment -

- Dose-expansion has been initiated to explore 4.3 & 5.2 mg/kg in less heavily pre-treated patient population -

- STRO-002 investigators to present clinical data at KOL event today at 5pm Eastern Time -

SOUTH SAN FRANCISCO, Calif., Dec. 3, 2020 /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 provided a clinical update from the company's ongoing dose-escalation Phase 1 study of STRO-002, a folate receptor alpha (FolRα) targeting antibody-drug conjugate (ADC), for patients with ovarian cancer.

STRO-002-GM1 is a single-arm monotherapy dose-escalation study for patients with ovarian cancer not selected based on their FolRα-expression levels. The dose-escalation portion of the study was fully enrolled with 39 patients in August 2020. Patients were heavily pre-treated and had a median of 6 prior lines of therapy, including standard of care platinum-based regimens, bevacizumab, PARP inhibitors, and checkpoint inhibitors.

The dose-escalation study included 34 patients treated with clinically active dose levels, 2.9 mg/kg or higher, of which 31 patients had post-baseline scans and were evaluable for RECIST responses. At the data cutoff of October 30, 2020, median time on treatment was 19 weeks and 10 patients remained on treatment. Results out of 31 evaluable patients included:

- 10 patients met RECIST criteria for response. Of which, 1 patient achieved a complete response (CR) and 9 patients achieved a partial response (PR). Of the PRs, 3 were confirmed PRs (cPRs) and 6 unconfirmed PRs (uPRs)

- 23 patients (74%) achieved disease control at 12 weeks
- 18 patients (58%) achieved disease control at 16 weeks
- 4 patients (13%) were on treatment for 52 weeks. 3 patients remained on treatment beyond 64 weeks

STRO-002 continues to be well-tolerated and 86% of all treatment-emergent adverse events (AEs) were Grade 1 or 2. Of note, prophylactic corticosteroid eye drops have not been required and no ocular toxicity signals have been observed. The most common Grade 3 and 4 AEs were reversible neutropenia. Grade 3 arthralgia (15.4%) and neuropathy (7.7%) were observed and managed with standard medical treatment, including dose reductions or delays without evidence of compromised efficacy.

"We are encouraged to see meaningful clinical benefit from STRO-002 for patients with advanced platinum-resistant and refractory ovarian cancer. The women on the study are heavily pretreated and have limited treatment options as many have received experimental agents and participated in other clinical trials," said Dr. Lainie P. Martin, Leader of Gynecology/Oncology Program at Hospital of the University of Pennsylvania and an investigator on the STRO-002 study. "The deepening of responses in patients as well as disease control over time demonstrates STRO-002 to be an important potential treatment option for patients with ovarian cancer."

"We are seeing improved outcomes in disease control and RECIST responses as the data matures and will continue to follow the patients who remain on study for further deepening of responses or clinical benefit," said Dr. Arturo Molina, Chief Medical Officer of Sutro Biopharma. "The broad therapeutic index of STRO-002 should allow for long-term dosing and dose intensity. Although a maximum tolerated dose was not reached, we have identified dose levels of 4.3 and 5.2 mg/kg that we plan to randomize in the dose-expansion. We plan to dose the first patient January 2021 and will be treating less heavily pre-treated ovarian cancer patients. An expansion cohort for FolRα-selected endometrial cancer is planned for next year."

"We are rapidly moving forward with further development of STRO-002, the FolRα-targeted ADC program. Based on emerging IHC data from our dose-escalation, we have seen responses and stable disease at various FolRα-expression levels. For dose-expansion, we will be collecting required tissue samples at enrollment and using an established assay to determine if a FolRα-selection enrichment strategy is needed," said Bill Newell, Chief Executive Officer of Sutro Biopharma. "Additional data from the dose-expansion will inform regulatory discussions, accelerate registration strategy, and identify the broadest population that may benefit from STRO-002."

STRO-002 Virtual Event Information

The data will be presented and discussed by investigators from two STRO-002 clinical trial sites:

- Lainie P. Martin, M.D. – Leader, Gynecology/Oncology Program and Associate Professor of Medicine at Hospital of the University of Pennsylvania; Dr. Martin is also a member of Sutro's Clinical Advisory Board
- R. Wendel Naumann, M.D. – Professor & Director of Gynecologic Oncology Research and Associate Medical Director of Clinical Trials at Levine Cancer Institute – Atrium

Health in Charlotte, North Carolina; Dr. Naumann is also a member of Sutro's Clinical Advisory Board

To access the live virtual event on Thursday, Dec. 3, at 2pm PT (5pm ET), please click here. An archived webcast of the event will be available on the Investor section of the company's website at ir.sutrobio.com for approximately 30 days.

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.

Additional multimedia content from Sutro regarding STRO-001 and STRO-002 can be found here and here.

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 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 studies 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.

Investor Contact
Annie J. Chang
Sutro Biopharma
+1 650-255-8806
ajchang@sutrobio.com

Media Contacts
David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

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