

# Sutro Biopharma Presents Encouraging Preliminary Clinical Data in Ongoing Phase I Study for STRO-002 Antibody-Drug Conjugate in Patients with Advanced Ovarian Cancer

- Data is being presented as a poster today at AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference in Boston

- STRO-002 was well tolerated in patients with advanced relapsed and refractory ovarian cancer and demonstrated preliminary evidence of anti-tumor activity

# - Potent anti-tumor activity was seen in preclinical endometrial cancer models

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2019 /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 oncology therapeutics, today announced initial safety data in ovarian cancer patients from its ongoing Phase I study of STRO-002, a folate receptor alpha (FolRα)-targeting antibody-drug conjugate (ADC) and potent anti-tumor activity in preclinical endometrial cancer patient-derived xenograft (PDX) models.

To date, 13 patients have been treated in the Phase I study of STRO-002 and the maximum tolerated dose (MTD) has not been reached. Dose escalation continues with two patients currently being treated at the 6 mg/kg dose level and having completed the dose limiting toxicity (DLT) observation period. There have been no DLTs and no infusion reactions to date in these heavily pre-treated patients. Preliminary evidence of anti-tumor activity was observed in a patient who achieved a confirmed partial response by RECIST 1.1 criteria. This patient also achieved and confirmed a CA-125 response for at least 28 days. Stable disease by RECIST 1.1 has been confirmed in two ongoing patients at cycles 5 and 10 of study treatment. Three ongoing patients at the 4.3 mg/kg dose level have unconfirmed stable disease per RECIST 1.1 at cycle 3. Patients are not receiving prophylactic corticosteroid eye drops. Ninety-five percent (95%) of adverse events were grade 1 or grade 2. The preliminary pharmacokinetic (PK) profile reveals an estimated half-life for the total antibody of 22-76 hours with increasing exposure in an apparent dose dependent manner.

Anti-tumor activity of STRO-002 was assessed in preclinical PDX models of endometrial

cancer that expressed varying levels of FolR $\alpha$ . High FolR $\alpha$ -expressing models showed the highest tumor growth inhibition. Some models with low and medium FolR $\alpha$  expression also exhibited good tumor growth inhibition.

"The emerging safety profile of STRO-002 is very promising," said Arturo Molina, M.D., Chief Medical Officer at Sutro Biopharma. "Antibody-drug conjugates offer the ability to preferentially kill tumor cells while avoiding healthy cells. Early signs of clinical benefit are encouraging, and we believe STRO-002 has potential in this heavily pre-treated population of patients with advanced, relapsed and refractory ovarian cancer."

Bill Newell, Sutro's Chief Executive Officer added, "STRO-002 is our second proprietary ADC in clinical trials, and one of our four ADC clinical product candidates from our platform in the past three years, including those of our collaborators. Our goal is to continue to develop targeted therapies for cancer patients. The STRO-002 data add to the growing body of evidence that our ADC development platform and pipeline of products has the potential to help patients with life-threatening cancers."

The ongoing Phase I, open-label, multicenter, dose escalation study with dose expansion of STRO-002 is designed to identify the MTD, the recommended Phase II dose and to evaluate the safety, tolerability, and preliminary anti-tumor activity of STRO-002 in adults with advanced epithelial ovarian cancer, including fallopian or primary peritoneal cancer, and endometrial cancer. This trial is registered with clinicaltrials.gov identifier <u>NCT03748186</u>.

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

The poster will be accessible through the Clinical/Scientific Presentation and Publication Highlights page of the News section of the company's website at <u>www.sutrobio.com</u>.

#### **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 and site-specific conjugation platform, XpressCF+<sup>™</sup>, led to the discovery of STRO-001 and STRO-002, Sutro's first two internally-developed ADCs. STRO-001 is a CD74 ADC currently being investigated in a Phase I 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 (FoIRα) ADC, currently being investigated in a Phase I 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+<sup>™</sup> technology platform. A third program, BCMA-targeting ADC, which is part of Sutro's collaboration with Celgene, recently received FDA clearance for its IND. Sutro's proprietary technology was responsible for the discovery and manufacturing of the BCMA ADC, for which Celgene has worldwide development and commercialization rights. Sutro is entitled to development and regulatory milestone payments and tiered royalties from Celgene 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 has designed cytokine-based immuno-oncology therapies, ADCs, vaccines and bispecific antibodies primarily directed at clinically-validated targets for which the current standard of care is suboptimal.

Sutro's 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 structureactivity 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<u>www.sutrobio.com</u> 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, 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 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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