

# Sutro Biopharma Announces Encouraging Interim Phase 1 Safety Data on a Potential First-in-Class Antibody-Drug Conjugate STRO-001 for the Treatment of B-cell Malignancies at the European Hematology Association Congress

- Interim results show STRO-001 was generally well tolerated and antitumor activity was observed in two patients with recurrent diffuse large B-cell lymphoma (DLBCL)
- STRO-001 is the first antibody-drug conjugate generated with Sutro's novel cell-free protein synthesis technology and site-specific conjugation to be tested in the clinic

SOUTH SAN FRANCISCO, Calif., June 15, 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 encouraging interim safety data from an ongoing Phase 1 dose escalation clinical trial of its product candidate STRO-001, a novel, specific and homogeneous anti-CD74 antibody-drug conjugate (ADC), as a potential therapy for patients with B-cell malignancies. The interim data from the trial includes 21 patients and separate dosing cohorts for multiple myeloma (10 MM patients) and non-Hodgkin lymphoma (11 NHL patients), was presented at the 24th European Hematology Association (EHA) Congress in Amsterdam. The data also showed encouraging preliminary anti-tumor activity for the ADC, including one complete response (CR) and one partial response (PR) among a cohort of heavily pre-treated patients with DLBCL. Overall, STRO-001 was generally well-tolerated.

"CD74 is expressed on B cells throughout differentiation and appears to be an attractive target for the treatment of non-Hodgkin lymphoma and multiple myeloma," said Dr. Nirav Shah, Assistant Professor of Medicine at Medical College of Wisconsin. "The interim safety results from the early dose escalation cohorts of the STRO-001 Phase 1 clinical trial are encouraging, especially considering the complete response seen in one of our patients."

Bill Newell, Sutro's Chief Executive Officer added, "There is a continuing need for new treatment options for patients with B-cell malignancies as many patients relapse or become refractory to even the newest treatment regimens. STRO-001 was designed to directly target

cancer cells to deliver a cytotoxic payload, an approach that enables greater precision in treating tumors. We view the data as encouraging and believe that STRO-001 can be an important new treatment option to address an unmet need for patients with B-cell malignancies."

The ongoing Phase 1, open-label, multicenter, dose escalation trial of STRO-001 is designed to evaluate the safety, tolerability and preliminary anti-tumor activity of STRO-001 in adults with B-cell malignancies. Based on interim data from the clinical trial through May 14, 2019, STRO-001 has been generally well-tolerated. The most common treatment emergent adverse events included fatigue, nausea, chills and infusion reactions. Neither ocular toxicity signals nor anti-drug antibodies have been observed and the maximum tolerated dose for both dosing cohorts has not been reached.

Sutro's cell-free protein synthesis and site-specific conjugation (XpressCF+™) platform technology was used to discover and develop STRO-001, a CD74-targeting ADC. STRO-001 contains a potent maytansinoid warhead conjugated to two specific sites (drug-to-antibody ratio of 2) using a stable non-cleavable linker. The interim data as of May 14, 2019, included 21 patients across two cohorts: cohort A for MM and cohort B for NHL. The patients enrolled in the trial were generally heavily pre-treated with a median of six lines of prior therapy. STRO-001 was administered as a 60-minute IV infusion on Days 1 and 15 of a 28-day cycle until disease progression or dose limiting toxicity. As of May 14, 2019, the MM cohort was at dose level 0.65 mg/kg and the NHL dose cohort was at 0.91 mg/kg. The trial continues to enroll patients in dose escalation in both MM and NHL cohorts. This trial is registered with clinicaltrials.gov identifier NCT03424603.

# **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 discovering and advancing next-generation oncology therapeutics.

Sutro's proprietary and integrated cell-free protein synthesis and site-specific conjugation platform, XpressCF+<sup>TM</sup>, led to the discovery of STRO-001 and STRO-002, Sutro's first two internally-developed ADCs. STRO-001 is an anti-CD-74 Antibody Drug Conjugate (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 an anti-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>TM</sup> technology platform. A third program, anti-BCMA 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 anti-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 anti-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 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<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 anticipated financial trends. 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 forwardlooking 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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