

January 5, 2022



## **Sutro Biopharma Announces Interim Data from Dose-Expansion Cohort of STRO-002 Phase 1 Study for Patients with Advanced Ovarian Cancer**

- 33% Objective Response Rate (ORR) was observed in 33 RECIST evaluable patients across all FolR $\alpha$  expression levels and both dose levels.**
- Dose response was observed, with a 47% ORR in 17 patients who started at the 5.2 mg/kg dose level.**
- Tumor proportion score (TPS) was selected as an appropriate scoring algorithm for identifying an enriched target patient population based on FolR $\alpha$  expression levels.**
- An ORR of 40% was observed for patients with TPS >25%, which, based on our patient data, represents about 70% of the advanced ovarian cancer patient population.**
- Emerging safety profile was generally consistent with prior STRO-002 data, with no new safety signals observed, including the absence of keratopathy.**
- Co-principal investigator, Dr. Naumann, and Sutro management will present data at a STRO-002 virtual event at 2 pm PT/5 pm ET today.**

SOUTH SAN FRANCISCO, Calif., Jan. 5, 2022 /PRNewswire/ -- Sutro Biopharma, Inc. ("Sutro" or the "Company") (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, fully enrolled, dose-expansion Phase 1 study of STRO-002, a folate receptor alpha (FolR $\alpha$ )-targeting antibody-drug conjugate (ADC), for patients with advanced ovarian cancer. Discussion of these data will be held at a STRO-002 Virtual Event at 2 pm PT/5 pm ET today.

"These interim data in the dose-expansion cohort showing deep responders in ovarian cancer patients treated with STRO-002 are compelling," said Dr. R. Wendel Naumann,

Professor & Director of Gynecologic Oncology Research, Associate Medical Director of Clinical Trials at Levine Cancer Institute, and an investigator on the STRO-002 study. "Patients entered the study with progressive disease and were a heavily pre-treated population and had experienced up to three lines of prior treatment. The interim data show that STRO-002 could potentially improve the lives of an underserved ovarian cancer patient population."

The dose-expansion cohort for ovarian cancer enrolled 44 patients who had experienced up to three prior lines of therapy. As of the interim data cutoff date of Nov. 8, 2021, 43 patients had been randomized into dose levels starting at 4.3 mg/kg and 5.2 mg/kg, and one patient had not yet been dosed. 81% of the patients were platinum-resistant, and 63% and 65% of the patients had been treated previously with bevacizumab and PARP inhibitors, respectively. Of the 43 patients, 33 had at least one post-baseline scan and, therefore, were evaluable for RECIST v1.1 responses.

- As of the Nov. 8, 2021, the interim data cutoff date, the Best Overall Response (BOR) for evaluable patients were as follows (N=33):
  - Seven patients had achieved partial responses (PR), which were confirmed with at least two post-baseline scans.
  - Five patients had unconfirmed partial responses (PRu), based on having received only one post-baseline scan as of the interim data cutoff date. Their next scheduled scan, subsequent to the interim data cutoff date, revealed the following: Four PRs were confirmed and one patient was in stable disease (SD).
  - An ORR of 33% (11 PRs out of 33 patients) was demonstrated in all evaluable patients, unenriched for FolR $\alpha$ -expression levels at both dose levels.
  - 14 total patients experienced SD, and 8 patients had progressive disease (PD).
- Dose response was observed, with an ORR of 47% (8 PRs out of 17 patients), for patients who started at the 5.2 mg/kg dose level, unenriched for biomarker status.
- Higher FolR $\alpha$  expression levels using TPS are correlated with higher response rates.
  - TPS has been identified as a potentially appropriate scoring algorithm for STRO-002 with respect to the biomarker enrichment strategy.
  - Based on an exploratory cut-off of TPS > 25%, a 40% ORR (10 PRs out of 25 patients) was observed. TPS  $\leq$  25% demonstrates 13% ORR.
- Based on our data, an enrichment approach of TPS > 25% FolR $\alpha$  expression may enable treatment of about 70% of the advanced ovarian cancer patient population.
- Safety signals from the 43 safety evaluable patients at the 5.2 mg/kg and 4.3 mg/kg starting dose levels were consistent with data from the dose-escalation cohort.
  - No new safety signals were observed in the dose-expansion cohort, including the absence of keratopathy.
  - 85.5% treatment-emergent adverse events (TEAEs) were Grade 1-2.
  - Neutropenia was the leading TEAE, resulting in treatment delay or dose reduction. The majority of the cases of neutropenia were generally asymptomatic and resolved with a one week dose delay or, in other cases, with standard medical treatment, including the use of G-CSF.
  - There were limited observed cases of febrile neutropenia, including one Grade 5 event at the 5.2 mg/kg starting dose level and one Grade 3 event at the 4.3 mg/kg starting dose level. The trial protocol was subsequently updated to require dose reduction for Grade 4 neutropenia.
- Data from the STRO-002 dose-expansion cohort are expected to provide further

information to inform regulatory discussions and a global registration strategy.

Dr. Arturo Molina, Chief Medical Officer of Sutro, added, "We are encouraged by the investigator interest in STRO-002 in the dose-expansion cohort, with full patient enrollment in under a year. These interim data underscore our confidence in STRO-002 as a potential therapeutic for patients with ovarian cancer, and we will continue to follow the patients who remain on treatment. With additional data continuing to mature, we expect to confirm our dosing regimen and our patient selection strategy based on FolR $\alpha$  expression. We plan to advance STRO-002 into the next phase of clinical development and leverage our Fast Track designation for continuous engagement with the FDA."

In addition to the STRO-002-GM1 Phase 1 clinical trial, a STRO-002 study for patients with ovarian cancer in combination with bevacizumab and a study for patients with endometrial cancer are both enrolling at sites in the United States and Europe. Nonclinical work to expand STRO-002 to non-small cell lung cancer (NSCLC) and potentially into other FolR $\alpha$ -expressing solid tumors is also ongoing.

### **STRO-002 Virtual Event Information**

The data will be presented by Sutro management and Dr. R. Wendel Naumann, Co-Principal Investigator in the STRO-002-GM1 studies. Dr. Naumann is a professor and Director of Gynecologic Oncology Research and Associate Medical Director of Clinical Trials at the Levine Cancer Institute, Atrium Health in Charlotte, North Carolina. Dr. Naumann is also a member of Sutro's Clinical Advisory Board.

To access the event by webcast, please click here:

[https://event.webcasts.com/starthere.jsp?ei=1520589&tp\\_key=62ffe993bc](https://event.webcasts.com/starthere.jsp?ei=1520589&tp_key=62ffe993bc)

To access the event by phone, please dial: (877) 405-1224 or (201) 389-0848

The webcast and dial-in information will also be available through the News and Events page of the Investor Relations section on the Company's website at [www.sutro.bio.com](http://www.sutro.bio.com). An archived replay will be available for at least 30 days after the event.

### **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 (FolR $\alpha$ )-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, 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 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.

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 biotechnology companies to discover and develop novel, next-generation therapeutics.

Follow Sutro on Twitter, [@SutroBio](https://twitter.com/SutroBio), and at [www.sutro.bio](http://www.sutro.bio) 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 announcements of clinical results, potential benefits of STRO-002 and the Company's other product candidates and platform, potential future milestone and royalty payments, and potential market opportunities for STRO-002 and the Company's other 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 and the Company's ability to successfully leverage Fast Track designation, the market size for the Company's product candidates to be smaller than anticipated, 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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