January 9, 2023

Sutro Biopharma Announces Update from STRO-002, Luveltamab Tazevibulin (Luvelta), Phase 1 Dose-Expansion Study and Registrational Plans in Advanced Ovarian Cancer

- Results from the STRO-002 (luvelta) Phase 1 dose-expansion study demonstrate that FolRα-selected patients experienced meaningful clinical benefit, with 43.8% ORR, median DOR of 5.4 months, and median PFS of 6.6 months at the higher starting dose of 5.2mg/kg -

- Meaningful clinical benefit was observed in FolRα-selected patients, defined as TPS>25%, which is potentially 80% of the advanced ovarian cancer patient population -

- Safety profile is generally consistent with prior data with asymptomatic neutropenia being the primary adverse event; no new safety signals were observed -

- Use of prophylactic pegfilgrastim reduced dose delays and neutropenia -

- Sutro plans to initiate Phase 2/3 registration-directed study called REFRaME in second quarter of 2023 -

- Webcast to be held today at 1:30 pm PT, or 4:30 pm ET -

SOUTH SAN FRANCISCO, Calif., Jan. 09, 2023 (GLOBE NEWSWIRE) -- Sutro Biopharma, Inc. (Sutro or the Company) (NASDAQ: STRO), a clinical-stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs), today announced results from a Phase 1 dose-expansion study of STRO-002 (luvelta), a novel Folate receptor alpha (FolRα)-targeting ADC and interim safety data from exploratory cohort C, a cohort of 15 patients with advanced ovarian cancer treated at the higher dose of luvelta, (5.2mg/kg), along with prophylactic pegfilgrastim. Additionally, the company provided details on the design of the registration-directed Phase 2/3 study, REFRaME, to start in the second quarter of 2023.

Results demonstrated that luvelta provided substantial clinical benefit in FolRα-selected patients, defined by Tumor Proportion Score (TPS) of >25%, with a 37.5% overall response rate (ORR), median duration of response (median DOR) of 5.5 months, and median progression free survival (median PFS) of 6.1 months, regardless of starting dose. Results also demonstrated the higher starting dose of 5.2 mg/kg providing greater patient benefit compared to the lower dose of 4.3mg/kg. FolRα-selected patients account for approximately 80% of the patient population in advanced ovarian cancer, as represented in the patient stratification in the Phase 1 study.

Consistent with prior luvelta data, the primary adverse event from the dose-expansion cohort was predominantly asymptomatic neutropenia, with no meaningful ocular toxicity signals or complications reported.

In cohort C, an additional 15 patients with advanced ovarian cancer were enrolled and treated with prophylactic pegfilgrastim on Day 8 after each 5.2 mg/kg administration of luvelta. Initial data on neutropenia and dose delays were available on the first 10 patients, which showed that patients in cohort C experienced substantial decreases in neutropenia and potential increases in dose intensity, due to decreased dose delays.

“Today, patients with this form of heavily pre-treated ovarian cancer have extremely limited treatment options available to them, and unfortunately, experience poor outcomes,” said Dr. R. Wendel Naumann, 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, and a co-lead principal investigator in the STRO-002-GM1 studies. “To date, luvelta continues to demonstrate encouraging efficacy data, which was further supported by results from the dose-expansion cohort. The safety profile was shown to be manageable and notably devoid of ocular complications across a broad spectrum of patients with FolRα-selected ovarian cancer.”

Commented Bill Newell, Chief Executive Officer of Sutro: “We are pleased with our Phase 1 dose-expansion efficacy data, which are generally consistent with previously reported results and demonstrate luvelta’s potential in a difficult-to-treat patient population. Through the addition of cohort C, we were able to evaluate patients at the higher dose of luvelta at 5.2mg/kg with the use of prophylactic pegfilgrastim and determined that the rates of asymptomatic neutropenia and dose delays could be diminished. Our meeting with the FDA in 2022 provided a framework for our path forward on the registration-directed Phase 2/3 trial for platinum resistant ovarian cancer patients, called REFRaME, which we plan to initiate in the second quarter of 2023.”

Summary of Results from Phase 1 Dose-Expansion Study

- **Based on the results, luvelta has demonstrated the potential to provide meaningful clinical benefit to a substantially broader patient population than the on-label patient population of the approved FolRα-targeting agent**
    - Patients who were FolRα-selected, defined by TPS>25%, regardless of starting dose, demonstrated an ORR of 37.5% (n=32) with a median DOR of 5.5 months (n=12) and a median PFS of 6.1 months (n=35)
    - Targeted luvelta patient population is approximately 80% of advanced ovarian cancer patients based on pooled Phase 1 biomarker data
    - Luvelta demonstrated a FolRα-dependent response, with patients who were unselected for FolRα (TPS≤25%) demonstrating an 11.1% ORR (n=9) with a median DOR of 2.9 months (n=1) and a median PFS of 3.8 months (n=9)

- **Luvelta, when given to patients at a starting dose of 5.2 mg/kg, provided greater patient benefit than a starting dose of 4.3 mg/kg**
    - FolRα-selected patients given the higher dose of luvelta (5.2 mg/kg) demonstrated higher response rates
        - ORR of 43.8% (n=16)
        - Median DOR of 5.4 months (n=7)

        - Median PFS of 6.6 months (n=16)
    - FolRα-selected patients given the lower dose of luvelta (4.3 mg/kg) demonstrated
        - ORR of 31.3% (n=16)
        - Median DOR of 13 months (n=5)
        - Median PFS of 6.1 months (n=19)

- **Consistent with earlier reported data, the primary adverse event from the dose-expansion cohort was asymptomatic, transient neutropenia**

- **Cohort C was initiated to explore the use of prophylactic pegfilgrastim for patients treated with the higher dose of luvelta (5.2mg/kg). Early results in the initial 10 patients in cohort C, when compared to patients who were not given prophylactic pegfilgrastim in the dose-expansion cohort at the higher dose (5.2mg/kg), showed substantial reductions in Grade 3+ neutropenia and in instances of dose delays**

    - Grade 3+ neutropenia was reduced from 66.7% to 10.0%, resulting in an 85.0% decrease in Grade 3+ neutropenia rates at the first cycle of luvelta (p=0.006)
    - Instances of dose delays at the second cycle of luvelta were reduced by 60.6% (p=0.021)

Planned Phase 2/3 Study Details

As discussed with the U.S. Food and Drug Administration (FDA), the Phase 2/3 REFRaME study is planned to begin with a randomized, run-in dose confirmation phase. In this phase of the trial, 25 patients will be evaluated at the 5.2 mg/kg dose with pegfilgrastim delivered prophylactically for two cycles followed by a step-down dose to 4.3 mg/kg. The other 25 patients will be evaluated from the start at the 4.3 mg/kg dose without prophylactic pegfilgrastim. Following this 50-patient phase of the study, additional patients will be randomized between these two luvelta dose levels, and standard of care (chemotherapy). Upon agreement with FDA on the go-forward dose versus standard of care, the dose level of luvelta not chosen will be dropped. Upon having data on approximately 110 patients in the selected dose of luvelta arm, Sutro will look to apply for accelerated approval based on ORR as the primary endpoint. At the end of the Phase 3 portion of the trial, full approval can be sought based on PFS as the primary endpoint comparing the luvelta arm (n=160) and the standard of care arm (n=160).

Webcast Details

The data will be presented by members of the Sutro management team and Dr. R. Wendel Naumann, a co-lead 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.

- Monday, January 9, 2023 at 1:30 pm PT, or 4:30 pm ET
- To access and register for the live audio webcast, please go to https://ir.sutrobio.com/news-events/ir-calendar

The webcast information will also be available through the News & Events section of the Investors portion of the Company's website at www.sutrobio.com. An archived replay will be available for at least 30 days after the event.

About Sutro Biopharma
Sutro Biopharma, Inc., headquartered in South San Francisco, is a clinical-stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs). Sutro has two wholly owned ADCs in the clinic—STRO-002, a folate receptor alpha (FolRα)-targeting ADC, in clinical studies for ovarian and endometrial cancers; and STRO-001, a CD74-targeting ADC, in clinical studies for B-cell malignancies. Additionally, Sutro is collaborating with Bristol Myers Squibb (BMS) on CC-99712, a BCMA-targeting ADC in the clinic for patients with multiple myeloma; with Merck KGaA, Darmstadt, Germany, known as EMD Serono in the U.S. and Canada (EMD Serono), on M1231, a MUC1-EGFR bispecific ADC in clinical studies for patients with solid tumors, particularly non-small cell lung cancer (NSCLC) and esophageal squamous cell carcinoma; with Merck, known as MSD outside of the United States and Canada, on MK-1484, a selective IL-2 agonist in clinical studies as a monotherapy and in combination with pembrolizumab for the treatment of solid tumors; and with Astellas Pharma (Astellas) on novel modality, immunostimulatory antibody-drug conjugates (iADCs). Sutro's platform technology also enabled the spin out of Vaxcyte and the creation of VAX-24, a 24-valent pneumococcal conjugate vaccine in clinical studies for the prevention of invasive pneumococcal disease. Sutro's rational design and precise protein engineering has enabled six product candidates in the clinic. 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 announcements of clinical results, trial initiation and regulatory filings, 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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