

# Sutro Biopharma Highlights Potential Multi-Cancer Opportunity for Luvelta, a FolRα-targeting ADC

Ovarian cancer data supports registration-enabling trial of luvelta for women with platinumresistant ovarian cancer

Potential benefit to 8 out of 10 platinum-resistant ovarian cancer patients, including addressing unmet need in patients with low-medium FolRα expression

Promising clinical activity and tolerability of luvelta as both a monotherapy and in combination across multiple cancers may provide for a significant commercial opportunity

Investor webcast today at 1:30 p.m. PT / 4:30 p.m. ET

SOUTH SAN FRANCISCO, Calif., Jan. 04, 2024 (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), is hosting an investor webcast today highlighting the significant potential of luveltamab tazevibulin (luvelta), a novel folate receptor- $\alpha$  (FolR $\alpha$ ) targeting ADC. The presentation will include an overview of the clinical data supporting luvelta's broad opportunity to address the unmet need in several FolR $\alpha$ -expressing cancers, including platinum-resistant ovarian cancer (PROC), endometrial cancer, CBFA2T3::GLIS2 (CBF/GLIS; RAM phenotype) acute myeloid leukemia (AML), and non-small cell lung cancer (NSCLC).

"Luvelta has been studied in over 180 patients to-date, and has demonstrated both promising clinical activity and a tolerable safety profile. We are optimistic about its potential to change the cancer treatment landscape," said Bill Newell, Sutro's Chief Executive Officer. "This includes the potential to be the first ADC to treat ovarian cancer patients with low to medium FolRα expression, which could double the current eligible patient population relative to the FolRα-targeting ADC on the market. In 2024, we look forward to advancing two synergistic registrational clinical trials for luvelta in ovarian cancer and CBF/GLIS AML, while continuing to progress the development of additional indications."

The event will feature presentations by key members of Sutro's senior management team and external oncology expert, Bradley Monk, M.D., Professor, the Division of Gynecologic Oncology, University of Arizona College of Medicine and Creighton University School of Medicine and Vice President and Co-Director, GOG Partners. Sutro management and Dr. Monk will participate in a Q&A session at the end of the presentation.

# **Luvelta FolRα-targeting ADC Franchise Upcoming Milestones:**

• The registration-directed trial, REFRαME-O1, in PROC is enrolling, with 26 active sites

- across 5 countries and an anticipated ~140 sites in ~20 countries by the end of 2024. Part 1 of the trial is expected to be completed in the first half of 2024.
- Initiation of REFRαME-P1, a registration-enabling trial for pediatric patients with CBF/GLIS AML, is planned for the first half of 2024.
- An Investigational New Drug (IND) application submission is planned in non-small cell lung cancer (NSCLC) in the first half of 2024.
- Continued clinical development is planned in endometrial cancer and in combination with bevacizumab for the treatment of ovarian cancer.

# **Compelling Luvelta Data:**

- Sutro presented an aggregated analysis of nearly 100 women with ovarian cancer from Company's Phase 1 program.
  - Treatment with luvelta demonstrated improved clinical outcomes and tolerability compared to historical results with standard of care chemotherapy in an evaluable patient population matching the eligibility criteria for the REFRαME-O1 trial.
  - The safety profile across the aggregated analysis remained consistent with previously reported data.
  - Safety data from an additional cohort with prophylactic G-CSF treatment showed significant reduction of neutropenia and resulting dose delays.
- New data in combination with bevacizumab demonstrated clinical activity in treated patients regardless of FolRα expression level.
- Preclinical data in a model of NSCLC demonstrated that a single dose of luvelta produced potent anti-tumor activity and that the combination of luvelta and PD-1 blockade (avelumab) demonstrated benefit and complete tumor regression.
- Promising clinical data in <u>late-stage endometrial cancer</u> and <u>CBF/GLIS AML</u> have been presented at ESMO and ASH in 2023.

#### Webcast Information:

To access the live audio webcast beginning at 1:30 p.m. PT / 4:30 p.m. ET please go to <a href="https://ir.sutrobio.com/news-events/ir-calendar">https://ir.sutrobio.com/news-events/ir-calendar</a>.

An archived replay of the webcast will be available on the Company's website following the event.

#### About Luveltamab Tazevibulin

Luveltamab tazevibulin, abbreviated as "luvelta" and formerly known as STRO-002, is a FolRα-targeting antibody-drug conjugate (ADC) designed to treat a broad range of patients with ovarian cancer, including those with lower FolRα-expression who are not eligible for approved treatment options targeting FolRα. Developed and manufactured with Sutro's cell-free XpressCF® platform, luvelta is a homogeneous ADC with four hemiasterlin cytotoxins per antibody, precisely positioned to efficiently deliver to the tumor while ensuring systemic stability after dosing. Sutro recently initiated REFRαME-O1, a Phase 2/3 registration-directed study for patients with platinum-resistant ovarian cancer. The Company has ongoing trials in patients with endometrial cancer and in combination with bevacizumab in patients with ovarian cancer. In the first half of 2024, the Company expects to initiate REFRαME-P1, a Phase 2/3 registration-directed study for patients with CBF/GLIS2 acute myeloid leukemia, a rare subtype of pediatric cancer, and expects to file an Investigational New Drug (IND) Application for the initiation of a non-small cell lung cancer study. The U.S. Food and Drug

Administration (FDA) has granted luvelta a Fast Track designation for Ovarian Cancer, as well as Orphan and Rare Pediatric Disease designations for CBF/GLIS2 Pediatric AML.

## **About Sutro Biopharma**

Sutro Biopharma, Inc., is a clinical-stage company relentlessly focused on the discovery and development of precisely designed cancer therapeutics, transforming what science can do for patients. Sutro's fit-for-purpose technology, including cell-free XpressCF®, provides the opportunity for broader patient benefit and an improved patient experience. Sutro has multiple clinical stage candidates, including luveltamab tazevibulin, or luvelta, a registrational-stage folate receptor alpha (FolRα)-targeting ADC in clinical studies. A robust pipeline, coupled with high-value collaborations and industry partnerships, validates Sutro's continuous product innovation. Sutro is headquartered in South San Francisco. For more information, follow Sutro on social media @Sutrobio, or visit <a href="https://www.sutrobio.com">www.sutrobio.com</a>.

### **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, including enrollment and site activation; timing of announcements of clinical results, trial initiation, and regulatory filings; outcome of regulatory decisions; potential benefits of luvelta and the Company's other product candidates and platform; potential expansion into other indications and combinations, including the timing and development activities related to such expansion; and potential market opportunities for luvelta 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, 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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