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# Sutro Biopharma Announces Initiation of Randomized Portion (Part 2) of REFRαME-O1 Trial

*– Part 2 of REFRαME-O1, the registration-directed study of luvelta for patients with platinum-resistant ovarian cancer (PROC), is open for enrollment –*

*– Planned 50 patients in Dose-Optimization (Part 1) of REFRαME-O1 have been enrolled and are in follow up –*

SOUTH SAN FRANCISCO, Calif., April 30, 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), today announced that the randomized portion (Part 2) of REFRαME-O1, the registration-directed trial of luveltamab tazevibulin (luvelta) in platinum-resistant ovarian cancer (PROC), is now open for enrollment, and the planned 50 patients in Part 1 of the trial have been enrolled. Luvelta is a novel Folate Receptor-α (FRα) targeting ADC with the potential to benefit 8 out of 10 PROC patients, including addressing high unmet medical need in patients with low-medium FRα expression.

"We are pleased to announce the initiation of the Phase 3 portion of our global, registration-directed clinical trial of luvelta, in patients with platinum-resistant ovarian cancer," said Anne Borgman, M.D., Sutro's Chief Medical Officer. "The speed with which we were able to enroll Part 1 of the trial speaks to the continued demand for a targeted therapy for patients that are not well supported by the standard of care. With evidence of clinical activity seen in all tumor types that have been tested with luvelta, we look forward to providing a promising treatment option to patients in need, including those with ovarian cancer and beyond."

REFRαME-O1 is a global registration-directed study evaluating the efficacy and safety of luvelta versus chemotherapy in women with PROC with FRα expression ≥25% Tumor Proportion Score (TPS), defined as at least 25% or greater of tumor expressing FRα, at any intensity (1+,2+,3+). In Part 2, approximately 500 patients will be enrolled and randomized 1:1 to the selected luvelta dose or investigators' choice of chemotherapy. The trial includes a planned interim analysis to support a potential application for accelerated approval.

## About Luveltamab Tazevibulin

Luveltamab tazevibulin, abbreviated as "luvelta" and formerly known as STRO-002, is a FRα-targeting antibody-drug conjugate (ADC) designed to treat a broad range of patients with ovarian cancer, including those with lower FRα-expression who are not eligible for approved treatment options targeting FRα. 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. REFRαME-O1, a Phase 2/3 registration-directed study for patients with

platinum-resistant ovarian cancer is ongoing. The Company has additional ongoing trials in patients with endometrial cancer and in combination with bevacizumab in patients with ovarian cancer. The Company expects to file an Investigational New Drug (IND) Application for the initiation of a non-small cell lung cancer study in the first half of 2024 and 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, in the second half of 2024. 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 our continuous product innovation. Sutro is headquartered in South San Francisco. For more information, follow Sutro on social media @SutroBio, or visit [www.sutro.bio](http://www.sutro.bio).

### **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; potential market opportunities for luvelta and the Company's other product candidates; and the Company's expected cash runway. 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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