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Sutro Biopharma Announces Selected Dose for Luvelta and Topline Results from Dose-Optimization Portion of REFRαME-O1 Trial in Platinum Resistant Ovarian Cancer

- 32% objective response rate (ORR) in evaluable patients at the 5.2 mg/kg starting dose – the selected dose for randomized portion (Part 2) of ongoing registrational REFRαME-O1 trial -

- These data confirm luvelta's robust response rate in patients with late-stage ovarian cancer expressing a broad range of folate receptor alpha (FRα) -

- Neutropenia well-managed; no new safety findings -

- Luvelta is positioned for an Accelerated Approval application in mid-2027 -

SOUTH SAN FRANCISCO, Calif., Dec. 10, 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 the selected dose from the dose-optimization portion (Part 1) of REFRαME-O1, the registration-directed trial of luveltamab tazevibulin (luvelta) in platinum-resistant ovarian cancer (PROC), following a meeting with the U.S. Food and Drug Administration (FDA).

"The topline results confirm luvelta's favorable safety and efficacy profile at the starting dose of 5.2 mg/kg, further supporting our confidence that it can improve clinical outcomes compared to chemotherapy in our ongoing registrational trial," said Anne Borgman, M.D., Sutro's Chief Medical Officer. "Consistent response rates were observed in patients across all levels of FRα expression of 25% or greater, reconfirming luvelta's potential to expand the benefit of a targeted treatment to 8 out of 10 PROC patients."

REFRαME-O1 (Part 1)

REFRαME-O1 (Part 1) evaluated luvelta in patients with PROC with low, medium, and high FRα expression levels. This includes patients with ≥25% Tumor Proportion Score (TPS), defined as at least 25% of tumor cells expressing FRα, at any staining intensity. In the dose-optimization (Part 1), patients were randomized 1:1 to a 5.2 mg/kg with prophylactic pegfilgrastim (G-CSF) for 2 cycles followed by 4.3 mg/kg for subsequent cycles (5.2 mg/kg group), or a 4.3 mg/kg dose of luvelta for all cycles (4.3 mg/kg group). We plan to present additional data at future medical meetings.

Topline Results from Evaluable Patients (5.2 mg/kg group; N = 25):

- Achieved an objective response rate (ORR) of 32%, which includes one partial response that confirmed post data extraction[1]
- Disease control rate of 96%
- Approximately half of the patients treated were ineligible for an approved FRα-targeting ADC
- 88% of patients received prior bevacizumab
- Grade 3 or higher neutropenia occurred in 32% of patients, no febrile neutropenia

“The clinical results from Part 1 of REFRαME-O1 provide compelling evidence that luvelta has the potential to be both first in class and best in class for patients who have low to medium expression of FRα. FRα is a validated target, and luvelta has the opportunity to reach more patients in need,” commented Bradley Monk, M.D., Florida Cancer Specialists and Research Institute; Director GOG Partners.

“The topline safety profile of luvelta from Part 1 is encouraging. Neutropenia rates were low, highlighting successful management guidelines. Furthermore, the lack of serious ocular damage, pancytopenia, or Interstitial Lung Disease provide further confidence in our ability to treat a broad group of women with PROC with a focus on their overall wellbeing,” stated Wendel Naumann, M.D., Professor, Levine Cancer, Atrium Health/Wake Forest University, Charlotte, NC.

REFRαME-O1 (Part 2) Registrational Trial

REFRαME-O1 (Part 2) is an ongoing global registrational trial for patients with PROC, evaluating a 5.2 mg/kg dose with prophylactic pegfilgrastim (G-CSF) for the first two cycles followed by a 4.3 mg/kg dose for subsequent cycles. Part 2 will enroll approximately 500 patients, randomized 1:1 to luvelta or investigators’ choice of chemotherapy. Luvelta is positioned for an Accelerated Approval application in mid-2027.

*1: Data as of Aug 16, 2024.

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 another ongoing registration-directed trial, REFRαME-P1, for patients with CBF/GLIS acute myeloid leukemia, a rare subtype of pediatric cancer, as well as additional ongoing trials in patients with endometrial cancer, non-small cell lung cancer, and in combination with bevacizumab in patients with ovarian cancer. 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/GLIS 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, to transform 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 www.sutrobio.com.

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 discussions with regulatory authorities; potential benefits of luvelta and the Company's other product candidates and platform; potential business development and partnering transactions; 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, 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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