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Sutro Biopharma Announces Updated Data from Phase 1b Study of Luvelta in Combination with Bevacizumab at ESMO 2024

- 4.3 mg/kg of luveltamab tazevibulin (luvelta) in combination with standard dose of bevacizumab (15 mg/kg) every 3 weeks resulted in a 56% objective response rate in patients with late-stage ovarian cancer and was selected to be the recommended phase 2 dose (RP2D) -

- Luvelta in combination with bevacizumab demonstrated encouraging preliminary antitumor activity (35% response rate) across all explored dose ranges -

- Expansion at RP2D is ongoing with an additional 23 patients enrolled to date; expansion data are expected in the first half of 2025 -

- No new safety signals were observed compared with either agent alone -

SOUTH SAN FRANCISCO, Calif., Sept. 14, 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 updated data from the ongoing Phase 1b study of luveltamab tazevibulin (luvelta) in combination with bevacizumab for patients with epithelial ovarian cancer (EOC) in a poster presentation at the 2024 European Society For Medical Oncology (ESMO) Congress in Barcelona, Spain.

In this study, luvelta plus bevacizumab has demonstrated encouraging antitumor activity in patients with late-stage ovarian cancer irrespective of Folate Receptor-α (FRα) expression, including patients with no FRα expression, and prior bevacizumab treatment, with an overall response rate of 35%. These early data in combination may offer a non-biomarker driven approach to treat patients with EOC. The expansion phase of the study is ongoing at the recommended phase 2 dose (RP2D) of luvelta (4.3 mg/kg) in combination with bevacizumab (15 mg/kg) with an additional 23 patients enrolled to date; initial data is expected in the first half of 2025.

“We are encouraged by these results achieved with luvelta in combination with bevacizumab, which may offer the opportunity to benefit ovarian cancer patients regardless of FRα expression,” said Jane Chung, Sutro’s President and Chief Operating Officer. “We have already seen promising antitumor activity with luvelta as a monotherapy treatment and we believe these combination data support our goal to deliver effective therapies to more patients living with cancer. We look forward to sharing initial results from our expansion phase in the first half of 2025.”

ESMO Poster Presentation Highlights:

- 18 patients were enrolled; one patient remains on treatment.
- Luvelta plus bevacizumab demonstrated encouraging antitumor activity in 17 RECIST evaluable patients:
  - At the RP2D (4.3 mg/kg), an Objective Response Rate (ORR) of 56% (5/9) was observed; no (0/6) patients had a response at 3.5 mg/kg and 50% (1/2) of patients had a response at 5.2 mg/kg.
  - An ORR of 35% (6/17) was observed in the overall population with a median duration of response of 9.3 months.
  - In patients with ≥25% FRα expression, an ORR of 44% (4/9) was observed; in patients with <25% FRα expression, an ORR of 29% (2/7) was observed.
- No new safety signals were observed compared with either agent alone; consistent with previous reported luvelta safety results, the most common adverse event was neutropenia.

The Presentation will be accessible through the News & Events page of the Investor Relations section of the company's website at www.sutrobio.com.

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, non-small cell lung cancer, and in combination with bevacizumab in patients with ovarian cancer. 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, 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, 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; potential benefits of luvelta and the Company's other product candidates and platform; 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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