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Sutro Announces IND Submission and Conclusion of 30-Day Review Period for STRO-002, an Antibody-Drug Conjugate (ADC) Targeting Anti-Folate Receptor-α for Treatment of Ovarian and Endometrial Cancer

- Initiation of Phase 1 Trial Planned for Early 2019

- Company's Second Cell-Free ADC Addressing Unmet Medical Need in Oncology

SOUTH SAN FRANCISCO, Calif., Nov. 13, 2018 /PRNewswire/ -- Sutro Biopharma, Inc. (NASDAQ: STRO), today announced that the U.S. Food and Drug Administration (FDA) has concluded their 30-day review of the Investigational New Drug (IND) application for STRO-002 to be evaluated in a Phase 1 clinical study as a potential treatment for ovarian and endometrial cancer. The antibody-drug conjugate STRO-002 targets folate receptor-α, a cell-surface protein expressed in 80% of ovarian and endometrial cancers.

"The ability to begin our Phase I clinical study marks an important milestone that expands Sutro's clinical development pipeline and further validates our technology for the design of unique and potent antibody-drug conjugates," said Bill Newell, Sutro's Chief Executive Officer. "The Phase 1 clinical trial of STRO-002 is expected to begin in early 2019 with the goal to investigate the safety, tolerability and preliminary anti-tumor activity of STRO-002 in patients with gynecologic malignancies."

Patients with ovarian cancer will be enrolled during the dose escalation-phase of the study, and two separate cohorts for ovarian and endometrial cancer will be evaluated during dose expansion.

"Ovarian and endometrial cancer patients need targeted treatment options with better tolerability and efficacy," commented Dr. Wendel Naumann, MD Gynecologic Oncologist Professor, Dept. Ob/Gyn Levine Cancer Institute, Carolinas Medical Center.

In preclinical studies, STRO-002 effectively delivered its cytotoxin to targeted cancer cells without significant accumulation of a toxic metabolite in the blood. Testing of clinically relevant doses in non-human primates showed no evidence of ocular toxicity, a vexing problem associated with conventional ADCs containing standard tubulin-inhibiting agents.

"This is an important development for ADC-based cancer therapeutics and could provide

new means to achieving greater anti-tumor activity in the clinic before the onset of dose-limiting side effects," added Dr. Arturo Molina, Sutro's Chief Medical Officer.

Unlike first-generation ADCs, STRO-002 is a homogeneous, site-specific antibody-drug conjugate that incorporates a novel, proprietary linker-warhead, thereby enabling effective and precise payload delivery to targeted cancer cells. Preclinical studies demonstrated STRO-002's potent *in vitro* cytotoxicity in ovarian and endometrial cancer cell lines, and tumor growth inhibition in multiple *in vivo* ovarian and endometrial cancer models. Safety studies conducted in non-human primates have shown tolerability at clinically relevant doses with no observed ocular toxicity.

About STRO-002
STRO-002 was developed with Sutro's proprietary cell-free protein synthesis and site-specific conjugation platform, XpressCF+^{TM}, which enables precise design, rapid empirical optimization, and manufacture of site-specific ADCs. Sutro's technology results in highly optimized ADCs comprising a single molecular species, in contrast to first-generation commercial ADCs that comprise a mixture of imprecisely conjugated antibodies. STRO-002 has been engineered to use Sutro's novel, proprietary SC239 linker-warhead, designed for increased stability and potency, which results in effective targeting of cancer cells and precise delivery of the payload.

About Sutro Biopharma
Sutro Biopharma, Inc., located in South San Francisco, is a clinical-stage drug discovery, development and manufacturing company. Using precise protein engineering and rational design, Sutro is advancing next-generation oncology therapeutics.

Sutro's proprietary and integrated cell-free protein synthesis and site-specific conjugation platform, XpressCF+™, led to the discovery of STRO-001 and STRO-002, Sutro's first two internally-developed antibody-drug conjugates, or ADCs. STRO-001 is a potentially first-in-class ADC targeting CD74, a protein highly expressed in multiple myeloma and non-Hodgkin's lymphoma, and is currently in a Phase I study. STRO-002 is a potentially best-in-class ADC targeting folate receptor alpha, a cell-surface protein highly expressed in gynecological cancers.

Sutro is dedicated to transforming the lives of cancer patients by creating medicines with improved therapeutic profiles for areas of unmet need.

To date, Sutro's drug discovery efforts have focused on antibody-drug conjugates, cytokine-based immuno-oncology therapies, and bispecific antibodies primarily directed at clinically-validated targets for which the current standard of care is suboptimal.

Sutro's platform allows it to accelerate discovery and development of potential first-in-class and best-in-class molecules through rapid and systematic evaluation of protein structure-activity relationships to create optimized homogeneous product candidates.

In addition to developing its own oncology pipeline, Sutro is collaborating with select pharmaceutical and biotech companies to discover and develop novel, next-generation therapeutics. As the pace of clinical development accelerates, Sutro and its partners are developing therapeutics designed to more efficiently kill tumors without harming healthy cells.

Follow Sutro on Twitter, @Sutrobio, and atwww.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, the nature and timing of anticipated clinical development activities and the potential benefits of the company's product candidates and platform. 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, obtain regulatory approval of and ultimately commercialize its 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 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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