Sutro Biopharma Initiates Phase I Clinical Trial of STRO-002 for the Treatment of Ovarian and Endometrial Cancers

March 15, 2019

- STRO-002, Sutro's second clinical program, is designed to deliver "toxic payloads" to kill cancer cells

- Sutro plans to enroll up to 160 patients in open-label, multicenter study

SOUTH SAN FRANCISCO, Calif., March 15, 2019 /PRNewswire/ -- Sutro Biopharma, Inc. (NASDAQ: STRO) today announced that it has dosed the first patient in a Phase I study of STRO-002, an anti-folate receptor alpha (FoIRα) antibody-drug conjugate (ADC), in patients with ovarian and endometrial cancers. This is the second product candidate to be evaluated in clinical trials resulting from Sutro's XpressCF+™ technology platform.

The study is a multi-center, open-label, dose-escalation with dose expansion Phase I trial evaluating the safety, tolerability and preliminary anti-tumor activity of STRO-002. The study plans to enroll up to 160 women with advanced relapsed and/or progressive ovarian, fallopian, primary peritoneal or endometrial cancer.

"Moving our second product candidate into human clinical trials is another momentous milestone in Sutro's evolution from a technology platform company to a clinical stage company," said Sutro CEO Bill Newell. "Our goal is to ultimately help fill the unmet need for more targeted therapies for patients with ovarian and endometrial cancer and advancing STRO-002 into the clinic brings us one step closer to achieving this."

STRO-002 is designed to target FoIRα, a cell-surface protein highly expressed in ovarian cancer. In preclinical studies, STRO-002 demonstrated potent in vitro cytotoxicity in ovarian cancer cell lines and significantly inhibited tumor growth in multiple ovarian cancer xenograft models. In safety studies conducted in non-human primates, STRO-002 was well tolerated at clinically relevant doses. "Based on observations from pre-clinical studies, STRO-002 has the potential to overcome traditional dose-limiting factors in the clinical setting, including ocular toxicity, which is a vexing problem with some ADCs," said Sutro Chief Medical Officer, Arturo Molina, M.D.

Denise Uyar, M.D., Associate Professor of Gynecology Oncology at Medical College of Wisconsin, an investigator in the STRO-002 study added, "Sutro's unique ADC has the potential to be another important therapeutic option for oncologists in treating patients with ovarian and endometrial cancer. We look forward to evaluating the next-generation of ADCs in this study."

The Phase I study will consist of two parts: dose-escalation followed by dose-expansion. In both parts of the study, STRO-002 will be dosed as an intravenous infusion on Day 1 of 21-day cycles. Additional information can be found at https://clinicaltrials.gov/ct2/show/NCT03748186.

STRO-002 was developed using Sutro's proprietary cell-free protein synthesis and site-specific conjugation platforms, which facilitates precision design and rapid empirical optimization of ADCs and other product candidates.

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 CD74 ADC currently being investigated in a Phase I study of patients with advanced B-cell malignancies, including multiple myeloma and non-Hodgkin's lymphoma. STRO-001 was granted Orphan Drug Designation by the FDA for multiple myeloma in October 2018.

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 has designed cytokine-based immuno-oncology therapies, antibody-drug conjugates, vaccines 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 at www.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, planned 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.

Investor Contacts

John Graziano
Solebury Trout
+1 646-378-2942
jgraziano@soleburytrout.com

Xuan Yang
Solebury Trout
+1 646-378-2975
xyang@soleburytrout.com

Media Contacts

David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

Scott Stachowiak
Russo Partners
(646) 942-5630
(646) 300-3590 mobile
scott.stachowiak@russopartnersllc.com

View original content:http://www.prnewswire.com/news-releases/sutro-biopharma-initiates-phase-i-clinical-trial-of-stro-002-for-the-treatment-of-ovarian-and-endometrial-cancers-300812765.html

SOURCE Sutro Biopharma, Inc.