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Sutro Biopharma Earns Clinical Supply Milestone Payment from Merck KGaA, Darmstadt, Germany for Novel Bispecific Antibody Drug Conjugate Targeting Solid Tumors

SOUTH SAN FRANCISCO, Calif., Aug. 25, 2020 /PRNewswire/ -- Sutro Biopharma, Inc. (NASDAQ: STRO), a clinical-stage drug discovery, development and manufacturing company focused on the application of precise protein engineering and rational design to create next-generation oncology therapeutics, today announced that it has achieved a clinical supply milestone under its collaboration and license agreement with the healthcare division of Merck KGaA, Darmstadt, Germany and is entitled to receive a milestone payment. The candidate, M1231, was discovered using Sutro's XpressCF® and XpressCF+™ drug discovery and manufacturing technologies and includes a proprietary linker-warhead also discovered by Sutro. M1231 is a MUC1-EGFR bispecific antibody drug conjugate (ADC) for the treatment of solid tumors and relies on the strand-exchange engineered domain (SEED) platform from Merck KGaA, Darmstadt, Germany to generate bispecific antibody-like molecules.

The milestone was achieved with the delivery of GMP clinical trial supply to Merck KGaA, Darmstadt, Germany for the Phase 1 clinical trial testing of M1231 pursuant to a 2014 license agreement. As part of the agreement, Sutro will manufacture M1231 for early clinical supply and is eligible for further milestones and royalties. Merck KGaA, Darmstadt, Germany will be responsible for filling and finishing the drug product, in addition to its clinical development and commercialization.

"Reaching the clinical supply milestone in our collaboration with Merck KGaA, Darmstadt, Germany underscores our continued commitment to deliver novel therapies to patients with cancer," said Bill Newell, Sutro's Chief Executive Officer. "M1231 bispecific ADC was generated with Sutro's XpressCF® and XpressCF+™ drug discovery and manufacturing technologies which enabled the use of iterative optimization through cell-free protein synthesis and site-specific conjugation with the goal of an improved therapeutic window. Through our continued collaboration with Merck KGaA, Darmstadt, Germany, we hope to move closer to bringing new treatment options to cancer patients."

"M1231 is the first bispecific ADC targeting both MUC1 and EGFR. By combining XpressCF+™ technology with the SEED antibody platform, Merck KGaA, Darmstadt, Germany and Sutro in collaboration have developed a unique next generation ADC that has the potential to increase the therapeutic window by selectively targeting tumors that co-express two different tumor antigens.," said Trevor Hallam, PhD, Sutro's Chief Scientific Officer.

"We look forward to working with Merck KGaA, Darmstadt, Germany to apply our proprietary GMP manufacturing platform to supply M1231 for the early clinical studies," said Shabbir Anik, PhD, Sutro's Chief Technical Officer.

Under the terms of the 2014 license agreement, Sutro and Merck KGaA, Darmstadt, Germany have collaborated to discover and develop ADCs utilizing Sutro's cell-free protein synthesis and site-specific conjugation platforms, XpressCF® and Xpress CF+™. Further financial details are not being disclosed.

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 platform XpressCF® and site-specific conjugation platform, XpressCF+™, led to the discovery of STRO-001 and STRO-002, Sutro's first two internally-developed ADCs. STRO-001 is a CD74-targeting ADC currently being investigated in a Phase 1 clinical trial of patients with advanced B-cell malignancies, including multiple myeloma and non-Hodgkin lymphoma. STRO-001 was granted Orphan Drug Designation by the FDA for multiple myeloma in October 2018. STRO-002 is a folate receptor alpha (FolRα)-targeting ADC, currently being investigated in a Phase 1 clinical trial of patients with ovarian and endometrial cancers. This is the second product candidate to be evaluated in clinical trials resulting from Sutro's XpressCF® and XpressCF+™ technology platforms. A third program, CC-99712 (BCMA-targeting ADC), which is part of Sutro's collaboration with Bristol Myers Squibb (formerly Celgene Corporation), is enrolling patients for its Phase 1 clinical trial of patients with multiple myeloma. Sutro's proprietary technology was responsible for the discovery and manufacturing of CC-99712, for which Bristol Myers Squibb has worldwide development and commercialization rights. Sutro is entitled to development and regulatory milestone payments and tiered royalties from Bristol Myers Squibb for this BCMA ADC. 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, ADCs, 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.

Additional multimedia content from Sutro regarding STRO-001 and STRO-002 can be found here and here.

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, anticipated preclinical and clinical development activities, timing of announcements of clinical results, potential benefits of the company's product candidates and platform and potential market opportunities for the company's 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, the impact of the COVID-19 pandemic on the Company's business, 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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