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Sutro Initiates First Clinical Trial of CD74-Targeting ADC for Lymphoma & Multiple Myeloma Treatment; The First of a New Generation of Precisely Engineered ADCs

SOUTH SAN FRANCISCO, Calif., April 26, 2018 /PRNewswire/ -- [Sutro Biopharma](#), Inc. has begun dosing patients in its initial clinical trial of its potential first-in-class antibody drug conjugate, or ADC, product candidate, STRO-001, targeting CD74, a protein highly expressed in B-cell malignancies such as myeloma and lymphoma. The Phase 1 clinical trial of STRO-001 is the first clinical trial to be conducted with a product candidate created using cell-free protein synthesis. With the commencement of patient dosing with STRO-001, Sutro seeks to establish itself as a leader in cell-free protein synthesis for the discovery and development of cancer therapeutics.

STRO-001 is Sutro's first internally-developed antibody drug conjugate product candidate.

The U.S. Food and Drug Administration granted Sutro permission to proceed with the study in January 2018.

Sutro expects to enroll up to 220 patients in the open-label, multicenter, dose escalation and dose expansion study across approximately 50 sites in the United States and Europe. The primary outcome measures are safety and tolerability of STRO-001 in dose escalation and preliminary anti-tumor activity in dose expansion.

"Based on preclinical research findings, we are hopeful that this Phase 1 study will demonstrate that STRO-001 has preliminary activity in patients with multiple myeloma and non-Hodgkin's lymphoma with progressive disease following standard of care therapies," said Bill Newell, Sutro's Chief Executive Officer.

Preclinical research findings presented by Sutro at the American Society of Hematology's 2017 annual meeting and at other scientific meetings last year highlighted the specificity of STRO-001's anti-CD74 antibody component, the high prevalence of CD74 expression in myeloma and lymphoma tumor samples, STRO-001's potent *in vitro* cytotoxicity in multiple B-cell tumor cell lines and its anti-tumor activity in multiple myeloma and lymphoma xenograft models.

"Ultimately, we aim to demonstrate that STRO-001 can be an important new treatment option to address an unmet need for targeted therapies for patients who have multiple myeloma and non-Hodgkin's lymphoma," Mr. Newell added.

Building a Better ADC

"The launch of our first Phase 1 clinical trial is a milestone in Sutro's evolution from a platform company to a clinical-stage drug developer," said Dr. Arturo Molina, a medical oncologist and Sutro's Chief Medical Officer.

Nirav Shah, MD, Assistant Professor of Medicine, Lymphoma/BMT program at Medical College of Wisconsin said, said: "As lymphoma and multiple myeloma progress, it becomes harder to find well tolerated treatments that effectively target the tumor. I'm hoping that this clinical trial, like the preclinical studies before it, will demonstrate that STRO-001 may be a potent new option for targeting tumors with greater precision."

STRO-001 was developed with Sutro's proprietary cell-free protein synthesis and site-specific conjugation platforms, which facilitate precision design and rapid empirical optimization of ADCs. Sutro's platform enables design and manufacture of a highly optimized single molecular species within the product, rather than the usual mixture of imprecisely conjugated antibodies that comprise an ADC development product using conventional cell-based manufacturing platforms.

"Sutro's XpressCF+™ platform enabled us to design STRO-001 to directly and highly efficiently target cancer cells to deliver a cytotoxic payload," Dr. Molina added.

"The XpressCF+™ platform allows the incorporation of non-natural amino acids into specific positions on the generated antibody, allowing for site-specific conjugation of cytotoxins with a linker and warhead to enable consistent, stable, pinpoint placement of STRO-001's toxic payload resulting in highly efficient delivery of cytotoxin to tumor cells," said Dr. Trevor Hallam, Sutro's Chief Scientific Officer. "By contrast, earlier generations of ADCs result in products that can have unpredictable and sub-optimal pharmacologic properties, resulting in the potential for sub-optimal stability, compromised efficacy and poor tolerability for patients."

Sutro's technology enables the company to iteratively discover and test molecules preclinically in a cycle of weeks rather than months to more rapidly determine the optimal molecular attributes for safety and potency.

Sutro's manufacturing center in San Carlos, California, the world's only cGMP cell-free manufacturing facility, is built to maximize the speed and efficiency of XtractCF™ cell-free extract and protein production. XtractCF™ is manufactured by a multi-day continuous process producing cell-free extract for large scale XpressCF™ and XpressCF+™ reactions.

This past October, Sutro received a manufacturing milestone payment from Celgene for successfully scaling-up production in its cGMP manufacturing facility, from which Sutro has generated the XtractCF™ cell-free extract and antibody for its STRO-001 Phase 1 clinical trial materials.

About Sutro Biopharma

Sutro Biopharma, located in South San Francisco, has pioneered a compelling and unique way of discovering, developing and manufacturing therapeutics. Sutro's focus is primarily next generation cancer therapeutics — antibody drug conjugates, or ADCs, bispecific antibodies, and engineered cytokines and cytokine conjugates. Unconstrained by traditional methods of cell-based methods for protein discovery, Sutro is working to design and develop

targeted medicines by efficiently combining both recombinant and synthetic components in drug design, with the goal of establishing a new drug discovery and development paradigm.

Sutro believes its approach to discovery is also transcending the limitations of biologics manufacturing. Sutro's state-of-the-art manufacturing facility confers an important competitive advantage as Sutro initiates its first clinical trial.


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 demonstrating a more efficient approach to killing tumors without harming healthy cells.

Follow Sutro on Twitter, @SutroBio, and at www.sutro.bio.com to learn more about our passion for changing the future of oncology.

Media Contacts

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

Amiad Finkelthal
Russo Partners
(646) 942-5626
(917) 217-1838 mobile
amiad.finkelthal@russopartnersllc.com

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