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Sutro Biopharma Announces Research Collaboration with the FDA to Advance Regulatory Standards for Antibody Drug Conjugates

SOUTH SAN FRANCISCO, Calif., July 22, 2025 (GLOBE NEWSWIRE) -- Sutro Biopharma, Inc. (Sutro or the Company) (NASDAQ: STRO), an oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs), today announced that it has entered into a collaboration with the U.S. Food and Drug Administration (FDA) to develop reference materials to improve regulatory standards and enhance analytical methods for ADC drug development. The collaboration will leverage Sutro's cell-free XpressCF® technology to precisely engineer ADCs with predefined attributes, as well as FDA's cutting-edge analytical capabilities to fully characterize these materials.

"ADCs represent one of the most promising and fast-growing modalities for new biopharmaceuticals. We're honored to be among a select group collaborating with the FDA to help shape regulatory standards for ADC development and quality control," said Hans-Peter Gerber, Ph.D., Sutro's Chief Scientific Officer. "This collaboration underscores the precision and flexibility of our cell-free XpressCF® platform in advancing next-generation ADCs, and we look forward to the impact of this work across the industry, with regulators, and for the patient community. We thank the FDA for the opportunity to help define the future of ADC innovation."

As part of the collaboration, Sutro and the Office of Pharmaceutical Quality (OPQ) within the FDA Center for Drug Evaluation and Research (CDER) will jointly lead the study design and selection of target antigens, payload-linkers, and drug conjugation sites representative of both approved ADCs and those in development. The results will be published upon completion, and the insights gained from this collaboration are expected to enhance OPQ's ongoing research efforts aimed at bolstering the FDA's capacity for the analytical characterization of ADCs to enhance ADC quality assessments.

About Sutro Biopharma
Sutro Biopharma, Inc., is 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 is advancing a robust early-stage pipeline of novel exatecan and dual-payload antibody drug conjugates (ADCs), coupled with high-value collaborations and industry partnerships, which validate its 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; outcome of discussions with regulatory authorities; potential benefits of the Company's product candidates and platform; potential business development and partnering transactions; potential market opportunities for the Company's product candidates; and the potential benefits of the Company's collaboration with the FDA. 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 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 obtain, 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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