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Sutro Biopharma and Boehringer Ingelheim BioXcellence™ collaboration: Established first-in-class cell-free capabilities at commercial scale

SOUTH SAN FRANCISCO, Calif., Jan. 07, 2025 (GLOBE NEWSWIRE) -- Boehringer Ingelheim BioXcellence™ and Sutro Biopharma Inc. today announced that they successfully applied Sutro's proprietary cell-free expression technology on a commercial scale to manufacture luveltamab tazevibulin (luvelta), Sutro's Tubulin FRα-targeting antibody-drug conjugate (ADC) designed to treat a broad range of patients with ovarian cancer and other FRα expressing cancers.

For the first time, the cross-functional teams were able to scale up Sutro's cell-free protein synthesis platform from a small-scale Good Manufacturing Practice (GMP) production to a large-scale GMP production marking an industry milestone. All batches of luvelta manufactured in 4,500 L at Boehringer's large-scale manufacturing facility in Vienna, Austria, met the product quality criteria required for the use in clinical studies.

Sutro's cell free platform utilizes cellular components necessary for protein generation. The cell-free extract contains everything that is needed for synthesis, including energy production, transcription, and translation. By adding a specific DNA sequence, the desired protein can be synthesized. This technology has proven effective for a large range of molecule sizes, from small peptides to complex mammalian proteins such as monoclonal antibodies.

"We're thrilled that our long-standing partnership with Sutro built the foundation to choose our site to demonstrate its technology on a commercial scale, which proves our reputation as manufacturing experts," said Dr. Tilman Rock, site head Biopharma Austria at Boehringer Ingelheim. Ute Lehmann, Head of Business Development, Key Account Management & Marketing of Boehringer Ingelheim's contract manufacturing arm, BioXcellence, added: "Our partnership with Sutro shows how we can achieve more together. It's through these synergies that we enhance our capabilities, complementing our partners' expertise. This is the essence of our partnership approach at Boehringer Ingelheim BioXcellence™."

A unique advantage of the Sutro cell-free protein synthesis platform is its modular approach. It uses non-natural amino acids to achieve site-specific conjugation of proteins to chemicals in a way that isn't possible with cell-bound approaches. This is a crucial aspect in creating, for instance, next-generation ADCs for oncology treatments that are designed to have certain benefits in the safety and efficacy profile compared to ADCs produced by traditional methods. Sutro's lead candidate was selected to demonstrate commercial viability. These insights can be applied to their robust pipeline of next-generation ADCs targeting a variety of cancers.

“In our partnership with Boehringer Ingelheim BioXcellence™, we have been working toward demonstrating that ADCs built with our cell-free platform can be manufactured by a third party at commercial scale under GMP conditions,” said Venkatesh Srinivasan, PhD, Sutro’s Chief Technical Operations Officer. “Today we are excited to share that we have achieved this goal together with our partner. We look forward to applying these learnings to our broader ADC pipeline. Sutro is actively seeking business development partners to continue to advance and accelerate our technology platform’s potential and our product pipeline.”

Boehringer Ingelheim
Boehringer Ingelheim is a biopharmaceutical company active in both human and animal health. As one of the industry’s top investors in research and development, the company focuses on developing innovative therapies that can improve and extend lives in areas of high unmet medical need. Independent since its foundation in 1885, Boehringer takes a long-term perspective, embedding sustainability along the entire value chain. More than 53,500 employees serve over 130 markets to build a healthier, more sustainable, and equitable tomorrow.
Learn more at www.boehringer-ingelheim.com.

Boehringer Ingelheim BioXcellence™
Building on this, Boehringer Ingelheim BioXcellence™ collaborates with partners to reliably supply biopharmaceutical therapies. The companies’ extensive experience in their contract development and manufacturing has resulted in supplying more than 45 commercial products to patients in need worldwide. It operates a global manufacturing network in key technologies such as mammalian and microbial, turning biologic innovations into commercial successes.
Learn more at www.bioxcellence.com.

Sutro Biopharma, Inc.
Sutro Biopharma, Inc., is a clinical-stage company 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 has multiple clinical stage candidates, including luveltamab tazevibulin, or luvelta, a registrational-stage folate receptor alpha (FolRα)-targeting ADC in clinical studies. A robust pipeline, coupled with high-value collaborations and industry partnerships, validates Sutro’s 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, Sutro’s potential commercial-scale manufacturing capabilities; anticipated preclinical and clinical development activities; timing of announcements of clinical results, trial initiation, and regulatory filings; potential benefits of luvelta and Sutro’s other product candidates and platform; potential business development and partnering transactions; and potential market opportunities for luvelta and Sutro’s other product candidates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although Sutro believes that the expectations reflected in such forward-looking statements are reasonable, Sutro 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 Sutro's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to Sutro's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates and Sutro's ability to successfully leverage Fast Track designation, the market size for Sutro's product candidates to be smaller than anticipated, clinical trial sites, supply chain and manufacturing facilities, Sutro's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, Sutro's ability to fund development activities and achieve development goals, Sutro's ability to protect intellectual property, and Sutro's commercial collaborations with third parties and other risks and uncertainties described under the heading "Risk Factors" in documents Sutro 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 Sutro undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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