

# Sutro Biopharma Announces First Cohort of Patients Dosed in Phase 1 Trial of STRO-004, a Next-Generation Tissue Factor ADC, in TF-Expressing Solid Tumors

Initial clinical data expected mid-2026 –

SOUTH SAN FRANCISCO, Calif., Dec. 03, 2025 (GLOBE NEWSWIRE) -- Sutro Biopharma, Inc. (Sutro or the Company) (NASDAQ: STRO), a clinical stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs), today announced that the patients in the first cohort have been dosed in its Phase 1 trial evaluating STRO-004 in a range of Tissue Factor (TF) expressing solid tumors. STRO-004 is the Company's TF-targeting exatecan ADC engineered for best-in-class stability, potency, and tumor selectivity using Sutro's proprietary cell-free platform.

"Dosing the initial patients in this trial marks an important milestone in bringing forward new treatment options for patients with TF-expressing cancers—many of whom face limited therapy options and difficult prognoses. We've seen strong engagement from our clinical investigators, who recognize the potential of STRO-004 to address a pressing need in oncology—and we're proud of the speed and precision with which our team brought the program into the clinic," said Jane Chung, Chief Executive Officer of Sutro Biopharma. "STRO-004 is engineered to deliver potent, sustained anti-tumor activity and higher exposure compared to approved therapies, with the goal of reaching tumors that are resistant to standard approaches. Through this trial, we aim to generate early insights into safety and activity that will guide development in areas of urgent unmet need. We are deeply grateful to the patients and investigators participating in this study and look forward to sharing initial data in mid-2026."

The Phase 1 open-label, multicenter trial is designed to evaluate the safety, pharmacokinetics, and preliminary anti-tumor activity of STRO-004 in patients with advanced TF-expressing solid tumors, including non-small cell lung cancer, head and neck squamous cell carcinoma, cervical cancer, colorectal cancer, pancreatic ductal adenocarcinoma, and bladder cancer. The dose-escalation phase includes multiple cohorts with ascending dose levels, supported by strong tolerability in non-human primates at up to 50 mg/kg. Sutro's design enables high entry doses, with the goal of rapidly identifying a recommended Phase 2 dose and early signs of clinical activity.

More information can be found at: https://clinicaltrials.gov/study/NCT07227168.

STRO-004 is a next-generation antibody-drug conjugate (ADC) targeting tissue factor (TF), a clinically validated tumor-associated antigen expressed across multiple solid tumors. In preclinical studies, STRO-004 demonstrated robust anti-tumor activity, favorable tolerability, and higher exposure compared to approved therapies. Developed using Sutro Biopharma's proprietary cell-free platform, STRO-004 features an Fc-silent, high affinity antibody, with site-specific  $\beta$ -glucuronidase cleavable linker and exatecan payload at a drug-to-antibody ratio of 8 (DAR8). This design aims to enhance stability, reduce off-target toxicity, and maximize efficacy. It is currently being evaluated in a Phase 1 trial in patients with a range of TF-expressing solid tumors.

# **About Sutro Biopharma**

Sutro Biopharma, Inc. is advancing a next-generation antibody-drug conjugate (ADC) platform designed to deliver single- and dual-payload ADCs that enable meaningful breakthroughs for patients with cancer. By fully optimizing the antibody, linker, and payload, Sutro's cell-free platform produces ADCs that are engineered to improve drug exposure, reduce side effects, and expand the range of treatable tumor types. With unique capabilities in dual-payload ADCs, Sutro aims to overcome treatment resistance and redefine what's possible in cancer therapy. The Company's pipeline of single- and dual-payload ADCs targets large oncology markets with limited treatment options and significant need for improved therapies.

For more information, follow Sutro on social media @Sutrobio or visitwww.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; timing of announcements of clinical results; potential efficacy, safety and benefits of STRO-004; potential insights gained and benefits of the Phase 1 trial design; and potential benefits of the Company's other 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, 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.

# **Investor Contact**

Emily White Sutro Biopharma (650) 823-7681 <a href="mailto:ewhite@sutrobio.com">ewhite@sutrobio.com</a>

## **Media Contact**

Amy Bonanno Lyra Strategic Advisory <u>abonanno@lyraadvisory.com</u>



Source: Sutro Biopharma, Inc.