

# Astellas and Sutro Biopharma Announce Worldwide Strategic Collaboration to Advance Novel Immunostimulatory Antibody-Drug Conjugates (iADCs)

 iADCs are a next-generation modality for treating cancer and designed to boost anti-cancer activity, offering potential new options for patients who do not respond to existing cancer immunotherapies -

- Sutro will receive an upfront payment of US\$90 million to develop iADCs for three biological targets and may be eligible to receive up to an additional US\$422.5 million USD in development, regulatory and commercial milestones for each product candidate, plus royalties -

TOKYO and SOUTH SAN FRANCISCO, Calif., June 27, 2022 (GLOBE NEWSWIRE) -- Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and Sutro Biopharma, Inc. (NASDAQ: STRO, CEO: William J. Newell, JD, "Sutro") today announced a worldwide, strategic collaboration and licensing agreement focused on the discovery and development of novel immunostimulatory antibody-drug conjugates (iADCs). The collaboration leverages the unique cancer-fighting potential of iADCs as a novel modality, enabled by Sutro's ability to engineer complex conjugated antibodies, and Astellas' global oncology R&D expertise.

"We are delighted to work with Astellas, a premier biopharmaceutical company with substantial expertise in immuno-oncology, on this novel modality," said William J. Newell, Sutro's Chief Executive Officer. "iADCs hold promise well beyond the existing success of ADCs. Sutro's unique conjugation technology enables dual conjugations that site-specifically incorporate a potent cytotoxin that can directly kill tumor cells together with an immunostimulatory component that has the potential to locally prime an immune response to the patient's particular tumor cells. We look forward to collaboratively exploring the potential of this approach to treat cold tumors and bring new drug therapies to patients who do not respond to existing immunotherapies."

Naoki Okamura, Chief Strategy Officer, at Astellas commented, "Astellas considers Immuno-Oncology as one of the Primary Focuses of its R&D strategy; our goal is to bring effective drugs to patients who do not respond to existing immune checkpoint inhibitors. Sutro is a leading company in the area of iADCs, a new modality, and has its own original iADC technologies. The strategic partnership with Sutro will help us expand our pipeline and widen the choice of cancer immunotherapies."

A key challenge with cancer immunotherapies, including immune checkpoint inhibitors, is the tumor microenvironment<sup>\*1</sup> within cold tumors creating barriers to immune cell infiltration and

thus preventing the cure. The immune checkpoint inhibitors approved to date are efficacious as a monotherapy in only about 20% of cancer types, which vary widely\*1.

This strategic partnership will engage in the development of iADCs, a next generation modality with the potential for effective and efficient approaches for treatment of cold tumors so as to bring new drug therapies to patients who do not respond to existing therapies. An iADC, which combines an antibody with a small molecule compound that induces immunogenic cell death\*<sup>2</sup> in addition to an immune activating molecule, has the potential to boost the anti-cancer action.

This partnership will enable Astellas and Sutro to mutually leverage strengths in their respective fields to accelerate iADC development for three distinct biological targets; Sutro will engage in research and preclinical studies to identify candidate compounds and then Astellas will pursue clinical development. Sutro has advanced technologies for linking drugs to antibodies and proprietary component parts, including candidate antibodies and linkable cytotoxins and immunostimulatory molecules. For development of iADCs, Astellas will utilize the strength of its global R&D and commercialization capabilities in the area of antibodies and the small molecular components. These iADCs may have the potential to provide new therapeutic options for treatment of cancers for which no broadly effective therapy is currently available.

Under the terms of the agreement, Sutro will receive an upfront cash payment of US\$90 million to develop iADCs for three biological targets and may be eligible to receive up to US\$422.5 million in development, regulatory and commercial milestones for each product candidate, and tiered royalties ranging from low double-digit to mid-teens on worldwide sales of any commercial products that may result from the collaboration, subject to Sutro's cost and profit sharing option for the United States.

Sutro has the option to share in the costs and profits for developing and commercializing product candidates in the United States. If Sutro exercises this option for a particular product candidate, Astellas and Sutro will equally share the costs of such co-development and co-commercialization, with the resulting profits/losses from co-commercialization also shared equally in the United States.

- \*1: Cancer surrounds itself with an environment advantageous to its own survival, that is, to protect itself from the immune system and help facilitate its own growth and metastasis. Such an environment is called a "tumor microenvironment."
- \*2: Immunogenic cell death is cancer cell death through the "cancer immune cycle" by which cancer antigens released by chemotherapy are captured by dendritic cells and then presented to T cells activated to kill the cancer cells. Regarding "cancer immune cycle," please refer to the materials from Astellas' R&D meeting (held in December 2020). (https://www.astellas.com/system/files/rdmeeting2020 pre en.pdf)

### **About Sutro**

Sutro Biopharma, Inc. (Sutro), headquartered in South San Francisco, is a clinical-stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs). Sutro has two wholly owned ADCs in the clinic—STRO-002, a folate receptor alpha (FolRα)-targeting ADC, in clinical studies for ovarian and endometrial cancers; and STRO-001, a CD74-targeting ADC, in clinical studies for B-cell malignancies. Additionally, Sutro is

collaborating with Bristol Myers Squibb (BMS) on CC-99712, a BCMA-targeting ADC in the clinic for patients with multiple myeloma; with Merck KGaA, Darmstadt, Germany, known as EMD Serono in the U.S. and Canada (EMD Serono) on M1231, a MUC1-EGFR bispecific ADC in clinical studies for patients with solid tumors, particularly non-small cell lung cancer (NSCLC) and esophageal squamous cell carcinoma; with Merck Sharpe & Dohme LLC (Merck) on MK-1484, a biologic in clinical studies as a monotherapy and in combination with pembrolizumab for the treatment of solid tumors; and with Astellas Pharma (Astellas) on a novel modality, immunostimulatory antibody-drug conjugates (iADCs). Sutro's platform technology also enabled the spin out of Vaxcyte and the creation of VAX-24, a 24-valent pneumococcal conjugate vaccine in clinical studies for the prevention of invasive pneumococcal disease. Sutro's rational design and precise protein engineering has enabled six product candidates in the clinic. Follow Sutro on Twitter, @Sutrobio, and at www.sutrobio.com to learn more about our passion for changing the future of oncology.

# **Sutro 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 STRO-002 and Sutro's other product candidates and platform, potential future milestone and royalty payments, and potential market opportunities for STRO-002 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, the impact of the COVID-19 pandemic on Sutro's business, 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.

#### **About Astellas**

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+<sup>®</sup> healthcare solutions that combine our

expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <a href="https://www.astellas.com/en">https://www.astellas.com/en</a>.

# **Astellas Cautionary Notes**

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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