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# Samsung Biologics and Checkpoint Therapeutics Expand Manufacturing Partnership for Cosibelimab

INCHEON, South Korea and NEW YORK, Nov. 2, 2020 /PRNewswire/ -- Samsung Biologics Co., Ltd. ("Samsung Biologics") (KRX: 207940.KS) and Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), today announced the expansion of a long-term manufacturing partnership for Checkpoint's anti-PD-L1 antibody, cosibelimab. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for Checkpoint. Under the new agreement, Samsung Biologics will commence manufacturing in 2021 in Plant 1.


"We look forward to continuing our manufacturing partnership with Samsung Biologics for our lead product candidate, cosibelimab, currently in a pivotal clinical trial for metastatic cutaneous squamous cell carcinoma. Checkpoint is on track to report full topline results from the pivotal trial in mid-2021," said James F. Oliviero, President and Chief Executive Officer of Checkpoint. "This agreement provides Checkpoint access to a top-tier manufacturing site for the long-term commercial supply of cosibelimab after potential regulatory approvals worldwide."

"We are extremely proud of this extended partnership with Checkpoint to support our client and make an impact by helping broader patient populations in need," said Dr. Tae Han Kim, CEO of Samsung Biologics. "As a reliable contract development and manufacturing organization ("CDMO") service provider, Samsung Biologics offers the highest quality manufacturing for Checkpoint to assist in its endeavor to bring innovative treatments for

patients all around the globe."

Samsung Biologics recently announced it will break ground on its fourth plant within this year to commence manufacturing activities in the latter half of 2022, deliver world-class client satisfaction, and fulfill the needs of the growing biopharmaceutical market.

**About Cutaneous Squamous Cell Carcinoma**

Cutaneous squamous cell carcinoma ("CSCC") is the second most common human cancer in the United States, with an estimated annual incidence of 700,000 cases. While most cases are localized tumors amenable to curative resection, approximately 8% of patients will experience a local recurrence, 5% of patients will develop nodal metastases, and an estimated 2% of patients will die from their disease. Ten-year survival rates are less than 20% for patients with regional lymph-node involvement. For those patients who develop distant metastases, the median survival time is estimated to be less than two years. In addition to being a life-threatening disease, CSCC causes significant functional morbidities and cosmetic deformities based on tumors commonly arising in the head and neck region and invading blood vessels, nerves and vital organs such as the eye or ear.

**About Cosibelimab**

Cosibelimab (formerly referred to as CK-301) is a potential best-in-class, high affinity, fully-human monoclonal antibody of IgG1 subtype that directly binds to programmed death ligand-1 (PD-L1) and blocks the PD-L1 interaction with the programmed death receptor-1 (PD-1) and B7.1 receptors. Cosibelimab's primary mechanism of action is based on the inhibition of the interaction between PD-L1 and its receptors PD-1 and B7.1, which removes the suppressive effects of PD-L1 on anti-tumor CD8+ T-cells to restore the cytotoxic T cell response. Cosibelimab is potentially differentiated from the currently marketed PD-1 and PD-L1 antibodies through sustained >99% target tumor occupancy to reactivate an antitumor immune response and the additional benefit of a functional Fc domain capable of inducing antibody-dependent cell-mediated cytotoxicity ("ADCC") for potential enhanced efficacy in certain tumor types.

**About Checkpoint Therapeutics**

Checkpoint Therapeutics, Inc. ("Checkpoint") is a clinical-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is evaluating its lead antibody product candidate, cosibelimab, a potential best-in-class anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma intended to support one or more applications for marketing approval. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation epidermal growth factor receptor ("EGFR") inhibitor, as a potential new treatment for patients with EGFR mutation-positive non-small cell lung cancer. Checkpoint is headquartered in New York City and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.checkpointtx.com.

**About Samsung Biologics Co., Ltd.**

Samsung Biologics Co., Ltd ("Samsung Biologics") (KRX: 207940.KS) is a fully integrated CDMO offering state-of-the-art contract development, manufacturing, and laboratory testing services. With proven regulatory approvals, the largest capacity, and the fastest throughput, Samsung Biologics is an award-winning partner of choice and is uniquely able to support the development and manufacturing of biologics products at every stage of the process while meeting the evolving needs of biopharmaceutical companies worldwide. For more information, visit www.samsungbiologics.com.

**Forward–Looking Statements**

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our plans to submit one or more Biologics License Applications (BLAs) and seek approvals for cosibelimab, statements regarding the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, statements relating to the half-life and functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to the timing of the completion of enrollment and full top-line results, statements relating to how long we believe our cash will fund our operations, any statements relating to our growth strategy and product development programs, and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the ongoing Phase 1 study; risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our Securities and Exchange Commission filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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