Spruce Biosciences and Kaken Pharmaceutical Announce Strategic Partnership and Exclusive Licensing Agreement to Develop and Commercialize Tildacerfont for CAH in Japan

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Partnership aims to accelerate global development and commercialization plans for tildacerfont to address worldwide unmet medical need in congenital adrenal hyperplasia (CAH)

Deal advances strategy to partner tildacerfont commercial rights outside the United States

Spruce to receive $15 million upfront payment plus development and commercial milestone payments in addition to tiered double-digit royalties on net sales in Japan

SOUTH SAN FRANCISCO, Calif. & TOKYO--(BUSINESS WIRE)--Jan. 5, 2023-- Spruce Biosciences, Inc. (Nasdaq: SPRB) and Kaken Pharmaceutical Co. Ltd (Tokyo Stock Exchange: 4521) today announced that the companies have entered into an exclusive licensing agreement for the development and commercialization of Spruce's product candidate, tildacerfont, for the treatment of congenial adrenal hyperplasia (CAH) in Japan.

Under the terms of the agreement, Spruce will receive an upfront payment of $15 million from Kaken and will be eligible to receive additional payments upon the achievement of future development and commercial milestones, as well as tiered double-digit royalties on net sales in Japan. Kaken will be responsible for the clinical development and commercialization of tildacerfont in Japan, and Spruce will retain all rights to tildacerfont in all other geographies. As part of the agreement, Kaken will have the first right of negotiation to expand the scope of the agreement to include China (including Hong Kong, Taiwan, and Macau), South Korea and other specified Southeastern Asian (ASEAN) countries. Kaken will also be responsible for securing and maintaining regulatory approvals necessary to market and sell tildacerfont in Japan.

"We are excited to enter into this strategic partnership with Kaken Pharmaceutical designed to accelerate our global development plans and bring tildacerfont to patients in Japan who suffer from CAH," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "As a specialty pharmaceutical company with a strong presence in Japan, Kaken is the ideal strategic partner for the territory, and supports Spruce's partnering strategy to develop tildacerfont in markets outside of the United States. We believe Kaken's track record of development and commercialization in the Asia-Pacific region will be instrumental in delivering the full therapeutic potential of tildacerfont and bringing a new treatment option to CAH patients in Japan, if approved."

"We are pleased to begin a collaboration with Spruce, a company committed to transforming the lives of patients with CAH," said Hiroyuki Horiuchi, President and Representative Director of Kaken. "Through this collaboration, we hope we can contribute to CAH patients and their families, who currently have limited available treatment options in Japan."

About Tildacerfont

Tildacerfont is a potent and highly selective, non-steroidal, oral antagonist of the corticotropin-releasing factor (CRF) 1 receptor. The CRF1 receptor is abundantly expressed in the pituitary gland where it is the primary regulator of the hypothalamic-pituitary-adrenal (HPA) axis. By antagonizing the CRF1 receptor, tildacerfont has the potential to address the uncontrolled cortisol feedback regulatory pathway in CAH, and in turn reduce the production of adrenocorticotropic hormone (ACTH) in the pituitary, limiting the amount of androgen produced downstream from the adrenal gland. Tildacerfont has been evaluated in 235 patients across eight clinical trials in which it has been generally well tolerated. No drug-related serious adverse events have been reported across completed clinical trials. Tildacerfont is currently being evaluated in clinical trials for adult classic CAH, pediatric classic CAH, and polycystic ovary syndrome.

About Spruce Biosciences

Spruce Biosciences is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need. Spruce is initially developing its wholly-owned product candidate, tildacerfont, as the potential first non-steroidal therapy for patients suffering from classic congenital adrenal hyperplasia (CAH). Spruce is also developing tildacerfont for women suffering from polycystic ovary syndrome (PCOS) with primary adrenal androgen excess. To learn more, visit www.sprucebiosciences.com and follow Spruce on Twitter @Spruce_Bio, LinkedIn, Facebook and YouTube.

About Kaken Pharmaceutical

Kaken Pharmaceutical is a specialty pharmaceutical company in Japan with strong experience in developing and commercializing novel pharmaceuticals in the fields of orthopedics and dermatology. Kaken concentrates its R&D resources in areas such as immune system, nervous system, infectious diseases and rare diseases with unmet medical needs. Kaken, in its philosophy, strives to improve the quality of life of patients through the development and distribution of superior pharmaceuticals. For further information, visit www.kaken.co.jp/english.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the terms and conditions of the collaboration and license agreement, including Spruce's receipt of milestone and royalty payments; the design to accelerate Spruce's global development plans and bring tildacerfont to patients in Japan who suffer from CAH; the ability of Kaken to develop and commercialize tildacerfont in Japan; and the potential benefits of tildacerfont for use in patients with CAH. Because such statements are subject to risks and

uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “will”, “believe”, “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Spruce’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Spruce’s business in general, the impact of geopolitical and macroeconomic events, including the COVID-19 pandemic, and the other risks described in Spruce’s filings with the U.S. Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. Spruce undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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