Spruce Biosciences Honored at CARES Foundation 15th Annual Everyone CARES Gala

May 22, 2023

Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer, accepted the Corporate Partner Award

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 22, 2023-- Spruce Biosciences, Inc. (Nasdaq: SPRB), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need, was honored by the CARES Foundation, Inc. for its ongoing development of tildacerfont for patients with classic congenital adrenal hyperplasia (CAH). The CARES Foundation is the only U.S.-based nonprofit organization solely dedicated to improving the lives of the CAH patient community and seeks to advance quality health care. Spruce Biosciences' Chief Executive Officer, Javier Szwarcberg, M.D., M.P.H., accepted the Corporate Partner Award at the 15th Annual *Everyone CARES Gala* held in New York City on May 20.

"This recognition is a testament to our team's efforts in bringing novel solutions to the patient communities we aim to serve. Spruce is honored to receive this award as we endeavor to open a new chapter in the management of CAH with tildacerfont, a potentially life-changing medicine," said Dr. Javier Szwarcberg, Chief Executive Officer of Spruce Biosciences. "We are dedicated to making progress, leveraging breakthrough science, and delivering a quantifiable and meaningful improvement over today's standard of care. This is an incredibly important time for the CAH patient community."

"Spruce has been a terrific partner from the very beginning of its CAH program," said Dina Matos, Executive Director of CARES Foundation. "Their support of our community is worthy of recognition and that's why they have been selected to receive this year's Corporate Partner Award."

CAH is a genetic disorder that impacts approximately 20,000 to 30,000 people in the United States and approximately 50,000 people in the European Union throughout their entire lives. CAH affects the adrenal glands, leading to an inability to make cortisol, a stress hormone necessary for life, and an overproduction of adrenal androgens. Due to the severity of the disease, most developed nations across the world have established newborn screening programs. The overproduction of adrenal androgens can lead to life-compromising effects such as early puberty, overweight, short stature, acne, facial hair in females, acne, psychological effects, and impaired fertility in both sexes.

For approximately 70 years, glucocorticoid treatment, often at supraphysiologic doses, has been the standard of care to reduce adrenal androgen levels. However, supraphysiologic doses of glucocorticoids over a lifetime present serious side effects including cardiovascular complications, hypertension, insulin resistance, high lipids, cushingoid appearance, and bone loss resulting in fractures. Spruce is developing tildacerfont, an investigational once-daily, non-steroidal tablet designed to inhibit the production of adrenal androgens and potentially enable people with CAH to reduce their daily glucocorticoid doses to physiologic replacement levels.

Spruce is currently conducting the CAHmelia program in adults (18 years of age and older) and the CAHptain program in children and adolescents (2 to 17 years of age) with classic CAH. As part of the CAHmelia and CAHptain clinical programs, study participants who complete these studies will be eligible to continue receiving tildacerfont as part of an open-label extension.

About Congenital Adrenal Hyperplasia (CAH)

CAH is an autosomal recessive disease, driven by a mutation in the gene that encodes an enzyme necessary for the synthesis of key adrenal hormones. In CAH patients, the body is not able to produce cortisol, leading to serious health consequences. The absence of cortisol alters the normal feedback cycle of the hypothalamic-pituitary-adrenal (HPA) axis and leads to excess secretion of adrenocorticotropic hormone (ACTH), hyperplasia of the adrenal gland, and consequently high levels of endogenous androgen production. As a result, CAH patients suffer from premature puberty, impaired fertility, hirsutism, acne, the development of adrenal rest tumors, and an impaired quality of life, and additionally for females, virilized genitalia and menstrual irregularities. Currently, the only way to downregulate the production of excess androgens in CAH patients is to administer supraphysiologic doses of glucocorticoids, which present specific side effects, including increased risks of developing diabetes, cardiovascular disease, stunted growth, osteoporosis, thin skin, gastrointestinal disorders, and decreased lifespan.

About Tildacerfont

Tildacerfont is a potent and highly selective, non-steroidal, oral antagonist of the CRF1 receptor, which is the receptor for corticotropin-releasing factor (CRF), a hormone that is secreted by the hypothalamus. The CRF1 receptor is abundantly expressed in the pituitary gland where it is the primary regulator of the HPA axis. By blocking the CRF1 receptor, tildacerfont has the potential to address the uncontrolled cortisol feedback regulatory pathway in CAH, and in turn reduce the production of ACTH in the pituitary, limiting the amount of androgen produced downstream from the adrenal gland. By controlling excess adrenal androgens through an independent mechanism, tildacerfont has the potential to reduce the unwanted clinical symptoms associated with high androgen exposure and could also enable treating physicians to lower the supraphysiologic glucocorticoid doses given to CAH patients to near physiologic levels. Tildacerfont has been evaluated in over 200 subjects across eight completed clinical trials in which it has been generally well tolerated. No drug-related SAEs have been reported related to tildacerfont treatment in completed studies.

About CAHmelia and CAHptain Studies

Spruce Biosciences is currently conducting studies of tildacerfont in adults (18 years of age and older) and children and adolescents (ages 2 to 17 years of age) with classic CAH. For more information about the adult CAHmelia program, please visit https://www.sprucebio.com/cahmelia. For more information about the pediatric CAHptain program, please visit https://www.sprucebio.com/cahptain. As part of the CAHmelia and CAHptain clinical programs, study participants who complete these studies will be eligible to continue receiving tildacerfont as part of an open-label extension.

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 us on Twitter @Spruce_Bio, LinkedIn, Facebook and YouTube.

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 enrollment, results, conduct, progress and timing of Spruce’s clinical trials and tildacerfont being a potentially life-changing medicine and potentially enabling people with CAH to reduce their daily glucocorticoid doses to physiologic replacement levels. 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 “aim,” “anticipate”, “enable,” “expect”, “will”, “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, 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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