Spruce Biosciences Presents Phase 2 Data for Tildacerfont in Adults with Congenital Adrenal Hyperplasia at 23rd European Congress of Endocrinology

May 24, 2021

Richard Auchus, MD, PhD, Presents Phase 2 Data of Tildacerfont in Adult Classic CAH

Tildacerfont Demonstrates Normalization of Elevated Hormone Levels Without Increases to Daily Steroid Doses

CAHmelia Clinical Program in Adult Classic CAH Underway to Assess Hormone and Steroid Reduction

SAN FRANCISCO--(BUSINESS WIRE)--May 24, 2021-- 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, today presented data from its Phase 2 clinical trial of tildacerfont in adults with classic congenital adrenal hyperplasia (CAH) at the European Society of Endocrinology's 23rd European Congress of Endocrinology (ECE 2021), taking place virtually May 22 – 26, 2021.

SPR001-202 was an open-label, 12-week Phase 2a clinical trial, which assessed the ability of a daily dose of 400mg of tildacerfont to lower disease-driving hormones such as adrenocorticotropic hormone (ACTH), 17-hydroxyprogesterone (17-OHP), and androstenedione (A4) over a 12-week dosing period. These hormones are used by physicians as a means of measuring the severity of CAH. Patients were classified into two groups based on disease control using these baseline hormone levels, defined as either poor disease control or good disease control.

Patients with poor disease control upon study entry had mean baseline levels of ACTH, 17-OHP and A4 that were significantly above the upper limit of normal. Administration of tildacerfont to these patients resulted in mean maximum reductions of 84% in ACTH, 80% in 17-OHP, and 79% in A4 compared to baseline across the study period. This enabled reduction in the levels of these key hormones to normal or near normal levels, including normalization of ACTH levels in 60% and normalization of A4 levels in 40% of poor disease control patients during month three. Normalization of these highly elevated hormones in classic CAH patients without increases to daily steroid doses has not been reported to date with any other investigational product candidate. Patients with good disease control upon study entry, achieved by supraphysiologic glucocorticoid dosing, had mean baseline levels of ACTH, 17-OHP and A4 that were below the upper limit of normal. Administration of tildacerfont to these patients did not lead to significant changes in these levels. While this study did not evaluate the ability of tildacerfont to reduce the need for high glucocorticoid dosing in patients with good disease control, this objective is an important unmet need due to the long-term and serious side effects associated with chronic use of high doses of glucocorticoids and is currently being evaluated in the CAHmelia-204 study.

"It is encouraging to see that tildacerfont, an oral, once-daily, and non-steroidal investigational therapy, produced meaningful reductions in highly elevated hormone levels for classic CAH patients, including, in some cases, normalization of these hormone levels over twelve weeks," said Richard Auchus, MD, PhD, the study's lead investigator and Professor of Internal Medicine and Pharmacology, University of Michigan, Ann Arbor. "The data suggest that tildacerfont has the potential to improve the adverse consequences of androgen excess and to reduce the burden of daily glucocorticoid dosing for these patients. Patients with classic CAH should benefit from new treatment options, which effectively manage their disease, yet reduce the complications derived from chronic glucocorticoid exposure as the existing standard of care."

Spruce's CAHmelia program in adult classic CAH patients is underway and actively enrolling in sites within the United States and Europe. CAHmelia-203 is assessing the ability of tildacerfont to reduce excessive adrenal androgens in patients with poor disease control, while CAHmelia-204 is assessing the ability of tildacerfont to reduce glucocorticoid usage in patients with good disease control while maintaining control of androgens.

The presentation is on display in ECE 2021's virtual poster hall. Learn more about the full program and how to access the poster presentation details on the ECE 2021 website.

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. Tildacerfont has been evaluated in 171 patients across seven clinical trials in which it has been generally well tolerated. No drug-related serious adverse events have been reported related to tildacerfont treatment.

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 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). Classic CAH is a serious and life-threatening disease with no known novel therapies approved in approximately 50 years. Spruce is also developing tildacerfont for women suffering from a rare form of polycystic ovary syndrome (PCOS) with primary adrenal androgen excess, representing 3-5% of females with PCOS (estimated to be 150,000 to 200,000 patients in the United States). 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 results, conduct, progress and timing of Spruce's clinical trials. 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 "potential", "suggests", "demonstrates", "may" 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 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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