Spruce Biosciences Completes Enrollment in CAHmelia-204 Study for Adult Classic Congenital Adrenal Hyperplasia

January 22, 2024

100 Patients Enrolled, Exceeding Target Enrollment of 90 Patients

Topline Results for CAHmelia-204 Anticipated in the Third Quarter of 2024

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 22, 2024-- 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 announced completion of enrollment in its CAHmelia-204 clinical trial of tildacerfont for the treatment of adult classic congenital adrenal hyperplasia (CAH).

“Completing enrollment in our CAHmelia-204 clinical trial marks a significant milestone in our adult classic CAH program. This achievement reinforces the continued momentum within our tildacerfont program and positions us favorably to report topline results in the third quarter of 2024,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “Thanks to positive engagement from our patient community and study investigators alike, the CAHmelia-204 clinical trial enrolled 100 patients, exceeding target enrollment of 90 patients.”

Dr. Szwarcberg continued, “Looking ahead, assuming positive results from CAHmelia-203 in March and CAHmelia-204 in the third quarter, we plan to meet with the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory authorities to discuss the potential registrational path forward for tildacerfont as a treatment for adult classic CAH.”

CAHmelia-204 is a randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of tildacerfont, a potentially novel, once-daily, non-steroidal treatment option, in reducing glucocorticoid usage in 100 adults with classic CAH on supraphysiologic doses of glucocorticoids with normal or near normal levels of androstenedione (A4) at baseline. The primary endpoint of this clinical trial is the absolute change in daily glucocorticoid dose in hydrocortisone equivalents (HCe) from baseline at week 24.

About CAHmelia-203

CAHmelia-203 is a randomized, double-blind, placebo-controlled, dose ranging Phase 2b clinical trial evaluating the safety and efficacy of tildacerfont in adults with classic CAH and highly elevated levels of A4 at baseline while on stable glucocorticoid dosing. This clinical trial enrolled 96 subjects with elevated levels of A4. For the first six weeks, patients will receive blinded placebo to assess their adherence to their existing glucocorticoid therapy. Patients who continue to meet all eligibility criteria at the end of this period will enter a three-part treatment period. During the placebo-controlled treatment period, patients will be randomized in a blinded manner to receive placebo, 50mg, 100mg, or 200mg tildacerfont once daily. Dosing in the placebo-controlled treatment period will continue for 12 weeks. The primary endpoint of the clinical trial is the percentage change in A4 from baseline to week 12. Following the placebo-controlled treatment period, all patients will receive tildacerfont following a dose-escalation protocol that allows dose increase to 200mg once daily over 12 weeks. Following the 12-week dose-escalation period, all patients will continue receiving tildacerfont at 200mg once daily for an additional 46 weeks. Patients who achieve control of A4 while on supraphysiologic glucocorticoid treatment will have the opportunity to reduce their glucocorticoid dosing in the open-label period according to a pre-specified algorithm in the protocol. For more information about the CAHmelia program, please visit https://www.sprucebio.com/cahmelia.

About CAHmelia-204

CAHmelia-204 is a randomized, double-blind, placebo-controlled Phase 2b clinical trial to evaluate the safety and efficacy of tildacerfont in reducing glucocorticoid usage in 100 adults with classic CAH on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 at baseline. This clinical trial is designed in two parts. In the first part of the clinical trial, patients will be randomized to receive 200mg tildacerfont once daily or placebo for 24 weeks. During the second part of the clinical trial, all patients will receive open-label 200mg tildacerfont once daily for 52 weeks. Throughout the trial, tapering of glucocorticoids will be guided according to a pre-specified algorithm and continue to the lowest level possible (physiologic replacement levels), as long as patients remain well controlled based on standard biomarkers and clinical assessments. The primary endpoint of this clinical trial is the absolute change in daily glucocorticoid dose in HCe from baseline at week 24. For more information about the CAHmelia program, please visit https://www.sprucebio.com/cahmelia.

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 adrenal 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, once-daily 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 nine completed clinical trials in which it has been generally well tolerated. No drug-related serious adverse events have been reported related to tildacerfont treatment in completed studies.

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, once-daily therapy for patients suffering from classic congenital adrenal hyperplasia (CAH) and other endocrine disorders. To learn more, visit www.sprucebio.com and follow us on X, 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; Spruce’s expectations regarding reporting results of its clinical trials in 2024; and Spruce’s plans to meet with the FDA and comparable foreign regulatory authorities to discuss the potential registrational path forward of tildacerfont for adult classic 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 “anticipate”, “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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