Spruce Biosciences Announces Pediatric Classic CAH Program Details During Virtual R&D Day

August 25, 2021

Phase 2 Program in Pediatric Classic Congenital Adrenal Hyperplasia (CAH) on Track to Initiate in 2021 with Data Expected by 1H 2023

Phase 3 Registrational Program in Pediatric Classic CAH Expected to Initiate in 2023

R&D Day Webcast Featuring Spruce Management, KOL Panel Discussion and Q&A Begins Today at 11:00 am ET

SAN FRANCISCO--(BUSINESS WIRE)--Aug. 25, 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 announced that it will discuss the details of its Phase 2 clinical program for tildacerfont in pediatric classic CAH during the company's virtual Research and Development (R&D) Day. The webcast will begin today at 11:00 am ET.

"We are pleased to initiate our Phase 2 clinical program of tildacerfont in children with classic CAH, a rare endocrine disorder where a significant unmet medical need exists for a non-steroidal treatment approach, this year," said Richard King, Chief Executive Officer of Spruce Biosciences. "The clinical profiles of, and goals of therapy for children with classic CAH vary between pre- and post-pubertal stages of development. Our program responds to these different clinical paradigms dependent on a child's stage of development."

The Phase 2 open-label study will utilize a sequential 3 cohort design to evaluate the safety, pharmacokinetics, and exploratory pharmacodynamics of tildacerfont in children aged 6 to 17 with classic CAH for up to 3 weight-adjusted doses, equivalent to adult doses of 50 mg, 100 mg, or 200 mg once daily of tildacerfont, for a duration of 2 weeks. Cohort 1 will include children between 11 and 17 years of age, at a dose of 50 mg once a day. Cohort 2 will also include children between 11 and 17 years of age, at a dose of up to 200mg once daily. Cohort 3 will include children between 6 and 10 years of age, at a dose of up to 200 mg once daily. The study drug will be dosed with an evening meal and will be formulated as granules to be sprinkled over food.

The Phase 2 program in pediatric classic CAH remains on track to initiate later this year with data expected by the first half of 2023. The Phase 3 registrational program in pediatric classic CAH is expected to initiate in 2023.

Spruce Biosciences R&D Day Webcast Details: Tildacerfont for Adult & Pediatric Classic CAH
Date: Wednesday, August 25, 2021
Time: 11:00 am – 1:00 pm ET
Registration and Webcast Link

Richard King, Chief Executive Officer of Spruce Biosciences, will be joined by members of the company's management team, as well as leading endocrinologists, Richard Auchus, MD, PhD, the James A. Shayman and Andrea S. Kevrick Professor of Translational Medicine at the University of Michigan, and Professor of Internal Medicine and Professor of Pharmacology at the University of Michigan Medical School, and Paul Thornton, MD, Medical Director, Endocrine and Diabetes Program, Cook Children's Medical Center.

Interested parties may also access the webcast from the Events section of the company's investor relations website. An archived replay of the webcast will be available after the conclusion of the presentation.

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 235 patients across eight 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 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). 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. 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 "plans," "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 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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