Spruce Biosciences Announces Launch of CAHstudy.com to Initiate Screening of Patients for CAH Clinical Program

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New website and patient resource will enable adults with Congenital Adrenal Hyperplasia (CAH) to register interest in Spruce's CAHmelia clinical program, launching later this year

San Francisco, Calif. – May 12, 2020 – Spruce Biosciences, a late-stage clinical development company focused on developing and commercializing novel therapies for rare endocrine disorders, today announced the launch of CAHstudy.com, a new website and patient resource to enable adults with Congenital Adrenal Hyperplasia (CAH) to register their interest in the CAHmelia clinical program, which is expected to commence in the second half of 2020.

The CAHmelia clinical program is designed to evaluate the efficacy of tildacerfont, an investigational, oral, once-a-day corticotropin-releasing factor type-1 receptor antagonist, in two placebo-controlled, late stage clinical studies in adults with Classic CAH. In September 2019, Spruce Biosciences announced positive results from a Phase 2, multicenter, 12-week study of tildacerfont in adult patients with Classic CAH. Classic CAH is a rare genetic disorder affecting the ability of the adrenal glands to function properly, affecting up to 35,000 individuals in the United States.

"Our previous studies have demonstrated promising safety and efficacy results from the use of tildacerfont in adults with Classic CAH," said Richard King, Chief Executive Officer, Spruce Biosciences. "We are excited to move forward with the CAHmelia clinical program and encourage patients with CAH and their families to visit CAHstudy.com to register their interest in the study and begin the screening process."

Interested clinical study participants across the United States are encouraged to visit CAHstudy.com to complete a short questionnaire and determine their eligibility for the CAHmelia clinical program.

About Congenital Adrenal Hyperplasia (CAH)
Classic CAH is a rare genetic disorder affecting the ability of the adrenal glands to function properly. CAH results from a mutation in the gene that encodes the enzyme 21-hydroxylase, which is necessary for the synthesis of key adrenal hormones. As a result, people with CAH have an impaired ability to produce the hormone cortisol, which can result in life-threatening adrenal crises. Cortisol is also known as "the stress hormone," and is critical for the body's response to stress, illness and injury.

In CAH, the adrenal glands often produce excessive levels of sex hormones or androgens. While both sexes need androgens for proper growth and development, an excess can cause problems that may include precocious puberty, short stature, hirsutism, increased risk of testicular adrenal rest tumors (TART) in men, and virilization and menstrual dysfunction in women.

Although CAH testing is part of the newborn screening program, the only approved therapy for CAH are glucocorticoids. Glucocorticoids (such as hydrocortisone, prednisone and dexamethasone) are commonly used to treat CAH but are associated with a wide range of side effects, including weight gain, reduced bone mineral density, metabolic abnormalities and increased cardiovascular risk. No new treatment options for CAH have become available for the past several decades.

About Tildacerfont
Spruce's investigational lead product candidate, tildacerfont (formerly SPR001) is a potent, highly selective, oral, small-molecule antagonist of the corticotropin-releasing factor type-1 (CRF1) receptor. Preclinical studies have shown that through targeted delivery, tildacerfont binds to CRF1 receptors to block CRF-stimulated receptor function, thereby decreasing the production of excess androgens (androstenedione [A4]), progestins (17-hydroxyprogesterone [17-OHP]) and adrenocorticotropic hormone (ACTH), the primary driver of adrenal gland enlargement. Tildacerfont may allow physicians to reduce the chronic use of high-dose steroids in and improve clinical outcomes for patients with congenital adrenal hyperplasia (CAH).

Tildacerfont has been granted orphan drug status by both the FDA and EMA. For more information on tildacerfont, please visit www.sprucebiosciences.com.

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