Spruce Biosciences Provides Corporate Update and Outlines Milestones for 2021

January 6, 2021

-CAHmelia Adult Classic CAH Program Underway in U.S. and Europe-

-Initiation of Phase 2 Pediatric Classic CAH Program Anticipated in Second Half of 2021-

-Initiation of Phase 2 Polycystic Ovary Syndrome Program Anticipated in Second Half of 2021-

-New Patent Issuance Extends Tildacerfont Patent Exclusivity through 2038-

SAN FRANCISCO--(BUSINESS WIRE)--Jan. 6, 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 need, today provided a corporate update and shared anticipated milestones for 2021.

“Our vision is to deliver groundbreaking therapies to patients living with rare endocrine disorders with significant unmet medical need,” said Richard King, Chief Executive Officer of Spruce Biosciences. “As we enter the new year, we are entirely focused on clinical study execution. Our potential registration-enabling CAHmelia program for tildacerfont in adult classic congenital adrenal hyperplasia (CAH) is underway. In parallel, we are preparing to advance tildacerfont into the clinic for the treatment of pediatric classic CAH and a rare form of polycystic ovary syndrome (PCOS).”

Mr. King continued, “Following our initial public offering in October 2020, we have sufficient resources to continue to advance our pipeline through major milestones. This includes the completion of our CAHmelia program and, dependent on trial results and subsequent interactions with regulatory agencies, potential submission of our first new drug application for tildacerfont for adults with classic CAH. At the same time, we expect 2021 to be a year of notable progress as we expand our portfolio of indications. Through this, we hope to deliver on the full potential of tildacerfont to bring therapeutic benefit to patients suffering from endocrine disorders driven by excess secretion of, or hyperresponsiveness to, adrenocorticotropic hormone (ACTH).”

Potential Registration-Enabling Phase 2 CAHmelia Program in Adult Classic CAH

Spruce Biosciences is focused on advancing tildacerfont in potential registration-enabling programs, dependent on clinical trial results, for the treatment of adult patients with CAH. Based on analyses of the company’s clinical data to date, the company has chosen to target two distinct groups of classic CAH patients with either good disease control or poor disease control. These two groups have differing disease challenges centered on the harmful effects of excessive glucocorticoid usage or excessive adrenal androgen levels respectively, both of which have the potential to be addressed by treatment with tildacerfont, if approved.

The company has initiated CAHmelia-203 in adult CAH patients with poor disease control and CAHmelia-204 in adult CAH patients with good disease control focused on glucocorticoid reduction. Study sites across the United States and Europe for both studies are active.

Phase 2 Program in Pediatric Classic CAH

Spruce Biosciences plans to investigate tildacerfont for the treatment of classic CAH in children. There is an urgent medical need to bring androgen-lowering and glucocorticoid-sparing therapies to pediatric classic CAH patients to reduce the risk of premature puberty and the adverse effects of glucocorticoids, including growth inhibition and short-stature as adults. Feedback received from both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) has been incorporated into the company’s Phase 2 development program.

The company plans to achieve the following milestones in 2021:

- Initiation of a Phase 2 clinical program in children in the second half of 2021; and
- Finalization of a Pediatric Investigational Plan to the Pediatric Committee of the EMA regarding a registrational program in pediatrics.

Phase 2 Program in a Rare Form of PCOS

PCOS is a hormonal disorder common among females of reproductive age typically characterized by elevated levels of androgens, irregular periods, and cysts in the ovaries. While the underlying causes of the disease are unknown, elevated levels of androgens may be due to a hyper-responsiveness to ACTH in a subset of women with PCOS. Tildacerfont has the potential to reduce ACTH and adrenal androgens, thereby reducing overall ACTH hyperresponsiveness. Tildacerfont may provide a therapeutic option for females with this rare form of PCOS, representing 3-5% of females with the disorder[1], which is estimated to be 150,000 to 200,000 patients in the United States.

The company plans to achieve the following milestones in 2021:

- Filing of an Investigational New Drug (IND) application in the first half of 2021; and
- Initiation of a Phase 2 proof-of-concept clinical trial in the second half of 2021.

Intellectual Property

Spruce Biosciences continues to expand its patent portfolio for tildacerfont to supplement its issued composition of matter patent that has an expiry date in 2027, and if tildacerfont is approved, will be eligible for patent term extension of up to 5 years. Upon regulatory approval, tildacerfont is also

entitled to market exclusivity afforded by orphan drug designation of tildacerfont in the U.S. and Europe for CAH.

In December 2020, the United States Patent and Trademark Office (USPTO) issued US Patent Number 10,849,908 titled “Corticotrophin releasing factor antagonists.” This newly issued patent covers broad claims regarding the use of a CRF1 receptor antagonist for the treatment of CAH and further extends exclusivity through 2038.

Financial Update

As of December 31, 2020, Spruce Biosciences had unaudited cash and cash equivalents of approximately $157 million. Spruce Biosciences had 23,260,399 shares of common stock outstanding as of December 31, 2020.

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 to offer markedly improved disease control and reduce steroid burden for patients suffering from classic CAH. Classic CAH is a serious and life-threatening disease with no known novel therapies approved in approximately 50 years.

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. 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”, “potential”, “anticipates” 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.

[1] Rosenfield RL, et al. (2016) Endocrine Reviews; 37(5):467–520.

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Media
Will Zasadny
Canale Communications
(619) 961-8848
Will@canalecomm.com
media@sprucebiosciences.com

Investors
Thomas Hoffmann
Solebury Trout
(646) 378-2931
thoffmann@soleburytrout.com
investors@sprucebiosciences.com

Source: Spruce Biosciences, Inc.