Spruce Biosciences Provides Clinical Program Updates and Outlook for 2024

January 4, 2024

Catalyst-Heavy 2024 with Topline Results from CAHmelia-203 in Adult Classic Congenital Adrenal Hyperplasia (CAH) and CAHptain-205 in Pediatric Classic CAH Anticipated in March 2024

Topline Results from CAHmelia-204 in Adult Classic CAH Anticipated in Q3 2024

Cash Runway Anticipated into the First Half of 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 4, 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 provided an update on its clinical programs, upcoming milestones and strategic priorities for advancing tildacerfont for the treatment of adult and pediatric classic congenital adrenal hyperplasia (CAH).

“2023 was a year of exceptional clinical execution across the board, and we were pleased to reach important milestones by completing enrollment in CAHmelia-203 for adult classic CAH and CAHptain-205 for pediatric classic CAH,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “We’re also nearing completion of enrollment in CAHmelia-204 for adult classic CAH and look forward to maintaining this momentum with a catalyst-heavy 2024, and plan to report topline results from CAHmelia-203 and CAHptain-205 in March 2024, along with results from CAHmelia-204 in the third quarter of 2024.”

Dr. Szwarcberg continued, “There is a significant unmet medical need in children and adults with CAH to alleviate the systemic risks and comorbidities associated with hyperandrogenemia and chronic overexposure to glucocorticoids (GCs). Tildacerfont, if approved, has the potential to alter the treatment paradigm by providing a new and potentially novel, once-daily, non-steroidal treatment option that reduces adrenal hormones and alleviates the daily burden of supraphysiologic exposure to GCs. We are committed to unlocking the full therapeutic potential of tildacerfont and delivering a quantifiable and meaningful improvement over today’s standard of care in CAH.”

Anticipated Upcoming Milestones

- Completion of enrollment in CAHmelia-204 clinical trial in adult classic CAH patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of androstenedione (A4) in January 2024
- Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with highly elevated levels of A4 in March 2024
- Topline results from all cohorts in the CAHptain-205 clinical trial in pediatric classic CAH patients in March 2024
- Topline results from the CAHmelia-204 clinical trial in adult classic CAH patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 in the third quarter of 2024

Tildacerfont Program Updates

Late-Stage CAHmelia Program in Adult Classic CAH

- **CAHmelia-203 Study in Adult Classic CAH Completes Enrollment:** Enrollment in CAHmelia-203 is complete with 96 patients, surpassing target enrollment of 72 patients. 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. The primary endpoint of the clinical trial is the percentage change in A4 from baseline at week 12. Topline results from the study are anticipated in March 2024.
- **Enrollment for CAHmelia-204 Study in Adult Classic CAH to be Completed in January 2024:** Enrollment in CAHmelia-204 is anticipated to be completed in January 2024, and will surpass target enrollment of 90 patients. CAHmelia-204 is a randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid usage in adults with classic CAH in patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 at baseline. Based on a statistical analysis of aggregated blinded data, the primary endpoint of this clinical trial is now the absolute change in glucocorticoid dose from baseline at week 24. Topline results from the study are anticipated in the third quarter of 2024.

Pediatric Classic CAH Program

- **CAHptain-205 Study in Pediatric Classic CAH Completes Enrollment:** Enrollment in CAHptain-205 is complete with 30 patients, surpassing target enrollment of 20 patients**.** CAHptain-205 is a Phase 2 open-label clinical trial, which utilizes a sequential three cohort design, to evaluate the safety, efficacy, and pharmacokinetics of tildacerfont in children two to 17 years of age. The primary endpoint of this clinical trial is safety. Additional secondary endpoints include the proportion of subjects who achieve reduction in A4 or daily glucocorticoid dosing at week 12 and the proportion of subjects with elevated

A4 at baseline who achieve a reduction in A4 at week 4. Topline results from the study are anticipated in March 2024.

Financial Update

Cash and cash equivalents as of December 31, 2023 were approximately $96 million. Based on the company's current operating plan, operating and capital expenditures are funded into the first half of 2025. Common shares outstanding as of December 31, 2023 were 41.0 million.

These amounts are unaudited and preliminary and are subject to completion of financial closing procedures. Additional information and disclosure would be required for a more complete understanding of the company's financial position and results of operations as of December 31, 2023.

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, the fulfillment of Spruce's strategic business objectives, the advancement of Spruce's drug development pipeline, and Spruce's planned operations, including its expectations regarding operating and capital expenditures being funded into the first half of 2025. 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 "plan", "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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