Spruce Biosciences and HMNC Brain Health Announce Strategic Collaboration to Develop Treatment for Major Depressive Disorder (MDD)

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Pairs Spruce's Investigational Product Candidate, Tildacerfont, with HMNC's Companion Diagnostic, the Proprietary Cortibon Genetic Selection Tool, to Treat MDD Patients Responsive to CRF_1 Receptor Antagonism

Provides Spruce with Option to In-License Exclusive Worldwide Rights to Cortibon Following Completion of Phase 2 Proof-of-Concept Study

HMNC to Initiate Phase 2 Study for the Treatment of MDD in Q4 2024

SOUTH SAN FRANCISCO, Calif. & MUNICH--(BUSINESS WIRE)--Jun. 4, 2024-- Spruce Biosciences, Inc. (Nasdaq: SPRB) ("Spruce"), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for endocrine and neurological disorders with significant unmet medical need, and HMNC Brain Health GmbH ("HMNC") , a global precision psychiatry biopharma company, announced today a strategic collaboration to develop Spruce's investigational product candidate, tildacerfont, a second-generation CRF $_1$ receptor antagonist, with HMNC's companion diagnostic, the proprietary Cortibon Genetic Selection Tool ("Cortibon"), for the treatment of MDD.

"We believe that Cortibon has the potential to enable tildacerfont to be advanced as a precision therapeutic for personalized medicine in patients with MDD," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer, Spruce Biosciences. "Hyperactive corticotropin-releasing factor (CRF) neurotransmission and CRF_1 receptor signal transduction are critical mechanisms for stress pathophysiology that may lead to major depression. Tildacerfont may mediate responses to stress, which has the potential to address up to 50% of the MDD patients worldwide using Cortibon. We are excited to collaborate with HMNC and initiate a Phase 2 proof-of-concept study of tildacerfont and Cortibon for the treatment of MDD later this year."

"Treatment of MDD is hampered by patient heterogeneity, meaning many patients will fail to respond adequately to currently used therapies. HMNC's collaboration with Spruce marks a significant step forward in our mission to bring innovative treatments to patients with depression. Combining our companion diagnostic with Spruce's promising therapeutic offers a new avenue for precision psychiatry," said Dr. Maximilian Doebler, Chief Business Officer, HMNC. "Traditional treatments often fall short, trapping patients in a costly trial-and-error cycle. Our platform uses genetic markers to predict responses to psychiatric medications, potentially enhancing treatment efficacy and reducing costs. This collaboration represents a new era in mental health management."

Under the agreement, HMNC will fund and conduct a Phase 2 proof-of-concept study of tildacerfont in MDD patients, who will be screened using Cortibon. Spruce has an option to in-license exclusive worldwide rights to Cortibon after completion of the study, if results are positive. If Spruce exercises its option, it will be responsible for the future worldwide development and commercialization of tildacerfont and Cortibon for the treatment of MDD under a collaboration framework that leverages HMNC's ongoing expertise in precision psychiatry and companion diagnostics. Pursuant to the license terms, HMNC would be entitled to receive certain milestone payments and tiered royalties on net sales of tildacerfont in MDD.

About Tildacerfont

Tildacerfont is a potent and highly selective, non-steroidal, oral antagonist of the CRF_1 receptor, which is the receptor for corticotropin-releasing factor (CRF), a hormone that is secreted by the hypothalamus. The CRF_1 receptor is abundantly expressed in the brain and pituitary gland, where it is the primary regulator of the hypothalamic–pituitary-adrenal (HPA) axis. By blocking the CRF_1 receptor, tildacerfont has the potential to address hyperactive brain CRF neurotransmission and aberrant functioning of the HPA axis in patients with major depressive disorder (MDD). No drug-related serious adverse events have been reported related to tildacerfont treatment in completed studies.

About Cortibon

Cortibon is HMNC's proprietary companion diagnostic, representing a potentially groundbreaking approach in the treatment of major depressive disorder (MDD). By utilizing genetic markers, Cortibon aims to identify MDD patients who are more likely to respond to CRF_1 receptor antagonism, thereby enhancing treatment outcomes and reducing the trial-and-error period typical in depression treatment. Traditional treatments often lead to long onset times and insufficient response rates, trapping patients in a costly and prolonged trial-and-error cycle. Cortibon may dramatically shift this paradigm by improving treatment efficacy and reducing both costs and time.

About Spruce Biosciences

Spruce Biosciences is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for endocrine and neurological disorders with significant unmet medical need. Spruce is developing its product candidate, tildacerfont, an oral, second-generation CRF_1 receptor antagonist, for the treatment of congenital adrenal hyperplasia (CAH), polycystic ovary syndrome (PCOS) and major depressive disorder (MDD). To learn more, visit www.sprucebio.com and follow us on X @Spruce_Bio, LinkedIn, Facebook and YouTube.

About HMNC Brain Health

HMNC Brain Health (HMNC Holding GmbH) is a global precision psychiatry biopharma company headquartered in Munich, Germany, which is pioneering the development of personalized therapies powered by predictive companion diagnostics, leading to higher remission rates in populations identified by companion diagnostics. The company develops unique pipelines for targeting both major depressive disorder (MDD) and treatment-resistant depression (TRD) and has three depression development programs in Phase 2. The company has presence in both Germany and the U.S.

and is backed by a renowned global VC, several family officers, and a strategic healthcare investor. More information at www.hmnc-brainhealth.com.

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 design, results, conduct, progress and timing of Spruce’s clinical trials; Spruce’s expectations regarding the initiation of the Phase 2 POC study of tildacerfont and Cortibon in patients with MDD in the fourth quarter of 2024; the potential for Cortibon to enable tildacerfont to be advanced as a precision therapeutics for MDD and other disorders; tildacerfont’s potential to mediate stress responses and Spruce’s product candidate, strategy and regulatory matters. 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”, “may,” “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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