Spruce Biosciences Announces Launch of MPS3BStudy.com

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Website Enables Families and Caregivers of Children with MPS IIIB to Learn About and Register Interest in the TA-ERT Expanded Access Program (EAP) and TrAnsform Confirmatory Study

TA-ERT EAP and TrAnsform Confirmatory Study Both Expected to Initiate in the Fourth Quarter of 2026

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 26, 2026-- Spruce Biosciences, Inc. (Nasdaq: SPRB), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for neurological disorders with significant unmet medical need, today announced the launch of MPS3BStudy.com, a dedicated online resource for families and caregivers of children with Sanfilippo Syndrome Type B (MPS IIIB). The website enables families and caregivers to learn about, and register their interest in, the planned Expanded Access Program (EAP) and TrAnsform confirmatory study of investigational tralesinidase alfa enzyme replacement therapy (TA-ERT), both of which are expected to initiate as early as the fourth quarter of 2026.

MPS3BStudy.com provides an overview of MPS IIIB, a devastating, rapidly progressing neurodegenerative disease that primarily affects children and for which there are no FDA-approved therapies, as well as information about investigational TA-ERT and detailed descriptions of the TA-ERT EAP and TrAnsform confirmatory study, including eligibility criteria for each. Through a simple registration form, families and caregivers can express interest in participation and receive updates as U.S. sites activate and enrollment begins.

TA-ERT Expanded Access Program

The TA-ERT EAP is the planned open-label, single-arm early access program designed to provide TA-ERT to children in the United States with attenuated and severe MPS IIIB who are not eligible to enroll in the confirmatory study. To be eligible, a child must have a diagnosis of MPS IIIB confirmed by deficient N-Acetyl-Alpha-Glycosaminidase (NAGLU) enzyme activity and be between ≥12 and ≤60 months of age with a BSID-III-C raw score ≥70 or >60 months of age regardless of cognitive level. The program is expected to enroll approximately 10 participants across U.S. sites, with TA-ERT administered weekly via an intracerebroventricular (ICV) delivery device. Its primary objective is to allow early access to treatment with TA-ERT for those participants who are not eligible for inclusion in the confirmatory study while evaluating the safety and tolerability of TA-ERT. Participation in the TA-ERT EAP is anticipated to continue for up to approximately one year or until TA-ERT becomes commercially available, if approved. Spruce expects to initiate TA-ERT EAP as early as the fourth quarter of 2026. More information about the TA-ERT EAP can be found at ClinicalTrials.gov.

TrAnsform Confirmatory Study

The TrAnsform confirmatory study is the planned randomized, single-blind, parallel-group, controlled, multicenter study evaluating the safety, tolerability, and efficacy of ICV-administered TA-ERT compared to standard of care in children between 1 and 5 years of age with severe (non-attenuated) MPS IIIB confirmed by deficient NAGLU enzyme activity. The study is expected to enroll approximately 14 participants, randomized to receive weekly TA-ERT or to a standard of care arm, with the primary objective of evaluating the effect of TA-ERT on cognition. Spruce expects to initiate the confirmatory study as early as the fourth quarter of 2026, while Spruce's planned biologics application is under review by the FDA. To address the progressive nature of MPS IIIB, participants in the standard of care arm who meet prespecified criteria for cognitive decline are eligible to switch to TA-ERT treatment. More information about the TrAnsform confirmatory study can be found at ClinicalTrials.gov.

About Sanfilippo Syndrome Type B (MPS IIIB)

Sanfilippo Syndrome Type B (MPS IIIB) is an ultra-rare, serious, and fatal genetic disease characterized by deficiency in NAGLU, an enzyme required for the catabolism of heparan sulfate in lysosomes. It is estimated that MPS IIIB affects fewer than one in 200,000 people in the United States. The accumulation of toxic levels of cerebral spinal fluid heparan sulfate in the brain is the underlying pathophysiology of MPS IIIB. Although signs and symptoms of MPS IIIB can vary amongst affected individuals, progressive neurodegeneration typically follows a predictable path to brain atrophy, cognitive and developmental impairment, hyperactivity with aggressive and destructive behavior, delayed speech, hearing loss, and motor skill deficits. Somatic manifestations include coarse facial features, hepatosplenomegaly, and gastrointestinal symptoms. The final stage of MPS IIIB is typically marked by severe dementia, loss of motor function, and seizure activity, with patients largely bed-ridden and requiring constant care, requiring feeding tubes for hydration and nutrition, and ultimately leading to death. The estimated life expectancy of individuals with MPS IIIB ranges from 15 to 19 years of age. Currently, there are no FDA-approved therapies for MPS IIIB, and management of the disease consists of limited palliative care to improve quality of life.

About Tralesinidase Alfa Enzyme Replacement Therapy (TA-ERT)

TA-ERT is a fusion protein comprised of recombinant human alpha-N-acetylglucosaminidase (rhNAGLU). TA-ERT is intended as an enzyme replacement therapy for the treatment of patients with MPS IIIB who lack rhNAGLU enzyme activity. TA-ERT is anticipated to restore rhNAGLU enzyme activity in the central nervous system following intracerebroventricular injection. rhNAGLU typically lacks the mannose-6 phosphate (M6P) residues that are essential for efficient cellular uptake via the M6P receptor pathway. As a result, the naked enzyme is poorly absorbed by cells, including neurons. To address this challenge, TA-ERT is fused to an insulin-like growth factor 2 peptide, which binds to the cation-independent M6P on cell surfaces. This fusion enables the enzyme to be internalized and delivered to the lysosome, thereby enhancing its therapeutic potential for treating MPS IIIB. By restoring NAGLU enzymatic activity and promoting clearance of lysosomal heparan sulfate and heparan sulfate non-reducing end in the brain, TA-ERT therapy is expected to preserve neuronal cell health and potentially halt or slow the neurological decline and improve clinical outcomes in affected patients. TA-ERT has been evaluated in three clinical studies in participants with MPS IIIB: the interventional study 201 and extension

studies 202 and 401. TA-ERT has been administered to 22 individuals diagnosed with MPS IIIB, and has demonstrated an adequate safety profile based on integrated six years of safety data.

About Spruce Biosciences

Spruce Biosciences is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for neurological disorders with significant unmet medical need. Spruce's lead product candidate, tralesinidase alfa enzyme replacement therapy (TA-ERT), is in late-stage development for the treatment of mucopolysaccharidoses type IIIB (MPS IIIB), or Sanfilippo Syndrome Type B, a devastating pediatric neurodegenerative disorder for which there are no FDA-approved therapies. TA-ERT has received Breakthrough Therapy Designation, Rare Pediatric Disease Designation, Fast Track Designation and Orphan Drug Designation from the FDA, as well as Orphan Drug Designation in the European Union. 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 expected timing, enrollment and conduct of the TA-ERT Expanded Access Program and TrAnsform Confirmatory Study. 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," "will," "believe," "could," "expect," "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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