Cure Sanfilippo Foundation and National MPS Society Make $5.5 Million Strategic Investment in Spruce Biosciences

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Investment Broadens Patient Access to Tralesinidase Alfa Enzyme Replacement Therapy (TA-ERT) for Sanfilippo Syndrome Type B in the TA-ERT Expanded Access Program (EAP)

TA-ERT EAP Expected to Initiate in the Fourth Quarter of 2026

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 12, 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 that Cure Sanfilippo Foundation and the National MPS Society have agreed to make a combined $5.5 million strategic investment in Spruce. The proceeds will be used to partially fund TA-ERT EAP, helping to broaden patient access to investigational TA-ERT for the treatment of Sanfilippo Syndrome Type B (mucopolysaccharidosis Type IIIB, or MPS IIIB).

“We are deeply grateful to Cure Sanfilippo Foundation and the National MPS Society for their partnership and their conviction in Spruce’s development of TA-ERT,” said Samir Gharib, President and Chief Financial Officer of Spruce Biosciences. “This investment is a powerful expression of what we can accomplish when industry and the patient community work together. Their support helps us expand access to investigational TA-ERT for children with MPS IIIB who urgently need treatment options today, while we continue our work to bring this therapy to all eligible patients.”

The strategic investment reflects a shared commitment among Spruce and two of the leading organizations serving the MPS and Sanfilippo communities to accelerate access to TA-ERT for the treatment of MPS IIIB, a devastating, rapidly progressing neurodegenerative disease that primarily affects children and for which there are no FDA-approved therapies. The Foundations’ and community fundraising efforts led to the initiation of EAP start-up activities earlier this year, including manufacturing of drug product, to accelerate access to children and families impacted by MPS IIIB in advance of potential U.S. FDA accelerated approval.

“Every day without treatment matters for a child living with Sanfilippo syndrome. As both a physician and a parent in this community, I know the urgency families feel as they watch this devastating disease take abilities from their children,” said Cara O’Neill, M.D., Chief Science Officer and Co-Founder of Cure Sanfilippo Foundation. “The encouraging clinical data for TA-ERT offer meaningful hope, and our investment reflects the Foundation’s deep commitment to advancing rigorous science while bringing promising therapies within reach for children who need time-sensitive access. We are proud to stand alongside Spruce Biosciences, the National MPS Society and our community of families to support continued research and access to TA-ERT for the brave individuals facing this disease today.”

Terri Klein, President and Chief Executive Officer, National MPS Society added, “For more than 50 years, the National MPS Society has worked to ensure that families affected by MPS are never alone in their fight, and that the research they place their hope in actually reaches them. Supporting Spruce’s Expanded Access Program is a meaningful step toward that goal for the MPS IIIB community. Investing directly in this effort reflects our belief that advocacy organizations can and should help bridge the gap between scientific progress and patient access. We are grateful to partner with Spruce and the Cure Sanfilippo Foundation to bring a potential treatment closer to the children and families who are counting on it.”

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.

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 fulfillment of Spruce's strategic business objectives, the expected timing, enrollment and conduct of the TA-ERT Expanded Access Program, the potential of TA-ERT to improve clinical outcomes in patients with MPS IIIB, the planned biologics license application submission for TA-ERT, potential regulatory approval, and potential commercial launch of TA-ERT. 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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