Spruce Biosciences Announces Positive Type B Meetings with U.S. FDA for TA-ERT for the Treatment of Sanfilippo Syndrome Type B (MPS IIIB)

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Based on FDA Feedback, Company Continues to Advance BLA Submission for TA-ERT Using CSF HS-NRE as Reasonably Likely Surrogate Endpoint for Accelerated Approval

BLA Submission for TA-ERT is Now Anticipated in the Fourth Quarter to Accommodate Drug Product PPQ Requirement

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 18, 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 successful completion of Type B meetings with the U.S. Food and Drug Administration (FDA or the Agency) regarding its planned upcoming biologics license application (BLA) submission for tralesinidase alfa enzyme replacement therapy (TA-ERT).

The company held two Type B meetings with the FDA ahead of its anticipated BLA submission for TA-ERT; the first in December 2025 to discuss the company's clinical data and regulatory strategy, and the second in January 2026 to discuss chemistry, manufacturing, and controls (CMC) requirements.

During the December 2025 meeting, the Agency confirmed that the integrated study data from interventional clinical studies of TA-ERT and the available natural history data could potentially serve as an adequate and well-controlled study for purposes of the Agency's review of the effects of TA-ERT on cerebral spinal fluid heparan sulfate non-reducing end (CSF HS-NRE), which could serve as a reasonably likely surrogate endpoint (RLSE) to support an accelerated approval. The Agency also provided recommendations to further support CSF HS-NRE as a RLSE, which the company is incorporating into its planned BLA submission. In addition, Spruce and the Agency discussed the timing and design of a required confirmatory study of TA-ERT, including an agreement to initiate the confirmatory study during BLA review.

Following the January 2026 CMC meeting, the Agency considered the company's plan to address drug product (DP) process performance qualification (PPQ) batch requirements for the BLA submission. In the official meeting minutes, which were received on February 12, 2026, the Agency shared its requirement for one DP PPQ batch at the time of BLA submission and data from a second DP PPQ batch prior to midcycle of BLA review. To accommodate this requirement, the timing of the BLA submission for TA-ERT is now anticipated in the fourth quarter of 2026.

"The company appreciates the productive and constructive engagement with FDA as we gain clarity on specific clinical and CMC requirements expected of us by the Agency for our planned upcoming BLA submission of TA-ERT," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "While the timing of our submission is now expected in the fourth quarter of this year, we believe in the strength of our long-term data for TA-ERT which demonstrates that reductions in CSF HS-NRE are associated with meaningful clinical benefits across cognition, communication, and motor skill acquisition. TA-ERT has the potential to provide a meaningful option to change the course of this fatal disease, and we are motivated every day to bring forward a treatment for families and patients with MPS IIIB who currently have no treatment options."

Dr. Szwarcberg continued, "As we work to bring TA-ERT to the market as efficiently as possible, I want to commend the tireless advocacy on behalf of patients that led to the reauthorization of the Rare Pediatric Disease Priority Review Voucher (PRV) program through September 2029, restoring a key incentive to develop therapies for rare pediatric diseases. The reauthorization of the PRV program has provided hope and renewed optimism to the Sanfilippo community and will enable us to successfully position TA-ERT, if approved, as potentially the first disease-modifying treatment option for MPS IIIB."

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 N-Acetyl-Alpha-Glycosaminidase (NAGLU), an enzyme required for the catabolism of heparan sulfate (HS) in lysosomes. It is estimated that MPS IIIB affects fewer than one in 200,000 people in the United States, but the true incidence and prevalence are difficult to ascertain because MPS IIIB is a disease currently not included in newborn screening. 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)

Tralesinidase Alfa Enzyme Replacement Therapy (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 Sanfilippo Syndrome Type B (MPS IIIB) who lack rhNAGLU enzyme activity. TA-ERT is expected to restore rhNAGLU enzyme activity in the central nervous system following intracerebroventricular injection. rhNAGLU typically lacks the mannose-6 phosphate 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 mannose-6-phosphate 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. TA-ERT has secured Breakthrough Therapy, Fast Track, and Rare Pediatric Disease Designations from FDA for the treatment of Sanfilippo Syndrome Type B (MPS IIIB).

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. 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 ability to seek accelerated approval of TA-ERT for MPS IIIB based on existing clinical data; the content, timing and likelihood of regulatory filings and approvals for TA-ERT, including advancing this program through a biologics license application submission and potential U.S. FDA approval; the potentially transformative clinical impact for TA-ERT; TA-ERT’s eligibility for a PRV; and TA-ERT’s potential to be the first disease-modifying therapy to treat MPS IIIB. 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,” “will,” “potential,” “intend,” “expect,” 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.

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