Precision BioSciences Receives FDA Fast Track Designation for PBGENE-DMD and Announces Duchenne Muscular Dystrophy Investor Event

March 9, 2026 at 7:01 AM EDT

– Fast Track designation aims to facilitate development and expedite review of drugs, such as PBGENE-DMD to treat serious conditions like Duchenne muscular dystrophy –

– March 17, 2026 virtual webinar to feature expert insights on potential clinical utility of PBGENE-DMD for patients with Duchenne muscular dystrophy and the planned Phase 1/2 FUNCTION-DMD clinical study –

DURHAM, N.C.--(BUSINESS WIRE)--Mar. 9, 2026-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company utilizing its novel proprietary ARCUS® platform to develop *in vivo* gene editing therapies for high unmet need diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to PBGENE-DMD for the treatment of Duchenne muscular dystrophy (DMD). The Company also announced that it will host a virtual key opinion leader (KOL) event on Tuesday, March 17, 2026, at 9:00 AM ET to discuss PBGENE-DMD and the planned Phase 1/2 FUNCTION-DMD clinical study.

“Fast Track designation is an important regulatory milestone for PBGENE-DMD and reflects the significant unmet need in DMD,” said Michael Amoroso, Chief Executive Officer of Precision BioSciences. “We believe this designation, together with our recent IND clearance, supports PBGENE-DMD’s continued momentum towards clinical investigation in boys living with DMD.”

Fast Track designation is intended to facilitate the development of investigational therapies for serious conditions with unmet medical need and may support more efficient interactions with the FDA as development advances. Precision believes this designation further underscores the potential of PBGENE-DMD and the urgent need for new DMD treatment options.

In addition, on March 17, 2026, Precision will host an investor event that will feature key DMD leaders Dr. Aravindhan Veerapandiyan, MD, Pediatric Neurologist and Associate Professor of Pediatrics, Arkansas Children’s Hospital, and Pat Furlong, Founding President of Parent Project Muscular Dystrophy. Parent Project Muscular Dystrophy (PPMD) is the largest nonprofit organization in the United States focused entirely on Duchenne muscular dystrophy and fights to end Duchenne by advancing research, improving care, and expanding access to therapies. The presenters will discuss the unmet need, current treatment landscape and PBGENE-DMD for Duchenne muscular dystrophy (DMD), including an overview of the clinical trial design for the FUNCTION-DMD trial.

About Duchenne Muscular Dystrophy Investor Event

Date and Time: Tuesday, March 17, 2026, at 9:00 AM ET

A live question-and-answer session with investors and analysts will follow the formal presentation. To register for the event, please click here. A replay of the webinar will be accessible in the Investors section of Precision’s website following the event.

About PBGENE-DMD

PBGENE-DMD, a novel first-in-class gene editing therapy, utilizes a gene excision approach that is clearly differentiated from existing microdystrophin and exon skipping treatments. PBGENE-DMD is designed to potentially provide durable functional muscle improvement for DMD patients with mutations in exons 45-55, representing up to 60% of boys with DMD. A single AAV encodes two ARCUS proteins designed to permanently edit a patient’s DNA within the dystrophin gene, resulting in a naturally-expressed, near full-length, functional dystrophin protein. Supported by robust preclinical evidence, PBGENE-DMD is designed to drive functional improvement over time by targeting muscle satellite cells.

In preclinical studies, PBGENE-DMD demonstrated the ability to target key muscle types involved in the progression of DMD and produced significant, durable functional improvements in a humanized DMD mouse model. PBGENE-DMD restored the body’s ability to produce a near full-length functional dystrophin protein across multiple muscles, including cardiac tissue, diaphragm and various key skeletal muscle groups. In addition, PBGENE-DMD edited satellite muscle stem cells, believed to be critical for long-term durability and sustained functional improvement.

About FUNCTION-DMD Trial:

The Phase 1/2 FUNCTION-DMD study is expected to enroll ambulatory DMD patients between the age of 2-7 with mutations between exons 45 and 55 representing up to 60% of boys with DMD. The objective of the FUNCTION-DMD study is to evaluate safety, tolerability, and efficacy, including dystrophin protein expression and functional outcomes in patients afflicted with DMD. For more information about this clinical trial and contact information, please visit www.clinicaltrials.gov and search for NCT07429240.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, expectations about operational initiatives, strategies, further development including dose expansion, and timing of additional updates or data

releases of PBGENE-DMD and the FUNCTION-DMD Trial; translation of results in preclinical studies of PBGENE-DMD to clinical studies in humans; expected timing and outcome of regulatory and institutional review board processes for PBGENE-DMD clinical trial; the design of PBGENE-DMD to potentially provide durable functional muscle improvement for DMD patients with mutations in exons 45-55 impacting up to 60% of boys with DMD; and the design of PBGENE-DMD to drive functional improvement in skeletal and cardiac muscle over time with the ability to target and edit muscle satellite cells. In some cases, you can identify forward-looking statements by terms such as “aim,” “anticipate,” “approach,” “belief”, “believe,” “contemplate,” “could,” “design,” “designed,” “estimate,” “expect,” “goal,” “intend,” “look,” “may,” “mission,” “plan,” “possible,” “potential,” “predict,” “project,” “pursue,” “should,” “strive,” “suggest,” “target,” “will,” “would,” or the negative thereof and similar words and expressions.

Forward-looking statements are based on management’s current expectations, beliefs, and assumptions and on information currently available to us. These statements are neither promises nor guarantees, and involve a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to, the progression and success of our programs and product candidates in which we expend our resources; our limited ability or inability to assess the safety and efficacy of our product candidates; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities and preclinical and clinical studies, including clinical trial and investigational new drug applications; our ability to advance product candidates into, and successfully design, implement and complete, clinical trials; changes in interim “top-line” and initial data that we announce or publish; our current and future relationships with and reliance on third parties including suppliers and manufacturers; and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2024 and our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2025, June 30, 2025, and September 30, 2025 as any such factors may be updated from time to time in our other filings with the U.S. Securities and Exchange Commission (SEC), which are accessible on the SEC’s website at **www.sec.gov** and the Investors page of our website under SEC Filings at **investor.precisionbiosciences.com**.

All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we have no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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Investor and Media Contact:
Naresh Tanna
Vice President of Investor Relations
naresh.tanna@precisionbiosciences.com

Source: Precision BioSciences, Inc.