Precision BioSciences Announces Positive DSMB Safety Review Supporting Additional PBGENE-DMD Dosing in Phase 1/2 FUNCTION-DMD Study

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- First patient completed observation period following PBGENE-DMD treatment with no reported safety concerns -

- Independent Data Safety Monitoring Board endorses proceeding with dosing additional patients -

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 5, 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 independent Data Safety Monitoring Board (DSMB) has completed its review of safety data from the first patient treated with PBGENE-DMD in the Phase 1/2 FUNCTION-DMD clinical trial for Duchenne muscular dystrophy (DMD). No serious adverse events or adverse events of special interest were reported in the first patient through week eight. Following completion of the patient's initial eight-week safety observation period, the DSMB identified no safety concerns and endorsed proceeding with dosing additional patients in Part 1 of the study.

"Successful completion of the initial safety assessment and DSMB authorization to proceed with treatment of additional patients represents an important milestone for the FUNCTION-DMD study," said Dr. Sam Collins, MBBS, Ph.D., Senior Vice President, DMD Clinical Development at Precision BioSciences. "This initial eight-week period is key in monitoring potential early safety events known to be associated with all AAV-based therapies, and we are encouraged by the DSMB's agreement that the safety results in the first patient support completing enrollment in Part 1 of the study. We remain diligent about safety monitoring as the trial progresses and are grateful to the patients, families, and clinical teams whose commitment is making it possible to evaluate this novel gene editing approach for Duchenne muscular dystrophy."

"We believe PBGENE-DMD has the potential to fundamentally change the treatment paradigm by addressing the underlying genetic cause of DMD. Unlike truncated microdystrophin treatments, PBGENE-DMD is designed to utilize the body's native dystrophin gene, excising the frequently mutated hotspot region to restore near full-length, functional dystrophin," said Cassie Gorsuch, PhD, Chief Scientific Officer of Precision BioSciences. "We remain committed to generating the clinical evidence needed to evaluate this novel approach for patients and families living with DMD, and look forward to providing safety and efficacy updates from the FUNCTION-DMD study throughout 2027."

About FUNCTION-DMD Trial

The Phase 1/2 FUNCTION-DMD study is enrolling ambulatory DMD patients between the ages of 2 and 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 living with DMD. For more information about this clinical trial and contact information, please visit **www.clinicaltrials.gov** and search for NCT07429240.

About PBGENE-DMD, A Muscle-Targeted Excision Program

PBGENE-DMD is Precision's clinical program for the treatment of DMD. DMD is a genetic disease caused by mutations in the dystrophin gene that prevent production of the dystrophin protein and affects approximately 15,000 patients in the U.S. alone. There are currently no approved therapies that can drive durable and significant functional improvements over time. PBGENE-DMD is designed to improve function by employing two complementary ARCUS nucleases delivered in a single AAV to excise exons 45-55 of the dystrophin gene. The aim of this approach is to restore a near full-length functional dystrophin protein native to the body as opposed to foreign and synthetic, truncated microdystrophin approaches which have led to limited functional benefit. The Phase 1/2 FUNCTION-DMD study is enrolling ambulatory DMD patients with mutations between exons 45 and 55 impacting up to 60% of boys with DMD. The clinical trial employs an appropriate immune modulation regimen and safety monitoring program to treat ambulatory patients at world-class specialized DMD clinical sites.

PBGENE-DMD was granted Orphan Drug Designation by the FDA in July 2025. PBGENE-DMD has received Rare Pediatric Disease Designation from the FDA for the treatment of DMD, and therefore PBGENE-DMD may be eligible for a Priority Review Voucher (PRV). PBGENE-DMD received Fast Track designation from the FDA in February 2026.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is a clinical stage gene editing company dedicated to improving life (DTIL) with its novel and proprietary ARCUS® genome editing platform that differs from other technologies in the way it cuts, its smaller size, and its simpler structure. These features are intended for ARCUS nucleases to drive more defined therapeutic outcomes. Using ARCUS, the Company's pipeline is comprised of clinical stage in vivo gene editing candidates designed to deliver lasting cures for the broadest range of genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences, please visit **www.precisionbiosciences.com**.

The ARCUS® platform is being used to develop *in vivo* gene editing therapies for sophisticated gene edits, including gene elimination (removing a viral genome e.g. viral DNA such as in the Company's PBGENE-HBV program), and excision (removing a large portion of a defective gene by delivering two ARCUS nucleases in a single AAV such as in the Company's PBGENE-DMD program) and gene insertion (inserting DNA into a gene to cause expression or add function).

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 expectations around timing of site activation, patient enrollment and data releases of PBGENE-DMD and the FUNCTION-DMD trial; the potential of PBGENE-DMD to fundamentally change the treatment paradigm by addressing the underlying genetic cause of DMD; translation of results in preclinical studies of PBGENE-DMD to clinical studies in humans; 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 patients with DMD; and the use of an appropriate immune modulation regimen. 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, our ability to become profitable; our ability to procure sufficient funding to advance our programs; risks associated with our capital requirements, anticipated cash runway, requirements under our current debt instruments and effects of restrictions thereunder, including our ability to raise additional capital due to market conditions and/or our market capitalization; our operating expenses and our ability to predict what those expenses will be; our limited operating history; 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; the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology; 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; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators’ or other licensees’ ability to identify, develop and commercialize product candidates; pending and potential product liability lawsuits and penalties against us or our collaborators or other licensees related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators’ or other licensees’ development of product candidates; our or our collaborators’ or other licensees’ ability to advance product candidates into, and successfully design, implement and complete, clinical trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; delays or difficulties in our and our collaborators’ and other licensees’ ability to enroll patients; changes in interim “top-line” and initial data that we announce or publish; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data protection, privacy and security regulations and our compliance therewith; our or our licensees’ ability to obtain orphan drug designation or fast track designation for our product candidates or to realize the expected benefits of these designations; our or our collaborators’ or other licensees’ ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the rate and degree of market acceptance of any of our product candidates; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate executives and personnel; effects of system failures and security breaches; insurance expenses and exposure to uninsured liabilities; effects of tax rules; effects of any pandemic, epidemic, or outbreak of an infectious disease; the success of our existing collaboration and other license agreements, and our ability to enter into new collaboration arrangements; our current and future relationships with and reliance on third parties including suppliers and manufacturers; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriation of intellectual property rights; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events; effects of sustained inflation, supply chain disruptions and major central bank policy actions; market and economic conditions; risks related to ownership of our common stock, including fluctuations in our stock price; our ability to meet the requirements of and maintain listing of our common stock on Nasdaq or other public stock exchanges; and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the annual period ended December 31, 2025 and Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2026, as any such factors may be updated from time to time in our other filings with the 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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