PepGen Announces Regulatory Updates on FREEDOM2

March 4, 2026

- U.S. FDA places FREEDOM2 trial on partial clinical hold related to preclinical pharmacology and toxicology -

- Received regulatory clearance to initiate FREEDOM2 in South Korea, Australia, and New Zealand and dosing of the 10 mg/kg cohort continues in the UK and Canada -

- PepGen reiterates guidance for reporting data from the FREEDOM2 5 mg/kg cohort in Q1 2026 and from the 10 mg/kg cohort in 2H 2026 -

BOSTON--(BUSINESS WIRE)--Mar. 4, 2026-- PepGen Inc. (Nasdaq: PEPG), a clinical-stage biotechnology company advancing the next generation of oligonucleotide therapies to treat severe neuromuscular and neurological diseases, today announced regulatory updates related to the FREEDOM2 trial.

The U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on the FREEDOM2-DM1 Phase 2 multiple ascending dose (MAD), randomized, placebo-controlled clinical trial of PGN-EDODM1 in patients with myotonic dystrophy type 1 (DM1). The partial clinical hold questions raised by FDA relate to previously submitted preclinical pharmacology and toxicology studies. The partial clinical hold did not cite any questions regarding blinded clinical data from the Phase 1 FREEDOM study previously submitted to the FDA in order to initiate the FREEDOM2 study in the U.S. As part of its ongoing dialogue with the FDA, the Company is submitting additional analyses, including the recently unblinded FREEDOM data, and is committed to working with the FDA to address their questions as quickly as possible.

PepGen was recently cleared to open the FREEDOM2 study in New Zealand, Australia, and South Korea.

Following the Data Safety Monitoring Board's recommendation to dose escalate, the FREEDOM2 trial is dosing patients at 10 mg/kg in Canada and the UK. No U.S. patients have been enrolled in FREEDOM2. Patients from the FREEDOM and FREEDOM2 studies in Canada are continuing into the Open Label Extension (OLE) study. The Company has received regulatory clearance for the OLE study in the UK and intends to open the OLE study in all geographies where FREEDOM2 is open.

The Company expects to report data from the 5 mg/kg cohort of FREEDOM2 in the first quarter of 2026, and from the 10 mg/kg cohort in the second half of 2026.

About PGN-EDODM1

PGN-EDODM1, PepGen's investigational candidate in development for the treatment of DM1, utilizes the Company's proprietary EDO technology to deliver a therapeutic oligonucleotide that is designed to restore the normal splicing function of MBNL1, a key RNA splicing protein. PGN-EDODM1 addresses the deleterious effects of cytosine-uracil-guanine (CUG) repeat expansion in the dystrophia myotonica protein kinase (DMPK) transcripts which sequester MBNL1, by binding to the pathogenic CUG trinucleotide repeat expansion present in the DMPK transcripts, and disrupting the binding between the CUG repeat expansion and MBNL1. PepGen believes this innovative therapeutic approach may have considerable advantages over oligonucleotide modalities that rely on knockdown or degradation of the DMPK transcripts as it will allow the DMPK transcripts to continue to perform their normal function within the cell, while also liberating MBNL1 to correct downstream mis-splicing events. The U.S. Food and Drug Administration has granted PGN-EDODM1 both Orphan Drug and Fast Track Designations for the treatment of patients with DM1. The European Medicines Agency (EMA) has recently granted Orphan Designation for PGN-EDODM1.

About PepGen

PepGen Inc. is a clinical-stage biotechnology company developing the next generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases. PepGen's Enhanced Delivery Oligonucleotide (EDO) platform is founded on over a decade of research and development and leverages cell-penetrating peptides to improve the uptake and activity of conjugated oligonucleotide therapeutics. Using these EDO peptides, the Company is generating a pipeline of oligonucleotide therapeutic candidates designed to target the root cause of serious diseases.

For more information, please visit *PepGen.com*. Follow PepGen on *LinkedIn* and *X*.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding the potential of our EDO platform to deliver high levels of oligonucleotide to the nuclei, the design and conduct of clinical trials with our candidates, including expected timelines for the initial data report from our FREEDOM2-DM1 trial, and ongoing and planned regulatory interactions, including the potential timing and resolutions of questions from the FDA relating to the partial clinical hold.

Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to risks related to: delays or failure to successfully initiate or complete our ongoing and planned development activities for PGN-EDODM1; our ability to enroll patients in our clinical trials, including FREEDOM2; that our interpretation of clinical and preclinical study results may be incorrect, or that we may not observe the levels of therapeutic activity in clinical testing that we anticipate based on prior clinical or preclinical results for PGN-EDODM1; that PGN-EDODM1 may not be safe and effective or otherwise demonstrate safety and efficacy in our clinical trials; adverse outcomes from our regulatory interactions, including delays in regulatory review, clearance to proceed or approval by regulatory authorities with respect to our programs, including release of the partial clinical hold or clearance to commence planned clinical studies of our product candidates, or other regulatory feedback requiring modifications to our

development programs, including in each case with respect to our FREEDOM2 program; changes in regulatory framework that are out of our control; unexpected increases in the expenses associated with our development activities or other events that adversely impact our financial resources and cash runway; and our dependence on third parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning PepGen's programs and operations are described in our most recent reports filed with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

This release discusses PGN-EDODM1, an investigational therapy that has not been approved for use in any country, and is not intended to convey conclusions about its efficacy or safety. There is no guarantee that PGN-EDODM1 or any other investigational therapy will successfully complete clinical development or gain regulatory authority approval.

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