PepGen Receives U.S. FDA Fast Track Designation for PGN-EDODM1 for the Treatment of Myotonic Dystrophy Type 1

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BOSTON, Feb. 20, 2024 (GLOBE NEWSWIRE) -- PepGen Inc. (Nasdaq: PEPG), a clinical-stage biotechnology company advancing the next generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to PGN-EDODM1, an investigational candidate for the treatment of myotonic dystrophy type 1 (DM1). “Receiving Fast Track designation from the FDA for PGN-EDODM1 is a significant milestone in our efforts to deliver a potentially transformative therapy to the DM1 community,” said James McArthur, Ph.D., President and CEO of PepGen. “Patients with DM1 currently have no available treatment options that target the root cause of the disease, which leads to progressive neuromuscular symptoms and reduction in life expectancy. Following robust preclinical data, we are now evaluating PGN-EDODM1 in the ongoing FREEDOM-DM1 Phase 1 trial and expect to report preliminary data later this year. We believe that PGN-EDODM1 has the potential to be disease-modifying and improve outcomes for patients living with DM1.”

The FDA’s Fast Track designation is a process designed to facilitate the development and expedite the review of drug candidates that treat serious conditions and fill an unmet medical need, with the goal of getting important new drugs to the patient earlier. Once a drug candidate receives Fast Track designation, early and frequent communication between the FDA and the drug company is encouraged throughout the entire drug development and regulatory review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients. For more information about Fast Track designation, please visit the FDA website (www.fda.gov).

PGN-EDODM1 is currently being evaluated in the ongoing FREEDOM-DM1 Phase 1 clinical trial for the treatment of people living with DM1. The Company expects to report initial data from the trial in 2024. (ClinicalTrials.gov identifier: NCT06204809)

The Company previously announced that the FDA granted Orphan Drug Designation to PGN-EDODM1 in September 2023.

About PGN-EDODM1

PGN-EDODM1 is an investigational candidate designed to deliver a peptide-conjugated antisense oligonucleotide (ASO) to restore cellular function. DM1 is caused by an expansion of CUG repeats that form hairpin loops in the DMPK RNA, resulting in sequestration of the MBNL1 protein, a key RNA processing factor. The sequestration of MBNL1 results in downstream mis-splicing events and aberrant expression of many proteins that play a critical role in muscle and other systemic functions (e.g. endocrine, gastrointestinal, central nervous system). By specifically blocking the toxic DMPK transcript CUG repeats, the goal of PGN-EDODM1 is to liberate MBNL1 protein and to restore functional downstream splicing and muscle and other systemic functions.

About Myotonic Dystrophy Type 1 (DM1)

Myotonic dystrophy type 1, or DM1 (also known as Steinert’s disease), is a progressively disabling, life-shortening genetic disorder. DM1 is the most prevalent form of the disease and generally the most severe. DM1 is estimated to affect 40,000 people in the U.S., and over 74,000 people in Europe. The average life expectancy for people living with DM1 is 45-60 years old. People living with DM1 typically present with myotonia (stiff or contracted muscles), muscle weakness, and cardiac and respiratory abnormalities. Many people living with DM1 also experience excessive daytime sleepiness, fatigue, and issues with gastrointestinal or cognitive dysfunction that significantly affect their quality of life.

About PepGen

PepGen Inc. is a clinical-stage biotechnology company advancing the next-generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases. PepGen’s Enhanced Delivery Oligonucleotide, or 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, we are generating a pipeline of oligonucleotide therapeutic candidates that are designed to target the root cause of serious diseases.

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 therapeutic potential and safety profile of our product candidates, including PGN-EDODM1, our technology, including our EDO platform, the design, initiation and conduct of clinical trials, including expected timelines and preliminary data reports from our FREEDOM-DM1 Phase 1 trial, dose levels, regulatory interactions, including development pathway for our product candidates, and our financial resources and cash runway.

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 our product candidates, including PGN-EDODM1; our ability to enroll patients in our clinical trials, including FREEDOM-DM1; 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; our product candidates, including 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 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 FREEDOM-DM1 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 annual report on Form 10-K and quarterly report on Form 10-Q that are filed with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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