PepGen Announces First Patient Dosed in Phase 1 FREEDOM-DM1 Clinical Trial of PGN-EDODM1 for Myotonic Dystrophy Type 1 (DM1)

December 18, 2023

- Safety, transcript splicing correction and clinical outcome measures data at 5 mg/kg PGN-EDODM1 dose level in patients from FREEDOM-DM1 clinical trial expected in 2024 -

- Clearance of Clinical Trial Application (CTA) by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) extends enrollment in FREEDOM-DM1 Phase 1 clinical trial to third country -

BOSTON, Dec. 18, 2023 (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 first patient has been dosed in its Phase 1 clinical trial, FREEDOM-DM1, evaluating PGN-EDODM1 for the treatment of DM1.

"We are pleased to announce we have dosed the first patient in our FREEDOM-DM1 clinical trial, which marks a significant milestone in our commitment to developing transformative therapies with potentially meaningful clinical outcomes for people living with DM1. We anticipate proof-of-concept data in patients in 2024, including safety, transcript splicing and clinical outcome measures, at the 5 mg/kg PGN-EDODM1 dose level," said James McArthur, Ph.D., President and CEO of PepGen. "We are also excited to announce the receipt of regulatory clearance to evaluate PGN-EDODM1 from the UK MHRA, marking the third obtained following clearances from the U.S. Food and Drug Administration and Health Canada. We look forward to continuing our progress and remain steadfast in our dedication to the development of PGN-EDODM1 for individuals around the globe who are living with DM1."

The FREEDOM-DM1 clinical trial is a randomized, placebo-controlled, single ascending dose (SAD) study, intended to enroll approximately 24 adult patients with DM1 to evaluate the safety and tolerability of PGN-EDODM1. In addition to safety, oligonucleotide muscle concentrations and PGN-EDODM1 correction of mis-splicing of transcripts, clinical outcomes impacted in DM1 will also be assessed at 28 days and at later time points following a single dose of PGN-EDODM1. Per the protocol, the dose will escalate from the starting dose of 5 mg/kg to 10 mg/kg and then 20 mg/kg. Each dose escalation will be determined based upon evaluation of safety data from the prior dose cohorts.

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.

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 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.

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, 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; 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 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, including PGN-EDODM1, or other regulatory feedback requiring modifications to our development

programs; 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.

Investor Contact

Laurence Watts
Gilmartin Group
Laurence@gilmartinir.com

Media Contact

Sarah Sutton
Argot Partners
pepgen@argotpartners.com