PepGen Announces Presentations at the 29th Annual Congress of the World Muscle Society

October 8, 2024

BOSTON--(BUSINESS WIRE)--Oct. 8, 2024-- 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 Company will be presenting a short oral presentation as well as five posters at the 29th Annual Congress of the World Muscle Society (WMS), being held October 8-12, 2024 in Prague, Czech Republic.

“We are pleased to be presenting preclinical and clinical data on our Duchenne muscular dystrophy and myotonic dystrophy type 1 programs at this premier global muscle meeting,” said James McArthur, PhD, President and CEO of PepGen. “Based on the totality of data in both our 5 mg/kg cohort and the ongoing 10 mg/kg cohort in the CONNECT1-EDO51 trial as of October 3, we believe PGN-EDO51 has a favorable emerging safety profile. There have been no serious adverse events, and all treatment-related adverse events have been mild and have resolved. Hypomagnesemia was observed in one patient and resolved with oral supplementation. All participants continue in the study as planned, with no discontinuations, dose interruptions or reductions.”

PGN-EDO51: Duchenne Muscular Dystrophy (DMD)
Short Oral Title: CONNECT1-EDO51: A 12-week open-label Phase 2 study to evaluate PGN-EDO51 safety and efficacy in people with Duchenne amenable to exon 51 skipping
Presentation Number: #403P
Session: Short Oral Presentations 6 - Terrace 2B
Date & Time: October 9th at 6:15-6:45pm CEST
Presenter: Michelle Mellion, MD, Chief Medical Officer

Poster Title: CONNECT1-EDO51: A 12-week open-label Phase 2 study to evaluate PGN-EDO51 safety and efficacy in people with Duchenne amenable to exon 51 skipping
Poster Number: #403P
Session: Poster Session 2 - Forum Hall
Date & Time: October 9th at 5:15-6:15pm CEST
Presenter: Michelle Mellion, MD, Chief Medical Officer

Poster Title: CONNECT2-EDO51: A Phase 2 placebo-controlled study to evaluate PGN-EDO51 safety and efficacy in people with Duchenne amenable to exon 51 skipping
Poster Number: #404P
Session: Poster Session 2 - Forum Hall
Date & Time: October 9th at 5:15-6:15pm CEST
Presenter: Michelle Mellion, MD, Chief Medical Officer

Poster Title: Single- and repeat-dose nonclinical data for PGN-EDO51 demonstrated favorable pharmacology and safety profiles for the treatment of DMD
Poster Number: #405P
Session: Poster Session 2 - Forum Hall
Date & Time: October 9th at 5:15-6:15pm CEST
Presenter: Ashling Holland, PhD, Director, Research & Preclinical Development

PGN-EDODM1: Myotonic Dystrophy Type 1 (DM1)
Poster Title: Nonclinical data for PGN-EDODM1 demonstrated nuclear delivery, mechanistic and meaningful activity for the potential treatment of DM1
Poster Number: #440P
Session: Poster Session 3 - Forum Hall
Date & Time: October 11th at 2:15-3:15pm CEST
Presenter: Ashling Holland, PhD, Director, Research & Preclinical Development

Poster Title: Evaluation of PGN-EDODM1: FREEDOM-DM1 and FREEDOM2-DM1 clinical trials in myotonic dystrophy type 1
Poster Number: #461P
Session: Poster Session 3 - Forum Hall
Date & Time: October 11th at 2:15-3:15pm CEST
Presenter: Jane Larkindale, DPhil, Vice President, Clinical Science

Following the conference, the presentations presented at the 29th Annual Congress of the WMS will be available on the Investors page of PepGen’s website under Scientific Publications.

About PGN-EDO51
PGN-EDO51, PepGen's lead clinical candidate for the treatment of Duchenne muscular dystrophy (DMD), utilizes the Company's proprietary Enhanced Delivery Oligonucleotide (EDO) technology to deliver a therapeutic phosphorodiamidate morpholino oligomer (PMO) that is designed to target the root cause of this devastating disease. PGN-EDO51 is designed to skip exon 51 of the dystrophin transcript, an established therapeutic target for approximately 13% of DMD patients, thereby aiming to restore the open reading frame and enabling the production of a truncated, yet functional dystrophin protein. The U.S. Food and Drug Administration (FDA) has granted PGN-EDO51 both Orphan Drug and Rare Pediatric Disease Designations for the treatment of patients with DMD amenable to an exon-51 skipping approach.

About PGN-EDODM1

PGN-EDODM1, PepGen's second 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. DM1 is a progressively disabling, life-shortening genetic disorder. DM1 is estimated to affect 40,000 people in the United States, and over 74,000 people in Europe. The U.S. FDA has granted PGN-EDODM1 both Orphan Drug and Fast Track Designations for the treatment of patients with DM1.

About PepGen
PepGen 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 (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 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 emerging safety profile of our product candidates, including, based on early data, PGN-EDO51, and our plans to continue to advance the CONNECT1 study.

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-EDO51; our ability to enroll patients in our clinical trials, including CONNECT1; 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, including for PGN-EDO51; our product candidates, including PGN-EDO51, 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 with respect to our CONNECT1 clinical trial; 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.

This release discusses PGN-EDO51, 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-EDO51 or any other investigational therapy will successfully complete clinical development or gain regulatory authority approval.

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