PepGen Inc. Announces Clinical Hold in the U.S. on IND Application to Initiate a Phase 1 Study of PGN-EDODM1 for Myotonic Dystrophy Type 1 (DM1)

May 30, 2023

BOSTON, May 30, 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 Company received a clinical hold notice from the U.S. Food and Drug Administration (FDA) regarding their Investigational New Drug Application (IND) to initiate a Phase 1 study of PGN-EDODM1 in patients with Myotonic Dystrophy Type 1 (DM1). The FDA indicated its intention to provide an official clinical hold letter to PepGen stating the reasons for the clinical hold within 30 days.

"We are disappointed to receive a clinical hold notice on our planned PGN-EDODM1 study in the U.S., and we will work closely with the FDA to lift the hold as quickly as possible," said James McArthur, Ph.D., President and CEO of PepGen. "In parallel, we continue to pursue the advancement of PGN-EDODM1 into the clinic outside the U.S. We remain well-capitalized to fund the continued development of both EDO51 and EDODM1, investigational treatments that may have life-changing impact on individuals with neuromuscular disorders."

As previously communicated, PepGen received a No Objection Letter (NOL) from Health Canada for its Clinical Trial application (CTA) to initiate the Phase 2 CONNECT1-EDO51 open label, multiple ascending dose (MAD) clinical trial of the Company's lead asset PGN-EDO51 in patients with Duchenne muscular dystrophy (DMD) amenable to an exon 51 skipping approach. The clinical hold in the U.S. placed on PGN-EDODM1 does not impact the CONNECT1-EDO51 study which has been cleared to proceed in Canada.

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 potential therapeutic benefits and safety profile of our product candidates, initiation and timeline of the Phase 2 CONNECT-1 study of PGN-EDO51 and the Phase 1 studies of PGN-EDODM1, the status of regulatory communications, and the sufficiency of our capital for conducting planned clinical studies of both PGN-EDO51 and PGN-EDODM1.

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 that we may experience delays or fail to successfully initiate or complete our planned clinical trials for PGN-EDO51 and PGN-EDODM1 and preclinical studies of other product candidates or to obtain regulatory approval before commercialization for marketing of such products; our interpretation of clinical and preclinical study results may be incorrect; our product candidates may not be safe and effective; there may be delays in regulatory review, clearance to proceed or approval by regulatory authorities with respect to our programs, including clearance to commence planned clinical development of our product candidates, including PGN-EDO51 and PGN-EDODM1, outside of the U.S.; changes in regulatory framework that are out of our control; we may not be able to nominate new drug candidates within the estimated timeframes; our estimation of addressable markets of our product candidates may be inaccurate; we may need additional funding before the end of our expected cash runway and may fail to timely raise such additional required funding; more efficient competitors or more effective competing treatments may emerge; we may be involved in disputes surrounding the use of our intellectual property crucial to our success; we may not be able to take advantage of certain accelerated regulatory pathways; we may not be able to attract and retain key employees and qualified personnel; earlier study results may not be predictive of later stage study outcomes; we may encounter liquidity distress due to failure of financial institutions with which we maintain relationship; disruption in financial markets may interfere with our access to cash, including our cash deposited in financial institutions, and we are dependent 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 on file with the SEC 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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