



PepGen Announces Clearance by Health Canada of CTA for PGN-EDO51 to Begin the Phase 2 Clinical Trial, CONNECT1-EDO51, for the Treatment of Duchenne Muscular Dystrophy

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- CONNECT1-EDO51 will assess dystrophin levels, exon skipping data and safety data following multiple doses of PGN-EDO51 in patients with mutations amenable to skipping exon 51 -

- Initial data readout is expected mid-2024 -

BOSTON, May 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 company has received a No Objection Letter (NOL) for its Clinical Trial Application (CTA) from Health Canada for its Phase 2 CONNECT1-EDO51 study to initiate an open label, multiple ascending dose (MAD) clinical trial of PGN-EDO51 in patients with Duchenne muscular dystrophy (DMD) amenable to an exon 51 skipping approach. The Company expects to begin dosing patients with PGN-EDO51 in 2H 2023.

"Today is the next step in our development of PGN-EDO51, a potentially transformative treatment candidate for people living with DMD. Building upon the encouraging safety, tolerability, and exon skipping data from our Phase 1 healthy volunteer (HV) study reported last year showing promising tolerability and exon-skipping activity, we are pleased to continue our work with the DMD community to develop a therapy that we hope will produce meaningful levels of a functional, skipped dystrophin protein," said James McArthur, Ph.D., President and CEO of PepGen. "In addition to our most advanced program, PGN-EDO51, we eagerly anticipate providing the community with updates on our progress to develop transformational therapies for myotonic dystrophy type one (DM1), and other exon skippable mutations for people living with DMD, including 53, 45 and 44. We are leveraging the power of our EDO technology to work to change the future for people living with these devastating diseases."

"PGN-EDO51 exhibited the highest levels of oligonucleotide delivery and exon 51 skipping in a clinical study following a single dose of 5, 10 and 15 mg/kg in healthy volunteers when compared to publicly available clinical data for other exon 51 skipping approaches," said Michelle Mellion, M.D., SVP and Head of Clinical Development at PepGen. "At these dose levels, the majority of treatment emergent adverse events (TEAE) were assessed as mild and resolved without any intervention. Looking ahead, and based on our nonclinical data, we believe CONNECT1-EDO51 may support a differentiated profile for PGN-EDO51 relative to other investigational and approved therapies based on previously observed meaningful and durable data on dystrophin production, as well as clinical assessments. In summary, we believe PGN-EDO51 offers the hope of a more complete correction of the disease pathology and look forward to sharing updates on the progress of our planned trial."

PepGen plans to evaluate PGN-EDO51 in approximately 3 cohorts of ambulatory and non-ambulatory boys and young men in the CONNECT1-EDO51 study, an open label, MAD clinical trial starting at 5 mg/kg, with plans to escalate to 10 mg/kg and potentially other doses following Drug Safety Monitoring Board (DSMB) review. The Phase 2 study will evaluate safety, tolerability, dystrophin levels, pharmacokinetics and clinical assessments.

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 candidates, expected outcomes, initiation and timeline of the Phase 2 studies in PGN-EDO51, our interpretation of results from the Phase 1 study in PGN-EDODM1 and other nonclinical studies, and statements about our programs and product candidates.

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, enroll, 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; we may encounter adverse safety signals, such as in our Phase 1 clinical trial where we observed a non-life threatening serious adverse event in one patient dosed with PGN-EDO51 at 15 mg/kg; there may be delays in regulatory review, clearance to proceed or approval or 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 to be 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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