NurExone Biologic Secures EMA Orphan Status for ExoPTEN in Spinal Cord Injury, Accelerating Pathway to European Markets

TORONTO and HAIFA, Israel, Nov. 13, 2024 -- NurExone Biologic Inc. (TSXV: NRX) (OTCQB: NRXBF) (Germany: J90) ("**NurExone**" or the "**Company**"), a biopharmaceutical company developing exosome-based regenerative therapies, is pleased to announce that the European Medicines Agency (the "**EMA**") has granted Orphan Medicinal Product Designation for the Company's ExoPTEN therapy, marking a significant step towards making this potential treatment available for acute spinal cord injury patients across Europe. This designation supports the development of ExoPTEN and opens a pathway for faster entry into European markets, where the Company expects demand for effective spinal cord injury therapies to be high. Designed to provide nerve regeneration and functional recovery following spinal cord injury, ExoPTEN uses mesenchymal stem cell-derived extracellular vesicles loaded with siRNA targeting PTEN, a key protein in nerve regeneration.

The EMA's Orphan Medicinal Product Designation offers valuable incentives, including 10 years of market exclusivity upon approval, access grants and incentives from the European Commission and Member States. Additionally, the Company may benefit from free or reduced-cost scientific advice and assistance with clinical trial design, which can streamline the regulatory process and reduce development costs. Moreover, some European Union countries also provide tax credits and other financial incentives to support orphan drug development.

"We are honored by the EMA's recognition of ExoPTEN through the Orphan Medicinal Product Designation, which significantly advances our ability to enter the European market and offers hope to those impacted by acute spinal cord injuries," said Dr. Lior Shaltiel, Chief Executive Officer of NurExone. "This designation, together with the recently granted United States Food and Drug Administration's Orphan Drug Designation, reinforces our ability to accelerate the global development of ExoPTEN and NurExone as a company to address the urgent unmet needs of patients globally."

According to the EMA, the acute spinal cord injury ("**SCI**") market faces considerable challenges, with approximately 20,000[1] new cases in the European Union each year. These patients often require lifelong care and effective therapeutic options are limited. ExoPTEN's innovative approach to promoting spinal cord recovery directly addresses this gap, with potential to meet a critical need in the European healthcare system.

Dr. Ina Sarel, NurExone's Head of CMC Quality and Regulation added, "the EMA's designation not only acknowledges ExoPTEN's potential, but also paves the way for essential regulatory support as we prepare to advance into clinical trials. We are eager to work closely with the EMA and other agencies to accelerate ExoPTEN's development and bring this innovative treatment to SCI patients across Europe."

About NurExone

NurExone Biologic Inc. is a TSX Venture Exchange ("**TSXV**") and OTCQB listed pharmaceutical company that is developing a platform for biologically guided exosome-based therapies to be delivered, non-invasively, to patients who have suffered Central Nervous System injuries. The Company's first product, ExoPTEN for acute spinal cord injury, was proven to recover motor function in 75% of laboratory rats when administered intranasally. ExoPTEN has been granted Orphan Drug Designation by the FDA. The NurExone platform technology is expected to offer novel solutions to drug companies interested in non-invasive targeted drug delivery for other indications.

For additional information and a brief interview, please watch Who is NurExone?, visit www.nurexone.com or follow NurExone on LinkedIn, Twitter, Facebook, or YouTube.

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[1] Jazayeri, S. B., Safdarian, M., Zadegan, S. A., Ghodsi, Z., & Rahimi-Movaghar, V. (2023). Incidence of traumatic spinal cord injury worldwide: A systematic review, data integration, and update. *World Neurosurgery: X*, *18*, 100171. https://doi.org/10.1016/j.wnsx.2023.100171

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FORWARD-LOOKING STATEMENTS

This press release contains certain "forward-looking statements" that reflect the Company's current expectations and projections about its future results. Wherever possible, words such as "may", "will", "should", "could", "expect", "plan", "intend", "anticipate", "believe", "estimate", "predict" or "potential" or the negative or other variations of these words, or similar words or phrases, have been used to identify these forward-looking statements. Forward-looking statements in this press release include, but are not limited to, statements relating to: the receipt of the Orphan Medicinal Product Designation having the intended benefits and incentives on the Company and its business as set out herein; the Company entering the European market and bringing its products to patients across Europe; the Company preparing to advance into clinical trials; the Company working with the EMA and other agencies to accelerate the development of ExoPTEN; and the NurExone platform technology offering novel solutions to drug companies interested in non-invasive targeted drug delivery for other indications.

These statements reflect management's current beliefs and are based on information currently available to management as at the date hereof. In developing the forward-looking statements in this press release, we have applied several material assumptions, including: the receipt of the Orphan Medicinal Product Designation having the intended benefits and incentives on the Company and its business as set out herein; the Company will enter the European market and bring its products to patients across Europe; the Company will advance into clinical trials; the Company will work with the EMA and other agencies to accelerate the development of ExoPTEN; and the NurExone platform technology will offer novel solutions to drug companies interested in non-invasive targeted drug delivery for other indications.

Forward-looking statements involve significant risk, uncertainties and assumptions. Many factors could cause actual results, performance or achievements to differ materially from the results discussed or implied in the forward-looking statements. These risks and uncertainties include, but are not limited to risks related to: the receipt of the Orphan Medicinal Product Designation not having the intended benefits and incentives on the Company and its business as set out herein; the Company not entering the European market and bringing its products to patients across Europe; the Company not advancing into clinical trials; the Company not working with the EMA and other agencies to accelerate the development of ExoPTEN; the NurExone platform technology not offering novel solutions to drug companies interested in non-invasive targeted drug delivery for other indications; and the risks discussed under the heading "Risk Factors" on pages 29 to 36 of the Company's Annual Information Form dated March 30, 2023, a copy of which is available under the Company's SEDAR+ profile at www.sedarplus.ca. These factors should be considered carefully, and readers should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in this press release are based upon what management believes to be reasonable assumptions, the Company cannot assure readers that actual results will be consistent with these forward-looking statements. These forward-looking statements are made as of the date of this press release, and the Company assumes no obligation to update or revise them to reflect new events or circumstances, except as required by law.

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