

New ExoPTEN Preclinical Study Indicates Significant Improvement in Walking Quality in Spinal Cord Injury Model

Medium and high doses improved movement quality in up to 100% of the animals in a dose-dependent manner

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/EINPresswire.com/ -- NurExone
Biologic Inc. (TSXV: NRX) (OTCQB:
NRXBF) (FSE: J90) ("NurExone" or the
"Company") is pleased to announce
new preclinical results demonstrating



that 100% of small animals treated with a higher dose of ExoPTEN regained motor function after spinal cord injury. The results of the preliminary, dose-ranging study were confirmed using precise measurements using the CatWalk XT system.



This is a significant milestone for our program, seeing the animals regain the ability to walk, with measurable improvement in locomotion function, is incredibly exciting."

Dr. Tali Kizhner, Director of Research and Development at NurExone Using the CatWalk XT system, researchers assessed ExoPTEN's effect on the animals' ability to walk. All animals (100%) in the higher-dose group demonstrated measurable gait recovery, in contrast to one animal in the untreated group which exhibited minimal stepping.

"This is a significant milestone for our program," said Dr. Tali Kizhner, Director of Research and Development at NurExone. "Seeing the animals regain the ability to walk, with measurable improvement in locomotion function, is incredibly exciting. The CatWalk XT provided us with objective data that strengthens the scientific foundation for ExoPTEN's potential to restore function after an acute

spinal cord injury."

In the study, researchers compared medium and high single doses of ExoPTEN, administered minimally-invasively on the day of spinal cord compression surgery, to a control group that received injection of the vehicle only. Medium and high doses used in this study refer to

escalating dose levels used to explore potential therapeutic effects and tolerability in animals.

The treatment demonstrated a dose-dependent effect, with 100% of animals in the high-dose group regaining walking ability in both hind limbs, compared to 50% in the medium-dose group, and only 1 out of 6 rats in the untreated control group (Figure 1 A-B).

The gait analysis data also showed dose-dependent improvement in walking function. Animals treated with higher dose of ExoPTEN displayed larger paw print areas (Fig. 1C), greater maximal contact area of their hind paws (Fig. 1D), a wider base of support (Fig. 1E), and an extended duration of the paw contact with the walkway (Fig. 1F). These indicators reflect improved balance, strength, coordination and weight bearing during walking.

Evaluation of additional study parameters is ongoing. Notably, the high dose was well tolerated, with no observed side effects. As part of this ongoing work, the Company plans to initiate additional studies to explore alternative dosing regimens, while also advancing the optimization of ExoPTEN's manufacturing processes and analytical methods. These efforts aim to refine the drug's therapeutic profile and facilitate engagement with regulatory authorities.

The CatWalk XT system, developed by Noldus Information Technology, is widely considered a leading tool for studying animal movement1. It uses an illuminated glass walkway to capture footprints and movement patterns, allowing researchers to collect precise, objective data on an animal's motor function.

NurExone continues to advance its research and development efforts, optimizing ExoPTEN's dosing strategies and manufacturing processes, and preparing for regulatory submissions as it aims to launch first-in-human clinical trials. The Company remains committed to developing treatments that bring new hope to people who suffer nervous system injuries.

About NurExone

NurExone Biologic Inc. is a TSX Venture Exchange ("TSXV"), OTCQB, and Frankfurt-listed biotech company focused on developing regenerative exosome-based therapies for central nervous system injuries. Its lead product, ExoPTEN, has demonstrated strong preclinical data supporting clinical potential in treating acute spinal cord and optic nerve injury, both multi-billion-dollar marketsi. Regulatory milestones, including obtaining the Orphan Drug Designation, facilitates the roadmap towards clinical trials in the U.S. and Europe. Commercially, the Company is expected to offer solutions to companies interested in quality exosomes and minimally invasive targeted delivery systems for other indications. NurExone has established Exo-Top Inc., a U.S. subsidiary, to anchor its North American activity and growth strategy.

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

1 <a href="https://www.frontiersin.org/journals/behavioral-neuroscience/articles/10.3389/fnbeh.2023.1147784/full-neuroscience/articles/10.3389/fnbeh.2023.11479/fnbeh.2023

For more information, please contact:

Dr. Lior Shaltiel Chief Executive Officer and Director

Phone: +972-52-4803034 Email: info@nurexone.com

Dr. Eva Reuter Investor Relations – Germany Phone: +49-69-1532-5857 Email: e.reuter@dr-reuter.eu

Allele Capital Partners Investor Relations – U.S. Phone: +1 978-857-5075

Email: aeriksen@allelecapital.com

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 Company plans to initiate additional studies to explore alternative dosing regimens; the Company advancing the optimization of ExoPTEN's manufacturing processes and analytical methods; CatWalk XT providing the Company with objective data that strengthens the scientific foundation for ExoPTEN's potential to restore function after acute spinal cord injury; the Company preparing regulatory submissions; the Company's aims to launch first-in-human clinical trials; and the NurExone platform technology offering novel solutions to drug companies interested in minimally invasive targeted drug delivery for other indications, including recovery of optic nerve function and overall visual health.

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 Company will have the ability to initiate additional studies to explore alternative dosing regimens; the Company will have the ability to advance the optimization of ExoPTEN's manufacturing processes and analytical methods; CatWalk XT has the ability to provide the Company with

objective data that strengthens the scientific foundation for ExoPTEN's potential to restore function after acute spinal cord injury; the Company has the ability to prepare regulatory submissions; the Company has the ability to launch first-in-human clinical trials; and the NurExone platform technology has the ability to offer novel solutions to drug companies interested in minimally invasive targeted drug delivery for other indications, including recovery of optic nerve function and overall visual health

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 Company's early stage of development; lack of revenues to date; the inherent uncertainty of preclinical drug development, including the risk that product candidates may not advance to clinical trials or receive regulatory approval; the possibility that results from preclinical studies and early-stage trials may not predict later outcomes; the uncertain timing, cost, and outcome of preclinical and clinical development activities; risks related to the clinical trial process, including potential delays or failure to achieve effective trial design or positive results; the inability to obtain or maintain required regulatory approvals; limited market acceptance of the Company's products, even if approved; the potential emergence of competing therapies that are safer, more effective, or more affordable; rapid technological change that may impact the relevance of the Company's technologies; the Company's dependence on key personnel and strategic partners; the inability to obtain adequate financing; risks related to the Company's ability to protect its intellectual property; the possibility that the Company's technologies, including its exosome-based platforms, may not achieve their intended therapeutic impact; the inability to produce or scale exosome-based products for clinical use; limited adoption in regenerative medicine or cell therapy applications; lack of growing clinical demand in targeted indications such as spinal cord injury, optic nerve repair, or other therapeutic areas; failure to meet planned development milestones or achieve commercial breakthroughs; the Company will not initiate additional studies to explore alternative dosing regimens; the Company will not advance the optimization of ExoPTEN's manufacturing processes and analytical methods; CatWalk XT will not provide the Company with objective data that strengthens the scientific foundation for ExoPTEN's potential to restore function after acute spinal cord injury; the Company will not prepare regulatory submissions; the Company will not launch first-in-human clinical trials; the NurExone platform technology not offering novel solutions to drug companies interested in minimally invasive targeted drug delivery for other indications, including recovery of optic nerve function and overall visual health; and the risks discussed under the heading "Risk Factors" on pages 44 to 51 of the Company's Annual Information Form dated August 27, 2024, 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.

Neither TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

i Spinal cord injury, Glaucoma

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/55d1ad19-cd1c-4998-9808-903db9711a5a

A video accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/32356826-a022-4cf4-9db6-8939f07e946e

Dr. Lior Shaltiel
NurExone Biologic Inc.
+ +972-52-4803034
email us here
Visit us on social media:
LinkedIn
Facebook
YouTube
X

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