

NervGen Pharma to Proceed with Landmark Phase 1b/2a Clinical Trial for NVG-291 in Spinal Cord Injury Having Completed FDA Review and Received IRB Approval

- Recruitment of individuals with spinal cord injury (SCI) initiated at Shirley Ryan AbilityLab in Chicago
- Chronic SCI cohort results expected in mid-2024 and subacute SCI cohort results in late 2024/early 2025

Vancouver, British Columbia--(Newsfile Corp. - August 8, 2023) - **NervGen Pharma Corp. (TSXV: NGEN) (OTCQX: NGENF)**, a clinical stage biotech company dedicated to developing innovative solutions for the treatment of nervous system damage, has received Institutional Review Board (IRB) approval for its landmark Phase 1b/2a proof-of-concept clinical trial protocol of its proprietary lead compound, NVG-291, in individuals with spinal cord injury (SCI). NervGen is now actively recruiting potential subjects. As previously announced, the U.S. Food and Drug Administration (FDA) completed its review of the clinical trial protocol and determined that the study may proceed. This first-in-kind trial is sponsored in part by a [grant of up to US\\$3.18 million from Wings for Life](#), a not-for-profit spinal cord injury research foundation. Preclinical studies of NVG-291 demonstrated unprecedented functional improvement in both acute and chronic spinal cord injury models as well as in five other models of nervous system damage.

"We are very excited to advance this unique and important clinical study in individuals with spinal cord injury and to soon administer our lead drug candidate, NVG-291, which we believe has the potential to repair nervous system damage," said [Mike Kelly](#), NervGen's President & CEO. "This study is essentially two studies in one as it will inform about NVG-291's efficacy in individuals with both subacute and chronic SCI. We are optimistic that the results of this study may be a key enabling step in advancing NVG-291 through the clinical development process toward approval. Most importantly, we are thrilled that we can offer hope to individuals with spinal cord injury as well as to their families and caregivers as there are no FDA approved drugs to promote sustained functional recovery."

Recruitment of the chronic cohort (1-10 years post-injury) is now open. Given the significant number of individuals suffering with chronic SCI and the tremendous anticipation of the trial within the SCI community, recruitment is anticipated to happen relatively quickly with results expected by mid-2024. Results from the subacute cohort (10-49 days post-injury) are expected in late 2024/early 2025. The trial is being conducted at Shirley Ryan AbilityLab in Chicago, a global leader in physical medicine and rehabilitation for adults and children with the most severe and complex conditions.

"Our team at Shirley Ryan AbilityLab is ready and excited to start this state-of-the-art clinical trial after extensive planning," stated Monica A. Perez, PT, PhD, Scientific Chair of the Arms + Hands Lab at Shirley Ryan AbilityLab; Professor of Physical Medicine & Rehabilitation at Northwestern University; Research Scientist at the Edward Hines Jr. VA Hospital; and the principal investigator of this trial. "This trial uses an innovative design that incorporates electrophysiology, not only as part of the outcome measures to monitor motor recovery, but also as part of the inclusion criteria of participants. Together, results from electrophysiological measures, combined with clinical measures, will help us to enhance our knowledge about the efficacy of NVG-291 and could result in a paradigm shift in the treatment of spinal cord injury."

About the NVG-291 Phase 1b/2a Trial

The placebo-controlled proof-of-concept trial (NCT05965700) will evaluate the efficacy of NVG-291 in two separate cohorts of individuals with cervical spinal cord injury: chronic (1-10 years post-injury) and subacute (10-49 days post-injury), given demonstrated efficacy in preclinical models of both chronic and acute spinal cord injury. The trial is designed to evaluate efficacy of a fixed dose of NVG-291 using multiple clinical outcome measures as well as objective electrophysiological and MRI imaging measures and blood biomarkers that together will provide comprehensive information about the extent of recovery of function, with a focus on improvements in motor function. Specifically, the primary objective is to assess the change in corticospinal connectivity of defined upper and lower extremity muscle groups following treatment based on changes in motor evoked potential amplitudes. Secondary objectives are to evaluate changes in a number of clinical outcome assessments focusing on motor function, upper extremity dexterity and grasping and mobility, as well as changes in additional electrophysiological measurements. Each cohort will be evaluated independently as the data becomes available. The grant funding from Wings for Life, which is to be provided in several milestone-based payments, will offset a portion of the direct costs of this clinical trial.

About Shirley Ryan AbilityLab

Shirley Ryan AbilityLab, formerly the Rehabilitation Institute of Chicago (RIC), is the global leader in physical medicine and rehabilitation for adults and children with the most severe, complex conditions - from traumatic brain and spinal cord injury to stroke, amputation and cancer-related impairment. The organization expands and accelerates leadership in the field that began at RIC in 1953. The quality of its care has led to the designation of "No. 1 Rehabilitation Hospital in America" by U.S. News & World Report every year since 1991. Upon opening in 2017, the \$550 million, 1.2-million-square-foot Shirley Ryan AbilityLab became the first-ever "translational" research hospital in which clinicians, scientists, innovators and technologists work together in the same space, surrounding patients, discovering new approaches and applying (or "translating") research real time. This unique model enables patients to have 24/7 access to the brightest minds, the latest research and the best opportunity for recovery. Shirley Ryan AbilityLab is a 501 (c)(3) non-profit organization. For more information, go to www.sralab.org.

About Wings for Life Accelerated Translational Program

Even with very promising discoveries, the translation from scientific discovery to applied therapeutics is a long and difficult road due to regulatory burdens, complexities of clinical trial design, patient recruitment and retention barriers, and the high cost of cutting-edge research. The Wings for Life Accelerated Translational Program (ATP) has been specifically designed to be able to accommodate obstacles to efficient clinical translation.

The ATP strives to assist applicants to find the best way forward in clinical translation of high caliber, promising therapies. The ATP is supported by a network of clinicians, scientists, and other professionals with expertise in all aspects of clinical trials. Select members of the ATP Support Network will be called upon, as required, to assist in ensuring that treatments with auspicious potential are translated in the most scientifically rigorous and efficient way possible.

About NVG-291

NervGen holds exclusive worldwide rights to NVG-291, a first-in-class therapeutic peptide targeting mechanisms that interfere with nervous system repair. NVG-291 is derived from the intracellular wedge domain of the receptor type protein tyrosine phosphatase sigma (PTP σ). NVG-291-R, a rodent analog of NVG-291, has been shown to promote nervous system repair and functional recovery in animal models of spinal cord injury (acute and chronic intervention), peripheral nerve injury, multiple sclerosis and stroke, through enhanced plasticity, axonal regeneration, and remyelination.

About NervGen

NervGen (TSXV: NGEN) (OTCQX: NGENF) is a clinical stage biotech company dedicated to

developing innovative treatments that enable the nervous system to repair itself following damage, whether due to injury or disease. NervGen's lead drug candidate, NVG-291, is to be evaluated in a Phase 1b/2a clinical trial. The Company's initial target indication is spinal cord injury. For more information, go to www.nervgen.com and follow NervGen on [Twitter](#), [LinkedIn](#), and [Facebook](#) for the latest news on the Company.

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This news release may contain "forward-looking information" and "forward-looking statements" within the meaning of applicable Canadian and United States securities legislation. Such forward-looking statements and information herein include, but are not limited to, the Company's current and future plans, expectations and intentions, results, levels of activity, performance, goals or achievements, or any other future events or developments constitute forward-looking statements, and the words "may", "will", "would", "should", "could", "expect", "plan", "intend", "trend", "indication", "anticipate", "believe", "estimate", "predict", "likely" or "potential", or the negative or other variations of these words or other comparable words or phrases, are intended to identify forward-looking statements. Forward-looking statements include, without limitation, statements relating to: the objectives, timing, rate of subject recruitment and study design of the clinical development of NVG-291 including the planned single site Phase 1b/2a clinical trial in SCI with Shirley Ryan AbilityLab; our belief that the results of the Phase 1b/2a clinical trial will enable us to advance our clinical pathway to approval; the innovative aspect of the trial increasing the probability of demonstrating efficacy of NVG-291; the possibility that NVG-291 could result in a paradigm shift in the treatment of SCI; the receipt of the milestone-based grant payments; the belief that targeting mechanisms that interfere with nervous system repair is a promising target for reducing the clinical effects of nervous system damage through multiple mechanisms; and the creation of innovative treatments of nervous system damage due to trauma or disease.

Forward-looking statements are based on estimates and assumptions made by the Company in light of management's experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate and reasonable in the circumstances. In making forward-looking statements, the Company has relied on various assumptions, including, but not limited to: the Company's ability to manage the effects of the COVID-19 pandemic; the accuracy of the Company's financial projections; the Company obtaining positive results in its clinical and other trials; the Company obtaining necessary regulatory approvals; and general business, market and economic conditions.

Many factors could cause our actual results, level of activity, performance or achievements or future events or developments to differ materially from those expressed or implied by the forward-looking statements, including without limitation, a lack of revenue, insufficient funding, the impact of the COVID-19 pandemic, reliance upon key personnel, the uncertainty of the clinical development process, competition, and other factors set forth in the "Risk Factors" section of the Company's Annual Information Form, Short Form Base Shelf Prospectus, financial statements and Management Discussion and Analysis which can be found on SEDAR.com. All clinical development plans are subject to

additional funding.

Readers should not place undue reliance on forward-looking statements made in this news release. Furthermore, unless otherwise stated, the forward-looking statements contained in this news release are made as of the date of this news release, and we have no intention and undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. The forward-looking statements contained in this news release are expressly qualified by this cautionary statement.



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