

NervGen Pharma on Track to Complete Enrollment, Deliver Data Readout in Phase 1b/2a Clinical Trial for NVG-291 in Spinal Cord Injury

- **On track to complete enrollment of the chronic cohort in Q2 2024**
- **Data readout from chronic cohort expected in Q3 2024**
- **Planning underway to make NVG-291 available to placebo-treated subjects following cohort completion**

Vancouver, Canada, February 15, 2024 – **NervGen Pharma Corp. (TSX-V: NGEN; OTCQX: NGENF)**, a clinical stage biotech company dedicated to developing innovative solutions for the treatment of nervous system damage, today announced that it is on track to complete enrollment in Q2 2024 and deliver the data readout in Q3 2024 of the chronic cohort in the Company’s Phase 1b/2a proof-of-concept, double blind, randomized placebo-controlled clinical trial for its proprietary investigational lead compound, NVG-291, in individuals with spinal cord injury (SCI). Preclinical studies of NVG-291 demonstrated functional improvement in both acute and chronic spinal cord injury models of SCI. The Shirley Ryan AbilityLab in Chicago, a global leader in physical medicine and rehabilitation for adults and children with the most severe and complex conditions and a pioneer in the use of objective, quantitative electrophysiological based motor connectivity assessments, is the single center for this clinical study.

Additionally, NervGen is developing plans to initiate a new study in which subjects completing the current trial who received placebo would have the option to receive open-label NVG-291 under a separate protocol. NervGen plans to initiate this open-label study, provided that an efficacy signal is observed in the chronic cohort, when the cohort is unblinded in the third quarter of 2024 and is contingent upon protocol approval by the U.S. Food and Drug Administration (FDA) as well as the study’s Institutional Review Board.

“We are pleased with the pace of enrollment and smooth execution of this landmark clinical study in spinal cord injury,” said NervGen’s Chief Medical Officer, [Dan Mikol, MD, PhD](#). “We believe the results of this study – once the study data are unblinded – will be a key enabling step that may bring us closer to the first approved therapy for spinal cord injury, and we look forward to the prospect of delivering positive results later this year. We are also very excited about our plans to offer open-label NVG-291 to those placebo-treated subjects who committed their time and energy in the current trial.”

“Our dedicated team at Shirley Ryan AbilityLab is thrilled to be well underway with this important clinical research trial in individuals with spinal cord injury, and is encouraged by the many inquiries we’ve received from willing research subjects,” 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 employs a cutting-edge design that incorporates electrophysiology both as part of the inclusion criteria of participants and to monitor motor recovery. A wealth of information about connectivity and function is being collected from each subject throughout the study, and we look forward to analyzing these results in order to fully assess the efficacy of NVG-291.”

Those interested in participation in this trial are invited to call 855-559-6902.

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

The double blind, 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 trial is being partially funded by a [grant from Wings for Life](#), which is being provided in several milestone-based payments that 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 (PTPσ). 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. NVG-291 has received Fast Track Designation from the FDA.

About NervGen

NervGen (TSX-V: 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 being 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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Cautionary Note Regarding Forward-Looking Statements

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, planned data readout and study design of the clinical development of NVG-291 including the single site Phase 1b/2a clinical trial in SCI with Shirley Ryan AbilityLab; our plans to initiate a new study to offer open-label NVG-291 for patients that received placebo in the current study subject to certain conditions being met; our belief that the results of the Phase 1b/2a clinical trial will be a key enabling step that may bring us closer to the first approved therapy for spinal cord injury; of the innovative aspect of the trial allowing us to fully assess the efficacy of NVG-291; the receipt of the milestone-based grant payments and the potential assistance from ATP; 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 COVID-19; 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 COVID-19, 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 SEDARplus.ca. 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.