NervGen Pharma Announces First Subject Dosed in Landmark Phase 1b/2a Clinical Trial for NVG-291 in Spinal Cord Injury

- **Chronic spinal cord injury cohort results expected in mid-2024**
- **Subacute spinal cord injury cohort results expected in late 2024/early 2025**

Vancouver, Canada, September 25, 2023 – **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 the first subject has been dosed in the Company's landmark Phase 1b/2a proof-of-concept placebo-controlled clinical trial for its proprietary lead compound, NVG-291, in individuals with spinal cord injury (SCI).

"This is a significant milestone for NervGen and also an exciting day for individuals with spinal cord injury as we progress this first-in-kind product candidate into clinical studies," said Mike Kelly, NervGen's President & CEO. "This unique trial design will allow us to evaluate NVG-291's efficacy independently for each cohort of subjects – subacute and chronic. We believe the results of this research study 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 next summer."

Given there are approximately 300,000 people with SCI living in the United States alone, the limited number of clinical trials in this area and the tremendous anticipation for this trial within the SCI community, recruitment for the chronic cohort (1-10 years post injury) 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 excited to have begun investigational treatment in this important clinical research trial in individuals with spinal cord injury," 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. "We look forward to fully recruiting this study and executing upon this innovative trial, which has the potential to change how we design and implement SCI clinical studies in the future."

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 trial is being partially funded by a grant from Wings for Life, which is to be provided in several milestone-based payments and 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.

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.

Contacts

Huitt Tracey, Corporate Communications
htracey@nervgen.com
604.537.2094

Nancy Thompson, Vorticom Public Relations
nancyt@vorticom.com
212.532.2208

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

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 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 evaluate NVG-291's efficacy independently for each cohort of subjects and advance our clinical pathway to approval; the innovative aspect of the trial having the potential to change the design of SCI clinical trials in the future; 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 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 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.