



NervGen Completes Enrollment in Chronic Cohort of its Phase 1b/2a Clinical Trial of NVG-291 in Spinal Cord Injury

- Topline data from the chronic cohort is expected in Q2 2025
- Institutional Review Board (IRB) protocol amendment changes approved, and screening has been initiated for subacute cohort

This news release constitutes a “designated news release” for the purposes of NervGen’s prospectus supplement dated December 19, 2024 to its short form base shelf prospectus dated November 25, 2024.

VANCOUVER, Canada, January 2, 2025 – NervGen Pharma Corp. (TSX-V: NGEN) (OTCQB: NGENF), a clinical-stage biotech company dedicated to developing neurorestorative therapeutics, today announced that it has enrolled the 20th and final subject in the chronic cohort of its Phase 1b/2a proof-of-concept, double-blind, randomized placebo-controlled clinical trial ([NCT05965700](#)) evaluating its lead candidate, NVG-291, in individuals with spinal cord injury (SCI). Furthermore, the company has received IRB approval for an amendment to its Phase 1b/2a clinical trial and has initiated the screening of subjects for the subacute cohort of the study.

“We are pleased to share that enrollment is complete in the chronic cohort of our Phase 1b/2a clinical trial in traumatic spinal cord injury,” said Daniel Mikol, MD, Ph.D., NervGen’s Chief Medical Officer. “Following the conclusion of the 16-week trial for the last enrolled patient, we can proceed with the next step, which is to ensure all data are thoroughly collected, and reviewed, including database lock, unblinding, and in-depth analysis of the results. When these critical steps are completed, we anticipate announcing topline results in the second quarter of this year.”

“Completing enrollment for the chronic cohort is an exciting and critical milestone for NervGen,” said Mike Kelly, NervGen’s President & CEO. “The team will now shift its focus to enrolling subjects in the subacute cohort. We believe our experience over the past year in recruiting for the chronic cohort together with the recently approved protocol amendment for the subacute cohort should help improve the recruitment process for this second cohort in addition to making the study less burdensome for participants.”

Mr. Kelly added, “This milestone is a great way to start the year as we continue to advance our clinical development efforts. We’ve made significant progress in 2024 and 2025 is poised to be a pivotal year for both NervGen and the SCI community. We remain fully committed to advancing NVG-291 through the clinical and regulatory process with a goal to eventually make it widely available to individuals living with SCI, the vast majority of whom remain without any therapeutic options.”

About Phase 1b/2a Trial

The double-blind, placebo-controlled proof-of-concept Phase 1b/2a clinical trial (NCT05965700) evaluates the safety and efficacy of NVG-291 in two separate cohorts of individuals with cervical spinal cord injury: chronic (1-10 years post-injury) and subacute (20-90 days post-injury), given demonstrated efficacy in preclinical models of both chronic and acute spinal cord injury. The trial is designed to evaluate the 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 and strength, as well as changes in additional electrophysiological measurements. The cohorts will be comprised of approximately 20 subjects each and 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 and will offset a portion of the direct costs of this clinical trial.

About NVG-291

NervGen holds exclusive worldwide rights to NVG-291, a first-in-class therapeutic peptide targeting nervous system repair. NVG-291's technology was licensed from Case Western Reserve University and is based on academic studies demonstrating the preclinical efficacy of NVG-291-R, the rodent prototype of NVG-291, in animal models of spinal cord injury. Effects of NVG-291-R reported in multiple independent academic studies include the promotion of neuroplasticity, remyelination, anti-inflammatory polarization of microglia, and functional improvement in preclinical models of spinal cord injury, stroke, and peripheral nervous system injury. NVG-291 has received Fast Track designation in spinal cord injury from the U.S. Food and Drug Administration.

About NervGen

NervGen (TSXV: NGEN, OTCQB: NGENF) is a clinical-stage biotech company dedicated to developing innovative treatments to promote nervous system repair in settings of neurotrauma and neurologic disease. The company is testing the clinical efficacy of its lead molecule, NVG-291, in a Phase 1b/2a clinical trial in spinal cord injury and has initiated preclinical evaluation of a new development candidate, NVG-300, in models of ischemic stroke, amyotrophic lateral sclerosis (ALS) and spinal cord injury. For more information, visit www.nervgen.com and follow NervGen on [X](#), [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, planned clinical endpoints, timing, expected rate of enrollment, and timing of data readout and study design of our Phase 1b/2a clinical trial of NVG-291 in individuals with spinal cord injury; our belief that our experience and approved protocol amendment should improve the recruitment process and make the study less burdensome for the subacute cohort participants; our belief that 2025 is poised to be a pivotal year for both NervGen and the SCI community; the development plans, timelines, expected benefits, and prospective target indications for NVG-300; the receipt of the milestone-based grant payments; and the creation of neurorestorative therapeutics to promote nervous system repair in settings of neurotrauma and neurologic 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, we have relied on various assumptions, including, but not limited to: our ability to obtain future funding on favourable terms or at all; the accuracy of our financial projections; obtaining positive results in our clinical and other trials; our ability to obtain necessary regulatory approvals; our ability to arrange for the manufacturing of our product candidates and technologies; 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, 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 most recently filed prospectus supplement, short form base shelf prospectus, annual information form, financial statements and management discussion and analysis all of which can be found on NervGen’s profile on SEDAR+ at www.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.