



NervGen Pharma Reports Positive Topline Data from the Chronic Cohort of its Phase 1b/2a Clinical Trial Evaluating NVG-291 in Spinal Cord Injury

- Study met its primary endpoint by achieving statistical significance on one of its two pre-specified co-primary endpoints, demonstrating increased electrical connectivity between the brain and hand muscle in individuals with a cervical level spinal cord injury (SCI).
- Study also showed a positive trend in the secondary endpoint evaluating change in “GRASSP” score, a measure designed specifically to assess hand function in people with cervical injuries.
- As the first pharmaceutical candidate to show improved motor recovery based on increased motor evoked potential amplitude, these study results represent a significant scientific advance and step forward in the potential to treat SCI, where there remains no approved pharmaceuticals to enable sustained functional recovery.
- Topline safety and efficacy results reinforce the potential of NVG-291 to promote nervous system repair in individuals living with traumatic cervical SCI; NervGen intends to review results and development plan with the U.S Food and Drug Administration (FDA).
- Topline results from the chronic cohort will be presented at the American Spinal Injury Association (ASIA) Annual Scientific Meeting on June 3, 2025.
- Investor and analyst call to review topline data results will be held on June 3, 2025.

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, June 2, 2025 – NervGen Pharma Corp. (TSXV: NGEN) (OTCQB: NGENF), a clinical-stage biotech company dedicated to developing neuroreparative therapeutics, today announced positive topline results from the chronic cohort (1-10 years post injury) of its Phase 1b/2a clinical trial evaluating its lead drug candidate, NVG-291, as a potential treatment for spinal cord injury. NVG-291 met one of its co-primary endpoints and demonstrated promising changes in “GRASSP” score, a measure designed specifically to assess hand function in individuals with cervical SCI.

Topline results from the trial support the potential of NVG-291 to promote nervous system repair. The trial met a co-primary endpoint demonstrating improved motor connectivity in individuals with cervical chronic SCI receiving NVG-291 (n=10) compared to placebo (n=10). Data showed that subjects receiving NVG-291 achieved a three-fold increase in the strength of motor connectivity to an important hand muscle (first dorsal interosseus), as measured by change in the normalized motor evoked potentials (MEP) amplitude. (Baseline/Week 12 actual results: 6.207/18.773 for NVG-291 vs. 6.527/7.760 for placebo, p-value 0.0155). The second co-primary endpoint evaluating connectivity in a leg muscle (tibialis anterior) did not achieve statistical significance. The co-primary endpoint approach to the trial design is intended to permit only one of the co-primary endpoints to achieve statistical significance, though with a more rigorous p-value of <0.025 being required.

“As a scientist and clinician dedicated to enhancing rehabilitation outcomes for individuals with SCI, I am encouraged by the results from the chronic cohort of the NVG-291 clinical trial,” said Monica A. Perez, PT, Ph.D., Scientific Chair, Arms + Hands Lab, Shirley Ryan AbilityLab and principal investigator of this trial. “A threefold increase in MEP is generally considered substantial and, in this study, the data separation from placebo is clear. I believe that data demonstrating changes in motor connectivity

underscore the potential of this new drug candidate to provide functional restoration and improve the quality of life for people with SCI.”

“We are excited to have achieved positive study results demonstrating both improved hand-motor connectivity and improved function in the chronic cohort of our Phase 1b/2a trial. This data supports the therapeutic potential of NVG-291 and represents a big step forward in advancing this drug candidate,” said Mike Kelly, NervGen’s President and Chief Executive Officer. “This data demonstrates, for the first time, that a drug candidate can assist in achieving functional improvement for individuals in the chronic stage of SCI who have plateaued in their recovery. It is important to highlight that changes in upper extremity motor function can provide individuals living with SCI the opportunity for meaningful improvements in their performance of daily functions as well as their independence. Lastly, on behalf of the entire team at NervGen, I would like to thank the investigators, all those involved in the trial at Shirley Ryan AbilityLab, and the individuals with SCI who participated in this trial.”

Positive trends were also seen in the secondary endpoint evaluating the change from baseline in the Graded Redefined Assessment of Strength, Sensation and Prehension (GRASSP) Test, with the strongest improvements being in quantitative prehension. GRASSP is a validated test of hand function, sensation and strength comprised of four tests and is designed specifically to assess hand function in individuals with cervical SCI. The quantitative prehension performance subtests scores an individual’s ability to carry out specific gross or fine motor tasks and requires control, orientation of the hand, strength and endurance. A positive trend, though not sufficient to reach statistical significance, toward improvement in the quantitative prehension score was observed (actual change from baseline at week 12: +3.7 for NVG-291 and +0.4 for placebo; linear mixed effects modeled results: +3.1 for NVG-291 1.0 for placebo group, $p=0.1416$); 50% of the individuals receiving NVG-291 vs. 10% in the placebo group had an improvement of at least 4 points.

“What I am particularly excited about are the changes in GRASSP scores as these are very important clinical outcomes for patients living with SCI,” said James Guest, MD, PhD, FACS, Professor of Neurological Surgery at the University of Miami. “For individuals with cervical SCI, their level of independence depends on their hand and arm functions. Based on my clinical experience, if an individual with a cervical SCI had to pick what is most important to them, upper extremity function is most often what they would choose. An increase in quantitative prehension can allow for a meaningful improvement in independence.”

In a preliminary *post hoc* analyses, positive trends toward improvement were also seen for changes on the nine-hole peg test (9-HPT), a measure of upper extremity dexterity. Although not statistically significant based on topline analyses, these results in the secondary endpoints warrant further analysis. We did not see any clear effects on changes in the other secondary endpoints of pinch force, 10-meter Walk Test and Upper and Lower Extremity Motor Scores, although additional analyses are ongoing and have the potential to provide additional insights into the data and NVG-291’s therapeutic effects.

“This is the first placebo-controlled trial of which we are aware that an investigational drug candidate has achieved statistical significance on a primary endpoint, in this case a quantitative biomarker of motor connectivity” said Daniel Mikol, MD, Ph.D., NervGen’s Chief Medical Officer. “We are highly encouraged by the clear trends in improved GRASSP scores, and we look forward to additional forthcoming analyses to gain further insights into the results already observed. Results from this trial will also guide us in the design of future trials in SCI. We plan to meet with the FDA in the coming months to discuss these results



and the path forward for NVG-291. In addition, we continue to enroll participants in the subacute cohort (20-90 days post injury) of the trial.”

We believe that the preliminary efficacy signal observed in the chronic cohort in this study supports clinical advancement of NVG-291 in chronic SCI. NVG-291 was generally safe and well tolerated. The most common adverse event was mild/moderate injection site reactions. There were no treatment discontinuations or serious adverse events in the NVG-291 group.

SCI results in a loss of connectivity that sends and receives electrical signals to and from the brain and can cause changes in feeling, movement, strength, and body functions below the site of injury. NVG-291 is a potential first-in-class therapeutic peptide that targets the body’s natural inhibitors of repair. It is thought to promote natural repair processes (such as axonal regeneration, neuroplasticity, and remyelination) to improve the connections disrupted by SCI. Since there are currently no approved pharmaceuticals to enable functional recovery in SCI, NervGen’s study represents a meaningful and significant step forward for the SCI treatment landscape.

ASIA Presentation Details

NervGen will present results from the chronic cohort of the ongoing Phase 1b/2a study of NVG-291 as an oral presentation on Tuesday, June 3, 2025 at 1:40pm EDT at the 52nd ASIA Annual Scientific Meeting being held June 2-4, 2025 in Scottsdale, AZ.

Presenting Author: Daniel Mikol MD, Ph.D., Chief Medical Officer, NervGen Pharma

Session Name: General Session 6: Clinical Trial Updates: Clinical Trials: What’s the Latest and When Will it Get Here?

Session Date: Tuesday, June 3, 2025

Session Time: 10:40 AM-11:40 AM MST

Location: Arizona Ballroom I, Grand Hyatt Scottsdale Resort, 7500 E. Doubletree Ranch Rd., Scottsdale, AZ

Analyst/Investor Call Details

The company will host a conference call for analysts and investors on Tuesday, June 3, 2025 at 4:15pm EDT to discuss the results from the chronic cohort of the ongoing Phase 1b/2a study of NVG-291. To join the call, dial toll-free 1-877-407-0789 or international 1-201-689-8562, conference ID 13753321.

Participants can use the dial-in numbers provided and be answered by an operator or click this [Call me™ link](#) for instant telephone access to the event. For those that would like to join by webcast, click [here](#).

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 motor incomplete 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 safety and efficacy of a fixed dose of NVG-291 using electrophysiological and MRI imaging measures, functional clinical outcome measures, and blood biomarkers that together will provide comprehensive information about the extent of recovery of somatic and autonomic function post-injury. Specifically, the co-primary objectives seek to assess changes in corticospinal connectivity of defined upper and lower extremity muscle groups following treatment, based on changes in normalized (as a percentage of the maximum motor response following direct electrical stimulation of the



corresponding peripheral nerve) motor evoked potential amplitudes. Secondary objectives evaluate changes in multiple clinical outcome assessments focusing on motor function, upper extremity dexterity, grasping and immobility, and additional electrophysiological measurements. The cohorts will be comprised of 20 subjects each and will be evaluated independently in a blinded manner 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. More information about participation in the subacute study is available at www.connectscistudy.com.

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 is licensed from Case Western Reserve University and is based on academic studies that demonstrated the preclinical efficacy of NVG-291-R, the rodent prototype of NVG-291, in animal models of spinal cord injury. These studies implicated several potential molecular and cellular mechanisms by which NVG-291-R promotes neurorepair and functional improvement in both central and peripheral nervous system injury models. The implicated mechanisms include the promotion of neuronal sprouting, or plasticity, remyelination, and promotion of a non-inflammatory phenotype in the microglial cells. NervGen has received Fast Track designation from the FDA for NVG-291 in individuals with spinal cord injury.

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 candidate, NVG-291, in a Phase 1b/2a clinical trial in spinal cord injury and has initiated preclinical test of concept evaluation of our pipeline candidate, NVG-300, in models of ischemic stroke and spinal cord injury. For more information, visit www.nervgen.com and follow NervGen on [X](#) and [LinkedIn](#) 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 (collectively, "forward-looking statements"). Such forward-looking statements 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 implications of our Phase 1b/2a clinical trial results of NVG-291 including the potential of NVG-291 to promote nervous system repair in individuals living with traumatic cervical SCI, the expected benefits of changes in upper extremity motor function for individuals living with SCI and the potential to otherwise treat SCI; future plans to review results and development plans with the FDA; the future development plans and benefits of NVG-291; our plans to further analyze secondary results from the Phase 1b/2a clinical trial; the subject matter to be presented at the upcoming conference; the development plans and expected benefits, and prospective target indications for NVG-300; the receipt of the milestone-based grant payments; and the creation of neuroreparative 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.