

NervGen Initiates Expanded Access Policy

- The U.S. Food and Drug Administration (FDA) informed the company that an expanded access protocol for NVG-291 may proceed

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, March 31, 2025 – NervGen Pharma Corp. (TSX-V: NGEN) (OTCQB: NGENF), a clinical-stage biotech company dedicated to developing neurorestorative therapeutics, today announced the company has initiated an expanded access policy to allow treatment use of the investigational product NVG-291 for those individuals with spinal cord injury (SCI) who have participated in NervGen clinical trials and meet specific eligibility criteria. The company received a request from a physician for expanded access to NVG-291 for a subject who participated in the chronic cohort of the Phase 1b/2a clinical trial. After the company submitted an expanded access protocol for NVG-291 to the FDA, the FDA informed the company that the study could proceed.

NVG-291 is an investigational drug in clinical development that has not been approved by regulatory authorities for marketed use. It is unknown whether it is effective for the treatment of individuals with SCI, and there may be unknown risks associated with its use. Expanded Access programs allow patients who have unmet medical needs with serious or life-threatening conditions to access investigational products that are not yet approved by the FDA outside of a clinical trial.

“NervGen is committed to the continued clinical development and evaluation of NVG-291 as a potential novel treatment approach in spinal cord injury,” said Daniel Mikol, M.D. Ph.D., NervGen’s Chief Medical Officer. “As we announce this expanded access policy for specific participants, we continue to enroll the subacute cohort of the Phase 1b/2a study in SCI as we prepare to unblind the efficacy and safety results from the chronic cohort of this study in early June 2025.”

The company’s expanded access policy provides a potential opportunity for individuals living with SCI who have participated in NervGen clinical trials to continue access to NVG-291 for treatment. The company’s decision to change its expanded access policy was based, in part, upon a special circumstance related to a physician request for access to NVG-291.

For information about NervGen’s expanded access policy for NVG-291 and the process to submit a request, please refer to the company’s [policy](#).

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 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. More information about participation in the subacute study is available at connectscistudy.com.

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.

Contacts

Huitt Tracey, Investor Relations

htracey@nervgen.com

604.537.2094

Bill Adams, Chief Financial Officer

info@nervgen.com

778.731.1711

David Schull or Ignacio Guerrero-Ros, Ph.D.

Russo Partners

david.schull@russopartnersllc.com

ignacio.guerrero-ros@russopartnersllc.com

858.717.2310

646.942.5604

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 (collectively, “forward-looking statements”). 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 potential access to NVG-291 through the company’s expanded access policy; 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; 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.