

NervGen Pharma Receives Fast Track Designation for NVG-291 for the Treatment of Individuals with Spinal Cord Injury

- Designation Facilitates and Expedites Development of Drugs for Patients with Serious Unmet Medical Needs
- Enrollment Progressing in NVG-291 Phase 1b/2a Clinical Trial, with Initial Cohort Data Expected in Mid-2024

Vancouver, Canada, October 23, 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its proprietary lead compound, NVG-291, in individuals with spinal cord injury (SCI). FDA's Fast Track program is designed to facilitate the development of drugs intended to treat serious conditions and fill unmet medical needs as part of the FDA's goal to get important new drugs to patients earlier. Fast Track also provides eligibility for both Priority Review, which can shorten the New Drug Development (NDA) review process, and for Accelerated Approval, which can allow for an earlier or faster approval based on a surrogate or intermediate clinical endpoint.

"The FDA's decision to grant Fast Track designation for NVG-291 underscores the significance and severity of the unmet medical need that exists for individuals living with spinal cord injury and their caregivers," said [Mike Kelly](#), NervGen's President & CEO. "We believe that NVG-291 has the potential to be the first approved treatment indicated to enable neurological/functional recovery following spinal cord injury, and we look forward to working closely with the FDA in the clinical development process with the goal of obtaining approval to market NVG-291 as soon as possible."

About Fast Track Designation

Fast Track designation is intended to facilitate development and expedite review of drugs to treat serious or life-threatening conditions so that a product can reach the market expeditiously. A drug that is intended to treat a serious or life-threatening condition that demonstrates the potential to address an unmet medical need may qualify for Fast Track designation. Features of this designation include opportunities for frequent interactions with the review team. These include meetings with the FDA to discuss items such as study design, extent of safety data required to support approval, dose-response concerns, accelerated approval, the structure and content of an NDA, and other critical issues. In addition, such a product could be eligible for priority review if supported by clinical data at the time of NDA.

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 (PTP σ). 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. NervGen has initiated a Phase 1b/2a placebo-controlled proof-of-concept trial (NCT05965700) to 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. Initial results are expected in mid-2024.

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 and study design of the clinical development of NVG-291 including the planned single site Phase 1b/2a clinical trial in SCI; the expected benefit of Fast Track designation and the timeline for approval of NVG-291; 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.