



## **NERVGEN PHARMA RECEIVES ORPHAN DESIGNATION FROM THE EUROPEAN MEDICINES AGENCY FOR NVG-291 FOR THE TREATMENT OF SPINAL CORD INJURY**

**Vancouver, Canada.** March 8, 2021 – **NervGen Pharma Corp. (TSX-V: NGEN) (OTCQX: NGENF)** (“NervGen” or the “Company”), a biotech company dedicated to creating innovative solutions for the treatment of nerve damage and neurodegenerative diseases, today announced the European Medicines Agency (“EMA”) has granted Orphan Designation for the treatment of spinal cord injury (“SCI”) to NVG-291, a specific and selective protein tyrosine phosphatase sigma (“PTP $\sigma$ ”) inhibitor. This new EMA designation provides NervGen with multiple incentives, including improved access to scientific advice, fee reductions, and 10 years of protection from market competition in Europe from similar medicines with similar indications following the date that the drug candidate receives marketing authorization (called market exclusivity).

“Obtaining Orphan Designation from the EMA underscores our confidence in NVG-291’s potential to provide a significant benefit to patients with traumatic or pathological alterations to the spinal cord,” stated Paul Brennan, NervGen’s President & CEO. “There are currently no approved pharmaceutical treatments for SCI and existing therapies are limited to preventing further injury. We are especially encouraged by our preclinical data demonstrating NVG-291’s potential to facilitate nerve repair and functional recovery following nerve injury. Limiting damage in the acute phase as well as repairing damage and restoring function in the chronic setting will enable us to reach a broader patient population than the current standard of care. We look forward to advancing this program into Phase 1 trials and will optimize our development plans to bring NVG-291 to patients as quickly as possible.”

Orphan Designation in the European Union (“EU”) is granted by the European Commission based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products. To qualify, an investigational medicine must be intended to treat a seriously debilitating or life-threatening condition that affects fewer than five in 10,000 people in the EU, and there must be sufficient non-clinical or clinical data to suggest the investigational medicine may produce clinically relevant outcomes. EMA Orphan Designation provides companies with certain advantages and incentives, including 10 years of market exclusivity upon marketing authorization, clinical protocol assistance, access to a centralized marketing authorization procedure valid in all EU member states and reduced regulatory fees.

### **About NVG-291**

NVG-291 is an inhibitor of PTP $\sigma$ , a promising target for treating damage to the spinal cord resulting in a loss of mobility, feeling and/or autonomic function. PTP $\sigma$  is a key neural receptor that inhibits nerve repair by inhibiting nerve regeneration, plasticity, and remyelination. NervGen believes that inhibiting PTP $\sigma$  has the potential to activate growth-promoting pathways and release enzymes that break up inhibitory chondroitin sulfate proteoglycans (“CSPG”) (an extracellular molecule upregulated at sites of neuronal injury), resulting in new and enhanced nerve growth, significant improvements of nerve function and clinically relevant sensorimotor recovery. The scientific evidence of PTP $\sigma$  as the target for preventing the inhibition of nerve regeneration following axonal damage, and the potential for NVG-291 treatment to reverse this effect, is well supported from non-clinical efficacy models.

Rodent animal models of SCI in numerous independent labs show that binding of the rodent variant of NVG-291 (NVG-291-R) to PTP $\sigma$  led to blockage of the growth inhibitory signaling cascade associated with CSPG binding, as well as the activation of growth associated pathways. Daily local subcutaneous injections



of NVG-291-R (also known as intracellular sigma peptide or ISP) promoted a dose-dependent return of voluntary bladder function, as well as significant locomotor recovery in numerous acute SCI models, correlating to anatomical evidence of enhanced regeneration, axonal plasticity and remyelination. Additional information about the study can be found at [www.nervgen.com/ptpσ-and-sci/](http://www.nervgen.com/ptpσ-and-sci/).

## **About NervGen**

NervGen is restoring life's potential by creating innovative solutions for the treatment of nerve damage and neurodegenerative diseases. The Company is developing drugs for the treatment of multiple sclerosis, spinal cord injury and Alzheimer's disease. NervGen's platform technology targets protein tyrosine phosphatase sigma ("PTPσ"), a neural receptor that impedes nerve repair. Inhibition of the PTPσ receptor has been shown to promote regeneration and remyelination of damaged nerves, as well as improvement of nerve function in animal models for various medical conditions.

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*Follow NervGen on Twitter (@NervgenP) and LinkedIn (NervGen Pharma Corp.) 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 clinical development of NVG-291 for spinal cord injuries, both sub-acute and chronic; obtaining Orphan Designation that provides multiple incentives and the realization of those incentives; NVG-291's potential to provide a significant benefit to patients with traumatic or pathological alterations to the spinal cord; our belief that NVG-291's potential to facilitate nerve repair and functional recovery following nerve injury will enable us to reach a broader patient population than the current standard of care; our belief that inhibiting PTPσ has the potential to



activate growth-promoting pathways and release enzymes that break up inhibitory CSPGs resulting in new and enhanced nerve growth, significant improvements of nerve function and clinically relevant sensorimotor recovery; steps taken to minimize the impact of the COVID-19 pandemic on our operations; and the creation of innovative solutions for the treatment of nerve damage and neurodegenerative diseases.

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 ability to move NVG-291 through clinical trials and 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, Amended and Restated Prospectus Supplement, financial statements and Management Discussion and Analysis which can be found on SEDAR.com. 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.