



## **NERVGEN PHARMA RECEIVES ETHICS BOARD APPROVAL FOR MULTIPLE ASCENDING DOSE PORTION OF NVG-291 PHASE 1 TRIAL**

- Phase 1 program supports plan to start clinical trials in H2 2022 for NervGen's NVG-291 in spinal cord injury, multiple sclerosis and Alzheimer's disease indications
- Screening of healthy volunteers has already started for the trial's multiple ascending dose (MAD) portion
- In preclinical studies, NVG-291 has been shown to promote repair of nervous system damage

**Vancouver, Canada.** December 22, 2021 – **NervGen Pharma Corp. (TSX-V: NGEN) (OTCQX: NGENF)** ("NervGen" or the "Company"), a clinical stage biotech company dedicated to creating innovative treatments that repair nervous system damage, is pleased to announce it has received ethics board approval from Bellberry Limited's Human Research Ethics Committee (HREC) to proceed with the multiple ascending dose (MAD) portion of its Phase 1 trial with its lead compound, NVG-291. In preclinical studies, NVG-291 has been demonstrated to promote repair mechanisms in the nervous system, including axonal regeneration, remyelination and enhanced plasticity. NervGen is now screening healthy volunteers for participation in the multiple dosing portion of the trial and expects to dose the first subjects early in 2022.

"Commencing the MAD portion of our Phase 1 trial is an important milestone for the development of NVG-291," stated Dr. Daniel Mikol, NervGen's Chief Medical Officer. "We were very encouraged by the results we obtained in the single ascending dose (SAD) portion of the trial. NVG-291 was well tolerated, showed favorable pharmacokinetic parameters, and the doses tested in the highest dose cohorts were substantially higher than the dose equivalents shown to be effective in various animal models of nervous system injury. Completing the MAD portion of the study is an important step as we move towards our Phase 1b/2 studies in spinal cord injury, multiple sclerosis and Alzheimer's disease, which we plan to start in the second half of 2022."

The MAD portion of the Phase 1 study will administer NVG-291 or a placebo in a blinded fashion once a day for 14 consecutive days. The study is expected to complete the three planned dose cohorts in the first half of 2022. Following completion of ongoing toxicology studies requested by the US Food and Drug Administration (FDA) and provision of available data from this Phase 1 study to the FDA, NervGen will seek removal of the partial clinical trial hold initiated by the FDA and evaluate the safety and pharmacokinetics of NVG-291 in cohorts of healthy males and healthy premenopausal females.

### **About NervGen**

NervGen is enabling the nervous system to repair itself by creating innovative treatments of nervous system injury due to trauma or disease. The Company is initially developing treatments for multiple sclerosis, spinal cord injury and Alzheimer's disease.

### **About NVG-291**

NervGen holds the exclusive worldwide rights to NVG-291 and is developing a unique new class of drugs around the technology. NVG-291 is a therapeutic peptide which is a mimetic of the intracellular domain of protein tyrosine phosphatase (PTP $\sigma$ ), a cell surface receptor known to interact with chondroitin sulfate proteoglycans (CSPGs) and to be involved in the regulation of neuroplasticity and central nervous system repair. In preclinical studies, NVG-291 has demonstrated the potential to promote repair mechanisms in



the nervous system, including axonal regeneration, remyelination, and enhanced plasticity. The demonstration of repair via these mechanisms in animal models of nervous system injury has been accompanied by recovery of multiple neurological functions, including motor, sensory, autonomic and cognitive functions. NVG-291 has shown efficacy in a range of animal models, including models of nervous system trauma (e.g. spinal cord injury, peripheral nerve injury) and disease (multiple sclerosis, stroke).

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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 timing of the clinical development of NVG-291; the timing and requirements to remove the partial clinical hold initiated by the FDA; the objectives and study design of the Phase 1 study in healthy volunteers; our belief that we will evaluate the therapeutic potential of NVG-291 in patients in multiple indications upon successful completion of the Phase 1 trial in healthy volunteers; the belief that inhibiting the activity of PTP $\sigma$  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 injury 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, 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.