



## **NERVGEN PHARMA PROVIDES REGULATORY UPDATE ON DEVELOPMENT PROGRAM FOR NVG-291**

*-Plans to Dose First Human Subjects in Phase 1 in Q2 2021-*

**Vancouver, Canada.** March 4, 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 provided a regulatory program update for NVG-291, a specific and selective protein tyrosine phosphatase sigma (“PTP $\sigma$ ”) inhibitor being developed for the treatment of spinal cord injury, multiple sclerosis and Alzheimer’s disease.

“The U.S. Food and Drug Administration (“FDA”) has provided feedback regarding our NVG-291 IND submission that allows us to proceed into a Phase 1 healthy volunteer study,” stated Paul Brennan, President and CEO of NervGen. “Although NVG-291 remains under a partial clinical hold, we are pleased that the FDA has now provided us with a path forward to initiate our Phase 1 program in the near-term, while we complete additional preclinical work in parallel. We believe the impact to our overall timelines should be minimal, and we still plan to initiate efficacy studies in the first half of 2022.”

“We are confident in our ability to ultimately meet all of the requirements that the FDA has requested in order to lift the partial clinical hold on our IND, and we will continue to collaborate with regulatory agencies on the overall development program for NVG-291,” added Brennan.

NervGen has been cleared by the FDA to proceed with the single ascending dose (“SAD”) portion of the trial in females, and the multiple ascending dose (“MAD”) portion of the trial in post-menopausal females. The FDA has asked for additional preclinical safety data prior to including males in the Phase 1 program, and prior to including premenopausal females in the MAD portion of the trial.

NervGen plans to initiate its first Phase 1 clinical trial in Australia under all of the conditions required by the FDA. Prior to dosing in Australia, NervGen must also obtain final approval from the ethics review board governing the study and provide notification to the Therapeutic Goods Administration. The Company will modify its proposed Phase 1 protocol and now expects to dose the first human subjects in this program in Q2 2021 in Australia after all requisite approvals have been obtained.

Pending a positive outcome of the Phase 1 results in healthy volunteers, NervGen intends to add a multi-dose Alzheimer’s disease patient cohort to the Phase 1 program. The Company also plans to initiate Phase 2 trials in spinal cord injury and multiple sclerosis after completion of Phase 1 and after resolution of the partial clinical hold. NervGen currently expects it will be able to initiate these trials in the first half of 2022.

### **About NVG-291**

NVG-291 is an inhibitor of PTP $\sigma$ , a promising target for reducing the clinical effects of nerve damage, either as a result of trauma, such as in the case of spinal cord injury, traumatic brain injury or stroke, or neurodegenerative diseases, such as multiple sclerosis or Alzheimer’s disease. NervGen believes that inhibiting the activity of PTP $\sigma$  has the potential to promote nerve repair mechanisms such as nerve regeneration, remyelination and plasticity; promote autophagy, a cellular self-cleaning mechanism; and to promote a non-inflammatory phenotype in microglia cells, the innate immune cells of the brain.



## **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 ("PTP $\sigma$ "), a neural receptor that impedes nerve repair. Inhibition of the PTP $\sigma$  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 (@NervgenC) 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 timing of the clinical development of NVG-291; the objectives and study design of the proposed Phase 1 study in healthy volunteers; our confidence in our ability to meet all of the requirements that the FDA has requested in order to lift the partial clinical hold on our IND; our belief that the impact to our timelines should be minimal, and we can be still be entering efficacy studies in the first half of 2022; our intent to conduct all of the recommended preclinical studies concurrently with the Phase 1 studies and to amend the IND and broaden the treatment population as soon as possible; our belief that inhibiting the activity of PTP $\sigma$  is a promising target for reducing the clinical effects of nerve damage through multiple mechanisms; 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 Company's ability to meet all of the requirements that the FDA has requested in order to lift the partial clinical hold on our IND; the Company's ability to obtain final approval from the ethics review board in Australia; 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, the inability to meet all of the requirements that the FDA has requested, failure to obtain final approval from the ethics review board in Australia, 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.