

## NERVGEN PRESENTS ADDITIONAL PHASE 1 CLINICAL TRIAL DATA FOR NVG-291 AT NEUROSCIENCE 2021

# Safety Review Committee Provides Recommendation to Proceed to Multiple Ascending Dose Portion of the Trial

Vancouver, Canada November 4, 2021 – NervGen Pharma Corp., (TSX-V: NGEN) (OTCQX: NGENF) ("NervGen" or the "Company"), a clinical stage biotech company dedicated to creating innovative treatments for nervous system damage, provided an update on its Phase 1 program with NVG-291 at the Society for Neuroscience's Neuroscience 2021 conference. NervGen's Chief Medical Officer, Dr. Daniel Mikol, presented blinded safety and pharmacokinetic data, including new data for the highest single ascending dose (SAD) cohort that demonstrated that NVG-291 was well tolerated and had favorable pharmacokinetic properties. NervGen is also pleased to announce that, after completing the six planned SAD cohorts, the safety review committee overseeing the study has recommended that the Company proceed to the multiple ascending dose (MAD) portion of the trial.

"The data that we presented is very encouraging as all adverse events reported in the study were mild and transient," stated Dr. Mikol. "We have tested doses in the SAD portion of the study that are substantially higher than the dose equivalents used in various animal efficacy studies, and for the highest SAD dose cohort, over 100x higher than the lowest effective dose in animal models. This wide safety margin provides flexibility as we move into the MAD portion of the study, and eventually into Phase 1b/2 clinical trials with patients."

Paul Brennan, NervGen's President & CEO, added, "These results continue to exceed our expectations. Not only is NVG-291 well tolerated, the positive pharmacokinetic characteristics that were reported previously appear to be maintained at the highest dose. We believe that this data provides us with very strong rationale to proceed to the MAD portion of the study, and provides us with a great deal of confidence that the efficacy results seen in multiple preclinical disease and injury models will translate to positive results in our upcoming clinical trials in Alzheimer's disease, multiple sclerosis and spinal cord injury patients which we plan to start in 2022."

Blinded safety data was provided from 37 healthy volunteers who participated in six cohorts of the SAD portion of the study and have been treated with either placebo or NVG-291. All reported adverse events have been mild and transient and there were no observed effects on vital signs, electrocardiograms or laboratory assessments. Subjects were dosed as high as 0.864 mg/kg, which, when using the appropriate dose conversion model, is 170% higher than the highest effective dose (0.32 mg/kg) studied in the various animal models of nervous system injury (effective dose range 0.01-0.32 mg/kg).

Pending approval of the SAD portion of the Phase 1 trial by the ethics review committee, the Company will proceed to the MAD portion of the study where subjects will be dosed in a blinded fashion with NVG-291 or placebo once a day for 14 consecutive days. The MAD portion of the study is expected to include three dose cohorts and complete in early 2022. Following completion of the MAD portion of the study and ongoing toxicology studies requested by the United States Food and Drug Administration (FDA), NervGen will seek removal of the partial clinical trial hold initiated by the FDA and perform bridging studies in healthy males and in healthy premenopausal females.



#### About NVG-291

NVG-291, a protein tyrosine phosphatase (PTPσ) modulator, has demonstrated the potential to promote repair mechanisms in the central nervous system such as axonal regeneration; remyelination; plasticity; autophagy (a cellular self-cleaning mechanism that removes unnecessary or dysfunctional components); and a non-inflammatory phenotype in microglia cells, the innate immune cells of the brain. PTPσ is a protein which has been shown to impede repair following injury to the nervous system. Nervous system injury can occur because of trauma, such as in the case of spinal cord injury or traumatic brain injury, or as a result of disease-specific mechanisms, such as multiple sclerosis or Alzheimer's disease.

A Phase 1 trial of NVG-291 in heathy subjects is ongoing. Following completion of the multiple ascending dose portion of the study and ongoing toxicology studies requested by the FDA, NervGen will seek removal of the partial clinical trial hold initiated by the FDA and perform bridging studies in healthy males and in healthy premenopausal females. Following completion of the bridging studies, NervGen intends to initiate a Phase 1b/2a trial in Alzheimer's disease patients. Concurrently, the Company also plans to initiate Phase 1b/2 trials in spinal cord injury and multiple sclerosis with each of these trials planned to start in 2022.

#### **About NervGen**

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

For further information, please contact:

Huitt Tracey, Corporate Communications htracey@nervgen.com 604.362.6209

Nancy Thompson, Vorticom Public Relations nancyt@vorticom.com 212.532.2208

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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 favorable tolerability and pharmacokinetic profile of NVG-291; the wide safety margin providing flexibility as we move into the MAD portion of the study; the Phase 1 results reported to date; our confidence that the efficacy achieved in multiple preclinical disease and injury models will translate into positive results in our upcoming clinical trials with patients; the timing and requirements to proceed to the MAD portion of the Phase 1 clinical trial and to remove the partial clinical hold initiated by the FDA; the clinical development of NVG-291 for Alzheimer's disease, multiple sclerosis and spinal cord injuries; our clinical trial designs and timing; 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 of the nervous system.

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.