



## **NERVGEN PHARMA RECEIVES APPROVAL TO PROCEED TO THE FINAL DOSE COHORT IN PHASE 1 CLINICAL TRIAL OF NVG-291 AND REPORTS Q1 2022 RESULTS**

- Safety Review Committee approves proceeding to third and highest dose cohort in multiple ascending dose portion of clinical trial
- No serious or severe adverse events reported in second dose cohort with NVG-291
- Successful completion of the second cohort establishes a clear pathway to selecting a dose for upcoming Phase 1b/2 clinical trials

**Vancouver, Canada.** May 12, 2022 – **NervGen Pharma Corp. (TSX-V: NGEN; OTCQX: NGENF)** (“NervGen” or the “Company”), a clinical stage biotech company dedicated to developing a first-in-class *neuroreparative* drug to treat nervous system damage, today announced it has received approval from the Safety Review Committee to advance to the third and highest dose cohort in the multiple ascending dose (MAD) portion of its Phase 1 clinical trial of the Company’s proprietary lead compound, NVG-291. In preclinical animal studies, NVG-291 has demonstrated the potential to promote repair mechanisms in the nervous system, including axonal regeneration, remyelination, and plasticity. The Company also reported its financial and operational results for the first quarter ended March 31, 2022.

“This second cohort in the MAD portion of our Phase 1 was a success in multiple ways,” stated Paul Brennan, NervGen’s President & CEO. “As with our other cohorts, we did not have any adverse events reported in this cohort that were either serious or severe. This is very encouraging as we plan for our upcoming patient studies since we have now demonstrated that NVG-291 is well tolerated after 14 days of administration at doses well above those found to be efficacious in animals. This provides us with a clear pathway to define our doses as we plan for our upcoming Phase 1b/2a efficacy studies in Alzheimer’s disease and spinal cord injury patients later in 2022 and a Phase 2 study in multiple sclerosis patients in early 2023.”

Mr. Brennan continued, “It is significant that the doses of NVG-291 administered in the second MAD cohort were 80% higher than the highest corresponding dose found to be efficacious in animal models and over 50 times higher than the lowest efficacious doses where functional improvements were observed.”

NervGen will now proceed to evaluate the highest dose level of NVG-291 in the third MAD cohort. This next step will provide greater flexibility in establishing doses for future patient studies and will provide additional important information about the safety and pharmacokinetic profile of NVG-291. Following completion of the third MAD dose cohort 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 evaluate bridging cohorts of healthy males and healthy premenopausal females.

### **Operational Highlights for Q1 2022**

- In January, we announced that we entered into a Memorandum of Understanding with Shirley Ryan AbilityLab with the intention of performing our first clinical trial in spinal cord injury patients. The single site clinical trial, which is expected to start in the second half of 2022, will be a placebo-controlled trial, assessing the safety and efficacy of NVG-291 in treating separate cohorts of individuals in the acute/subacute (<3 months post-injury) and chronic (≥1-year post-injury) stages.
- We continued to advance our Phase 1 clinical trial for NVG-291:
  - In March, we received approval from the Safety Review Committee to proceed to the second cohort in the MAD portion of our Phase 1 clinical trial.

- In April, our Chief Medical Officer, Dr. Daniel Mikol, presented unblinded safety data from the single ascending dose (SAD) portion of the Phase 1 clinical trial, and interim blinded data from the first MAD cohort, at the 2022 American Academy of Neurology Annual Meeting. Dr. Mikol reported that subjects were evaluated throughout the treatment phase and one week after the final dose of the study drug. Following a thorough safety evaluation, including a blinded review of adverse events, vital signs and laboratory data, the Safety Review Committee approved advancing to the second MAD cohort. Moreover, the day 1 and day 14 concentration-time curves for NVG-291 at the tested dose level were very similar to each other and to that for the same dose level in the SAD portion of the study. A reproducible pharmacokinetic profile is a highly desirable property for any drug being developed for human use.
- During the quarter, we expanded the expertise of our team and Board with the following additions:
  - In March, we announced the engagement of Apaton Finance GmbH for public relations and investor relations consulting, focused in the European Union.
  - Subsequent to the quarter end, on April 13, 2022, we announced the appointment of Craig Thompson to our Board of Directors. Mr. Thompson brings broad leadership experience and a proven track record of successful drug development and biotech fundraising, licensing, and mergers and acquisitions. Concurrently with Mr. Thompson joining the Board, Dr. Michael Abrams resigned from the Board.

## Financial Highlights

- **Cash and Investments:** NervGen had cash and investments of \$12.8 million as of March 31, 2022, compared to \$5.0 million as of March 31, 2021. The net cash burn for Q1 2022 from operating activities was approximately \$4.2 million. This was offset by approximately \$0.1 million in proceeds from the exercise of warrants during the quarter. Subsequent to the quarter ended March 31, 2022, we received a further \$1.9 million in proceeds from the exercise of warrants.
- **R&D Expenses:** Research and development expenses were \$3.6 million for the three months ended March 31, 2022, compared to \$0.7 million in the same period in 2021. The increase in the quarter ended March 31, 2022, was primarily due to costs related to the ongoing Phase 1 clinical trial, drug product manufacturing, toxicity preclinical studies and translational research initiated for Alzheimer’s disease and spinal cord injury.
- **G&A Expenses:** General and administrative expenses were \$1.4 million for the three months ended March 31, 2022, compared to \$1.5 million for the same period in 2021. The decrease was primarily due to non-cash stock-based compensation expense related to option grants to employees and consultants, and the timing of the related vesting, partially offset by increases in legal, professional, and financial and corporate communication services directed to increasing awareness about our technology and attracting investors.
- **Net Loss:** For the three months ended March 31, 2022, net loss, which included \$0.8 million of non-cash expenses, was \$5.0 million, or \$0.11 per basic and diluted common share. For the three months ended March 31, 2021, net loss, which included \$0.8 million of non-cash expenses, was \$2.2 million, or \$0.06 per basic and diluted common share.

## 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 that mimics the intracellular domain of the receptor protein tyrosine phosphatase sigma (PTPσ), a cell surface receptor known to interact with chondroitin sulfate proteoglycans (CSPGs). Both PTPσ and CSPGs have been shown to inhibit neural plasticity, axonal regeneration, remyelination and nervous system repair. In preclinical studies of nervous system damage and neuroinflammation, NVG-291 has been shown to promote nervous system repair mechanisms, including axonal regeneration, remyelination, and plasticity. The demonstration of repair via these mechanisms in animal models of nervous system damage have 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 spinal cord injury, peripheral nerve injury, multiple sclerosis and stroke.

## 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. The company's initial focus is on spinal cord injury, Alzheimer's disease and multiple sclerosis. Our lead product, NVG-291, entered a Phase 1 clinical trial in 2021. We plan to initiate our Phase 1b/2a clinical trials in patients in 2022. For more information, go to [www.nervgen.com](http://www.nervgen.com).

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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: our plans to develop a first-in-class neuroreparative drug to treat nervous system damage; our belief that we have a clear pathway to selecting a dose for our upcoming Phase 1b/2 clinical trials as we have demonstrated that NVG-291 is well tolerated after 14 days of administration at doses well above the levels found to be efficacious in animals; the timing of the clinical development of NVG-291; the objectives, timing and study design of the Phase 1 study in healthy volunteers; the timing and requirements to remove the partial clinical hold initiated by the FDA; our belief that the third MAD cohort will provide greater flexibility in establishing doses for future patient studies and additional important information about the safety and pharmacokinetic profile of NVG-291; our belief that the similarities in certain pharmacokinetic characteristics for NVG-291 in the MAD and SAD portions of the Phase 1 study is indicative of a highly desirable property for any drug being developed for human use; our clinical trial designs and timing to evaluate the therapeutic potential of NVG-291 in patients in Phase 1b/2 clinical trials in Alzheimer's disease, multiple sclerosis and spinal cord injury upon successful completion of the Phase 1 trial and bridging studies; the belief that modulating the activity of PTPo 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, 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.