



## **NERVGEN PHARMA RECEIVES FDA AUTHORIZATION TO EXPAND ENROLLMENT OF MALES AND PREMENOPAUSAL FEMALES IN PHASE 1 CLINICAL TRIAL OF NERVGEN'S NVG-291**

- *Dose(s) to be tested in bridging cohorts of males and premenopausal females resulted in significant functional improvements in animal models of nervous system damage*
- *NervGen has completed enrollment of third and final multiple ascending dose cohort of postmenopausal women*

**Vancouver, Canada.** October 25, 2022 – **NervGen Pharma Corp. (TSX-V: NGEN) (OTCQX: NGENF)** (“NervGen” or the “Company”), a clinical stage biotech company dedicated to developing innovative solutions for the repair of nervous system damage, announced that the U.S. Food and Drug Administration (FDA) has amended the partial clinical hold to permit the inclusion of males and premenopausal females at certain dose levels in the Company’s Phase 1 clinical trial of NervGen’s proprietary compound, NVG-291.

“We are pleased with the FDA’s decision to authorize us to expand the evaluation of NVG-291 to all females and males, up to certain dose levels,” said Bill Radvak, NervGen’s Executive Chairman & Interim Chief Executive Officer. “We’ve now achieved two more significant milestones for the Company: completing enrollment of the final multiple ascending dose (MAD) cohort in postmenopausal females and being able to enroll bridging cohorts of males and premenopausal females. The doses of NVG-291 studied in each of the MAD cohorts exceed the corresponding doses that resulted in significant functional improvements in animal models of nervous system damage. Being able to enroll the bridging cohorts underscores that we are a step closer to initiating the Phase 1b/2 efficacy studies in spinal cord injury, Alzheimer’s disease and multiple sclerosis patients.”

A partial clinical hold was placed on NVG-291 by the FDA in March 2020 when adverse dose-dependent reproductive organ toxicity results were observed in initial 7-day and 28-day preclinical toxicology studies. Under the partial clinical hold, NervGen was permitted to enroll females and postmenopausal females in the single ascending dose (SAD) and MAD portions of the study, respectively, and recently completed enrollment of the third and final MAD dose cohort. The FDA requested additional preclinical safety data prior to inclusion of males and premenopausal females in the Phase 1 program. NervGen conducted the preclinical studies requested by the FDA, in addition to conducting longer 13-week studies. Results from the follow-up preclinical studies did not show adverse reproductive organ toxicity effects, including a repeat 28-day study, a 13-week study, and female and male fertility and early embryonic development studies.

Dr. Daniel Mikol, NervGen’s Chief Medical Officer, commented, “The safety results from the follow-up preclinical studies we performed support the administration of NVG-291 to males and premenopausal females within the FDA-specified exposure limits. Importantly, we anticipate that the current maximal dose will exceed the equivalent doses demonstrated to be efficacious in preclinical models. The blinded safety data observed in the Phase 1 trial thus far have been encouraging.”

After the third and final dose cohort of postmenopausal females is completed, bridging cohorts of males and premenopausal females will be evaluated. The additional preclinical safety studies requested by the FDA will further investigate the preclinical safety margin of NVG-291, testing exposures of NVG-291 higher than those tested in the follow-up preclinical safety studies. Pending successful completion of these

preclinical safety studies and provision of available data from the ongoing Phase 1 study to the FDA, NervGen will seek full removal of the partial clinical hold.

### **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. NervGen's lead drug candidate, NVG-291, is currently in a Phase 1 clinical trial. The Company's initial target indications are spinal cord injury, Alzheimer's disease and multiple sclerosis. For more information, go to [www.nervgen.com](http://www.nervgen.com).

### **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 (PTP $\sigma$ ), a cell surface receptor known to interact with chondroitin sulfate proteoglycans (CSPGs). Both PTP $\sigma$  and CSPGs have been shown to inhibit neural repair mechanisms following nervous system damage. NVG-291-R, the rodent form of NVG-291, has been shown to promote functional recovery and enable nervous system repair in a range of animal models, including models of spinal cord injury, peripheral nerve injury, multiple sclerosis and stroke, through enhanced plasticity, axonal regeneration, and remyelination.

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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 preclinical results of the doses to be tested in the bridging cohorts; the timing and design of our planned bridging studies and Phase 1b/2a efficacy studies; our belief that the safety results from our preclinical studies support the administration of NVG-291 to males and premenopausal females within the FDA-specified exposure limits; our plan to

seek full removal of the partial clinical hold following completion of the additional preclinical safety studies requested by the FDA and the provision of available data from the ongoing Phase 1 study; our target indications; and the development of innovative treatments that enable the nervous system to repair itself.

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, Short Form Base Shelf Prospectus, 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.