

NervGen Pharma Corp. Expanded Access Policy for NVG-291

NervGen Pharma Corp. (“NervGen”) is committed to developing safe and effective therapies for individuals living with neurotraumatic and neurologic conditions with significant unmet medical need. Consistent with this commitment, NervGen remains diligently focused on conducting the clinical trials necessary to obtain regulatory approval and to make NVG-291 available to individuals as efficiently as possible.

NervGen recognizes that certain individuals living with spinal cord injury, who previously participated in NervGen-sponsored clinical trials, including the Phase 1b/2a CONNECT SCI Study, may have limited or no alternative therapeutic options. In such circumstances, and provided that NVG-291 remains in active clinical development and that adequate drug supply is available, NervGen may consider requests from treating physicians for expanded access to NVG-291 for the treatment of an individual outside of an ongoing clinical trial.

Any such request will be evaluated on a case-by-case basis and is subject to applicable regulatory requirements, medical appropriateness, and predefined eligibility criteria.

These eligibility criteria, though not exhaustive, include the following:

- The individual previously participated in the Phase 1b/2a CONNECT SCI Study (NVG-291-201), completed the study, is confirmed by NervGen to have received NVG-291 treatment, derived significant clinical benefit (as determined by the treating physician), and has no other available treatment options;
- The requesting physician is appropriately licensed and qualified to safely administer NVG-291, is able to comply with applicable local and regulatory requirements for expanded access, and agrees to monitor and report adverse events, as required by the Institutional Review Board, NervGen, and regulatory bodies; and
- A benefit-risk assessment, based on available clinical data and the requesting physician’s evaluation of the individual’s medical condition and history, supports the provision of NVG-291 under expanded access.

NervGen may modify, suspend, or discontinue this Expanded Access Protocol at any time for various reasons, including, but not limited to, the following:

- New information becomes available regarding the safety or efficacy of NVG-291 that materially alters the overall benefit-risk assessment.
- NVG-291 becomes commercially available.
- NervGen determines not to continue the clinical development of NVG-291 for chronic spinal cord injury.
- Limitations in drug supply, manufacturing capacity, or other operational considerations.

NervGen continually evaluates the benefit-risk profile of NVG-291 based on evolving clinical data. The availability of NVG-291 for a particular individual does not imply that expanded access will be granted for other individuals, as circumstances and medical histories may differ. All requests are evaluated on a case-by-case basis. NervGen is committed to reviewing requests in a fair and equitable manner.

All requests must be submitted by the individual’s treating physician; NervGen may request additional information as necessary to fully evaluate a request. Each request will be given careful consideration by NervGen. Physicians seeking expanded access for an individual should submit requests to EAP@nervgen.com. Requests should include sufficient information to permit evaluation in accordance with this policy. NervGen will acknowledge receipt of a request within five (5) business days. This policy may be updated from time to time and does not create or imply any contractual obligation.