



**EPINEURON**  
TECHNOLOGIES

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Epineuron Technologies, Inc. is a Canadian medical device company developing new treatment strategies for treating peripheral nerve injuries. In mid-2018 the US Food and Drug Administration (FDA) granted a Breakthrough Device Designation for the company's temporary peripheral nerve stimulation (TPNS) system.

The FDA Breakthrough Device Designation program is intended to provide patients with more timely access to devices that offer significant advantages over existing alternatives that treat life-threatening, or irreversibly debilitating, diseases or conditions, and which no approved or cleared alternative exists. The program allows companies to benefit by allowing for priority review of regulatory submissions and more timely and interactive engagement with the FDA to facilitate efficient development of the device.

Epineuron is one of the first Canadian companies to have a lead product be designated as a Breakthrough Device by the FDA. The new device is a temporary wearable that delivers a single, 1-hour dose of neuroregenerative therapy that improves sensory and motor function.

"Having the FDA grant Epineuron a Breakthrough Device Designation provides important validation that peripheral nerve injuries can be irreversibly debilitating for patients and that there currently are no adjunctive therapies to help patients recover," said Michael Willand, PhD, CTO and Co-Founder of Epineuron. "The existing clinical data in over 100 patients clearly demonstrates the effectiveness of neuroregenerative therapy. We are excited to bring this product to market and we believe that neuroregenerative therapy can accelerate patient recovery and reduce long-term healthcare costs"

Sergio Aguirre, Co-Founder and CEO of Epineuron, added, "With the FDA's recognition of the potential clinical benefit our system delivers and an avenue for faster market access, we are calling on surgeons and clinical partners to connect with us and join a growing number of collaborators as we explore studies across the spectrum of nerve injury. Unifying around the problem and our solution will be to the benefit of the approximately 1 million patients affected by nerve injury every year."

### **About Peripheral Nerve Injuries**

Peripheral nerve injuries are a common condition affecting millions of individuals each year. These injuries pose a broad range of symptoms, ranging from mild discomfort to life-long impairment, that greatly impact the quality of life, psychological well-being, and earning potential of a person. Traditional treatment for these injuries is limited to surgery, however, recovery of function still remains a long and uncertain process. Outside of surgery, there are no adjunctive therapies, such as drugs or devices, to enhance patient outcomes making this a widely recognized unmet clinical need.

### **About Neuroregenerative Therapy**

Over the last 20 years, numerous studies in animals and four human clinical trials have elucidated the appropriate stimulation parameters, therapeutic dosage, mechanism of action, effect on motor and sensory neurons, and clinical utility of brief electrical stimulation of injured nerves to accelerate their regeneration, so called neuroregenerative therapy. The single 1-hour "dose" of treatment results in significantly earlier and greater tissue reinnervation and significantly improved functional outcomes. The therapy works by increasing intracellular calcium levels of the neuron, which triggers an increase in biochemical precursors that result in the upregulation of growth associated genes (GAG). The upregulation of GAGs enhances transcription of proteins that form the building blocks of regenerating axons, promoting the outgrowth of the injured nerve.