GTX medical Granted FDA Breakthrough Device Designation for Go-2 Targeted Epidural Spinal Stimulation (TESS) System

Eindhoven, NL and Lausanne, CH: June 9, 2020 - GTX medical (GTX), today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its implantable Go-2 system which was designed to promote the recovery of leg motor functions and neurological control in adults with spinal cord injuries (SCI) and paralysis.

The Go-2 System provides Targeted Epidural Spinal Stimulation (TESS) therapy, promoting the recovery of leg motor functions and neurological control in adults with spinal cord injuries (SCI). Specifically, the device is designed to improve the reconnection of the brain with paralyzed muscles in individuals with traumatic spinal cord injury. The Company anticipates the first clinical trial for the complete Go-2 system in humans to take place in 2021.

GTX is also developing the wearable LIFT System, a transcutaneous approach that delivers Non-invasive Electrical Spinal Stimulation (NESS) therapy to treat SCI. The Up-LIFT pivotal trial planned to start in late 2020 aims to demonstrate improved or restored upper limb and hand strength and function through mild pulses delivered through the skin. The LIFT technology received Breakthrough Device Designation in 2017.

“The FDA Breakthrough Device Designation is an important regulatory milestone and underscores the transformative potential of the Go-2 system and the unmet medical need it addresses,” commented Jan Öhrström, Chairman of the GTX Board of Directors. “With Breakthrough Device Designation for the implantable Go-2 system and for the non-invasive LIFT technology, we are now on an accelerated pathway. Both designations support our aim to expeditiously bring GTX’ innovative therapies for improving functional recovery, enhancing quality of life and independence of people with spinal cord injury.”

The FDA Breakthrough Devices Program was established to help patients receive timely access to breakthrough technologies that provide a more effective treatment option compared to the current standard of care for life-threatening, or irreversibly debilitating diseases or conditions. The designation provides GTX the opportunity to frequently interact with FDA regulatory experts, thereby gaining valuable advice during the premarket review phase, and to receiving a prioritized review of GTX’ submissions.

About GTX medical
GTX medical is a MedTech company focused on the development and commercialization of innovative therapies to accelerate and augment functional recovery and quality of life of people with spinal cord injury.

For additional information about GTX medical, please visit www.gtxmedical.com

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