

## **Encora Therapeutics Granted FDA Breakthrough Designation for Device to Relieve Tremors in Adults with Essential Tremor or Parkinson's Disease**

*—Subsequent clinical trials expected to begin in 2021—*

**Boston, MA - March 23, 2021** Encora Therapeutics, a clinical-stage medical device developer, announced it has received the U.S. Food and Drug Administration's (FDA) Breakthrough Device Designation for its patent-pending tremor reduction wearable. Per the designation granting correspondence, "The device is intended to provide vibratory stimulation to the wrist. It is indicated to aid in the transient relief of hand tremors in adults with Essential Tremor (ET) or Parkinson's Disease (PD)."

The Encora device senses and dynamically counteracts a patient's motor symptoms in real time by applying customized vibratory stimulation to the wrist.

The Breakthrough Device Program was created to accelerate the path to market for innovative medical devices which demonstrate the promise to substantially improve the standard of care for patients with life-threatening or irreversibly debilitating conditions. The program fast-tracks development, assessment, and review by creating channels for prioritized communication and interaction between developers of new technologies and the experts at the FDA.

The Centers for Medicare and Medicaid Services (CMS) also recently finalized the Medicare Coverage of Innovative Technology (MCIT) program, a new coverage pathway specifically for Breakthrough Devices. The MCIT coverage policy provides up to 4 years of Medicare coverage beginning on the date that the FDA clears or approves a Breakthrough Device. The MCIT program is planned to go into effect on May 15, 2021, subject to an ongoing period of public review.

"Current pharmacological therapies for tremor are suboptimal and most treatments with powerful effects are invasive and require brain surgery e.g. (DBS) or brain lesions (using focused ultrasound). If proven, the Encora technology could represent an exciting non-invasive improvement in the standard of care," said Dr. Jeffrey Kordower, founding member of the Michael J. Fox Foundation Scientific Advisory Board and member of the Encora Scientific Advisory Board.

"Our number one priority is, and always has been, getting life changing technology into the hands of patients," said Daniel Carballo, co-founder and CEO of Encora. "We are thrilled to have the support of the FDA as we race to bring that vision to life."

Encora expects to begin clinical trials in 2021. These trials will aim to support subsequent FDA clearance and marketing activities. The Encora team can be reached for information about participating in clinical trials via the contact form at <http://encoratherapeutics.com/>

### **About Parkinson's Disease (PD)**

Parkinson's Disease is a progressive neurodegenerative disorder that affected an estimated 1 million individuals in the U.S. in 2017.<sup>1,2</sup> PD patients experience motor and non-motor symptoms, with tremors cited as one of the most

debilitating symptoms.<sup>3</sup> Hand tremor makes countless everyday tasks such as writing, using a computer, dressing, eating, and reading extremely difficult.<sup>4</sup> Over time, as PD progresses, the decreasing ability to do everyday tasks affects PD patients' quality of life and becomes a source of significant social anxiety and embarrassment—capable of destroying patients' self-image, sense of security, and well-being.<sup>4,5</sup>

#### **About Essential Tremor (ET)**

Essential Tremor is a chronic, progressive, irreversibly debilitating neurological disorder that affects an average of 7 million individuals in the U.S. (2012), approximately 2.2% of US population.<sup>6,7</sup> ET patients have kinetic tremor (tremor produced by voluntary contraction of muscle) and postural tremor (tremor present while maintaining position against gravity)<sup>8,9</sup> that make it difficult for the patients to eat, drink, read, write, dress, and groom<sup>10</sup>. ET also interferes with the patients' jobs and causes financial problems.<sup>10</sup> The inability to perform basic daily activities to lead an independent life can lead to embarrassment, social anxiety, fatigue, and depression that negatively impact patients' self-esteem, confidence, and quality of life.<sup>11–14</sup>

#### **About Encora Therapeutics**

Encora Therapeutics is an MIT-spinout medical device development firm founded in 2019. Encora is leveraging advances in wearable technology, lightweight signal processing, and patient monitoring to provide affordable, personalized, non-invasive remedies for patients with neurological movement disorders. Encora is based in Boston, MA with active research and development efforts spread across the country.



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