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FDA approves gammaCore for treatment of pain linked to cluster headache

April 21, 2017

electroCore, a neuroscience and technology company dedicated to improving patient outcomes through technological advancement, announced today that the U.S. Food and Drug Administration (FDA) released the use of gammaCore® (non-invasive vagus nerve stimulator) for the acute treatment of pain associated with episodic cluster headache in adult patients. gammaCore transmits a mild electrical stimulation to the vagus nerve through the skin, resulting in a reduction of pain. This is the first FDA product release for electroCore in the U.S.

"Cluster headache is a rare, debilitating and difficult to treat disorder with few effective acute therapies," said Stephen Silberstein, MD, Director, Headache Center, Jefferson University, Philadelphia, PA. "The FDA release of gammaCore is an important advance in the treatment of the pain associated with cluster headache. It is a way for patients to treat their symptoms as often as they need to use the device. It does not have the side effects or dose limitations of commonly prescribed treatments or the need for invasive implantation procedures, which can be inconvenient, costly and high-risk."

The FDA release of gammaCore is based on subgroup analyses from two trials in the ACT (Non–Invasive Vagus Nerve Stimulation for the ACute Treatment of Cluster Headache) clinical trial program evaluating the safety and efficacy of gammaCore for the acute treatment of episodic cluster headache. Both trials (ACT1 and ACT2) were prospective, double-blind, placebo-controlled, randomized studies evaluating the use of gammaCore versus placebo. Results from ACT1, evaluating 85 patients with episodic cluster headache, found that 34.2% of patients experienced a reduction in pain from episodic cluster headache (defined as the percentage of patients who reported mild or no pain 15 minutes after treatment initiation with gammaCore for the first treated cluster headache attack in the study; use of rescue medication within 60 minutes was considered a treatment failure) compared to 10.6% in patients treated with placebo (p=0.008). Results from ACT2, evaluating 182 attacks in 27 patients with episodic cluster headache, also found that a significantly higher percentage of attacks were pain-free (defined as pain-free at 15 minutes after the onset of pain from cluster headache with no use of rescue

medication through the 30-minute treatment period) in patients treated with gammaCore (47.5%) versus placebo (6.2%; p=0.003). In both trials, gammaCore was found to be safe and well-tolerated, with the majority of adverse events (AEs) being mild and transient and occurring during the time of active treatment.

"The U.S. release of gammaCore for the acute treatment of pain associated with episodic cluster headache in adult patients is a major milestone for electroCore, as it not only marks electroCore's first FDA-released product, but also underscores our company vision to improve patient outcomes through technological advancements," said Francis R. Amato, Chief Executive Officer of electroCore. "We are leading the way for the future of medicine through the development of patient-administered, non-invasive vagus nerve stimulation therapy, and we look forward to bringing gammaCore's breakthrough technology to patients in the U.S."

gammaCore is currently in use outside of the U.S., including in the European Union. In the U.S., electroCore expects commercial availability of gammaCore early in the third quarter of 2017.

About gammaCore®

gammaCore® is the first non-invasive, hand-held medical device applied at the neck that acutely treats the pain associated with episodic cluster headache in adult patients through the transmission of a mild electrical stimulation to the vagus nerve through the skin. Designed as a portable, easy-to-use technology, gammaCore can be self-administered by patients as needed to provide relief for the treatment of pain associated with episodic cluster headache without the potential side effects associated with standard of care. When placed on a patient's neck over the vagus nerve, gammaCore stimulates the nerve's afferent fibers resulting in the modification of pain signals.

gammaCore is CE-marked in the European Union for the acute and/or prophylactic treatment of primary headache (Migraine, Cluster Headache, and Hemicrania Continua) and Medication Overuse Headache in adults. gammaCore is also released/cleared, licensed, registered and/or approved in Australia, Canada, Colombia, Hong Kong, India, New Zealand, South Africa, and Vietnam. In Germany, gammaCore is distributed by Desitin.

Source:

http://www.electrocore.com/fda-releases-gammacore-the-first-non-invasive-vagus-nerve-stimulation-therapy-applied-at-the-neck-for-acute-treatment-of-pain-associated-with-episodic-cluster-headache-in-adult-patients