Having successfully completed three studies of non-invasive vagus nerve stimulation (nVNS) for prevention and treatment of cluster headache, electroCore is now expanding its clinical program with two new trials of its gammaCore nVNS therapy in episodic migraine. The first trial is focused on the prevention of migraine, and the second examines the efficacy of nVNS for the acute treatment of migraine attacks. Both are randomized, double blind, parallel group, sham-controlled studies.

The migraine prevention study, which is being run at 22 sites in six countries across Europe, will enroll up to 400 patients.Â Â Over 200 patients have been recruited so far and the study is due to be completed in 2017. The primary objective of the trial is to compare the change in the number of migraine days experienced by those using the gammaCore treatment from the change experienced by patients using a sham therapy, and specifically focused on the change during the last four weeks of the twelve-week randomized period as compared to the four-week run-in period.

The acute trial is recruiting at 10 sites across Italy.Â The first patient of up to 250 was enrolled in January. The primary outcome measure for this study is the pain-free rate for patients' first migraine attacks, measured two hours after treatment.Â This study will also be completed in 2017.

ElectroCore's nVNS therapy is delivered by placing the gammaCore device against the neck over the vagus nerve – where the carotid pulse is located. Prior scientific evidence shows that when the active device stimulates the afferent fibers of the vagus nerve, which project into the brain stem, there is a rapid and sustained change in brain chemistry characterized by the release ofÂ inhibitory neurotransmitters,Â including GABA, acetylcholine, serotonin, andÂ norepinephrine, and a decrease in the over-expression of the excitatory neurotransmitter glutamate.Â These sustained changes are believed to reducing the susceptibility of the individual to migraine attacks, and also to provide pain relief from migraines, if present.

JP Errico, CEO of electroCore, commented, "These studies are a continuation of our extensive scientific and clinical investigation of the effects of nVNS in headache. We believe that the studies will confirm both the results of previous trials into the effectiveness of nVNS in treating migraine, and clinical experiences already seen among patients using the therapy regularly."

Notes to editors

About electroCore

electroCore LLC, the New Jersey based bioelectric pharma company, is focused on developing non-invasive vagus nerve stimulation therapies (the gammaCore device) for the treatment of multiple conditions in neurology, psychiatry, gastroenterology, and respiratory fields. The company's initial target is the treatment of primary headaches (migraine and cluster headache), and the associated chronic co-morbidities of gastric motility, psychiatric, sleep, and pain disorders that drive disproportionately large direct and indirect costs within the healthcare system and society.

www.electrocoremedical.com