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NICE provides positive guidance on electroCore's gammaCore treatment for the prevention and acute treatment of migraine and cluster headache.

BASKING RIDGE, N.J: The UK's <u>National Institute of Health and Care Excellence</u> (NICE) has published guidance that

electroCore's non-invasive vagus nerve stimulation treatment

(gammaCore) for the prevention and acute treatment of migraine and cluster headache is safe and can now be used in the NHS.

The guidance issued by NICE showed that among the five separate clinical trials of gammaCore they reviewed, many patients experienced substantial and meaningful benefit from the therapy.

Among cluster headache patients, this benefit included significantly fewer headache attacks, complete headache relief in some patients within minutes of using the device, supplementary headache treatments were needed on fewer occasions, and there was an improved quality of life.

In the migraine trials reviewed, NICE found that there was pain relief in about half the patients and complete pain relief in around twenty percent of patients within two hours of using gammaCore. They also found that there was relief from sickness, sensitivity to light and noise in up to fifty percent of patients, recovery from disability in about thirty percent of patient within two hours and additional migraine treatments were only needed in about half the patients two hours after treatment.

JP Errico, CEO and founder of electroCore commented, "We are very pleased that with this guidance gammaCore can now be used across the NHS which will open up this treatment to more patients suffering from these very debilitating conditions. While these five studies

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represent a significant number of patients, we have conducted and continue to conduct a number of additional clinical trials that will be used to update NICE to advance the guidance available to patients and providers throughout the UK."

The gammaCore device, which is CE marked, is widely used across the world and is available across the UK at specialist headache clinics and through neurologists.

The treatment is easily self-administered by patients, by placing the gammaCore on the side of the neck, over the vagus nerve (where the pulse is felt), and stimulating for two minutes.ÂÂÂ Multiple doses can be administered, with a typical treatment lasting between four and six minutes. The number of treatments per day is dependent on the type of headache and treatment regimen advised by the treating clinician.

Two of the benefits of gammaCore are, first, that there are no serious side effects, particularly compared to other headache treatments (a few patients experienced a local skin irritation at the site of stimulation, but that was mild and transient), and second, that patients can take existing medications without any known drug interaction side effects. This allows the patient to decrease the use of some of their existing medications or to use combination treatments with minimal risk.

Dr Nicholas Silver, Consultant Neurologist at the Walton Centre for Neurology and Neurosurgery said: "We as specialists, very much welcome the emergence of new therapies such as gammaCore that may potentially provide safe, effective and reliable treatment, both to prevent attacks of headache and also to treat attacks when they occur. In my view, electroCore are to be congratulated on their innovation and the development of a high quality worldwide research program to find better treatments in these conditions."

A patient, Mrs Beasley said: "I am really pleased that NICE recognizes the great benefit gammaCore brings to patients with cluster headache. It has changed my life over the last three years. I tried everything including pills which made me feel terrible. The only treatment that works is gammaCore and while it has not eliminated them entirely it has reduced the incidence by more than 80 percent and I can easily live with that."

Simon Evans, the CEO of Migraine Action said: "We are really encouraged by the NICE review

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of the clinical evidence on the positive impact GammaCore can have on migraine in some patients. A non-invasive treatment, with no serious side-effects, will be welcomed by many, especially as it can be used in conjunction with existing treatments."

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.

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