Medtronic News

New Clinical Study Will Evaluate MRI-Guided Laser Ablation for a Common Form of Epilepsy

Drug-Resistant Mesial Temporal Lobe Epilepsy Is the Focus of Medtronic's SLATE Study

DUBLIN - June 17, 2016 - Medtronic plc (NYSE: MDT) announced today the U.S. Food and Drug Administration's (FDA) approval of the Investigational Device Exemption (IDE) application for the pivotal SLATE (Stereotactic Laser Ablation for Temporal Lobe Epilepsy) study. The clinical investigation is designed to support the expanded indication of the currently marketed Visualase(TM) MRI-Guided Laser Ablation Technology for treatment of epilepsy in patients with drug-resistant mesial temporal lobe epilepsy (MTLE), the most common form of partial or localization related epilepsy.

"Surgery is an effective, though underused, treatment for drug-resistant epilepsy. For some patients, laser ablation offers a minimally-invasive treatment option," said Michael Sperling, M.D., Baldwin Keyes professor of neurology at Thomas Jefferson University and director of the Jefferson Comprehensive Epilepsy Center at Thomas Jefferson University Hospital in Philadelphia, Pa. "If demonstrated to be effective, results from this clinical trial will help clinicians weigh the risks and benefits of laser ablation when discussing treatment options with their patients."

The study will include approximately 120 adult patients with drug-resistant MTLE treated at selected epilepsy centers across the United States. After the Visualase procedure, patients will be followed for 12 months and evaluated for freedom from seizures, quality of life, adverse events and neuropsychological outcomes.

"This is a significant step in collecting evidence regarding laser ablation as a treatment option for MTLE," said Robert Gross, M.D., Ph.D, MBNA/Bowman professor of neurosurgery and director, Functional, Stereotactic and Epilepsy Surgery Division at Emory University in Atlanta, Ga. "We are eager to begin enrolling patients."

Approximately three million people1 in the United States have epilepsy, and it is estimated that at least one-third become drug resistant2, continuing to have seizures regardless of the number or type of anti-epileptic drugs used.

"Uncontrolled seizures lead to a wide variety of medical consequences and can have significant lifestyle and psychosocial impacts," said Scott Hutton, vice president and general manager of the Neurosurgery business, which is part of the Restorative Therapies Group at Medtronic. "We're hopeful that people with drug-resistant MTLE can benefit from our innovative Visualase technology."

About the Medtronic Visualase(TM) System

The Visualase MRI-Guided Laser Ablation System is 510(k) cleared by the FDA to necrotize or coagulate soft tissue in neurosurgery and other surgical specialties. Through a minimally invasive procedure, laser energy is delivered to the target area using a laser applicator. As light is delivered through the laser applicator, temperatures in the target area begin to rise, coagulating the unwanted soft tissue under real-time MRI guidance.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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1http://www.cdc.gov/epilepsy/basics/fast-facts.htm/ accessed June 2016

2 Kwan P, Sander JW. The natural history of epilepsy: An epidemiological view. J Neurol Neurosurg Psychiatry. V.75(10):2004; 75: 1376-1381.

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