Study Shows Medtronic Deep Brain Stimulation Therapy for Treatment-Resistant Epilepsy Demonstrates Significant and Sustained Seizure Reduction at Five Years

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Results Also Show Sustained Safety, Intervals of Seizure Freedom, Improvements in Quality of Life and Reduction in Seizure Severity

DUBLIN - February 19, 2015 - Medtronic plc (NYSE: MDT) today announced five-year results from the pivotal SANTE (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy) trial, the largest clinical study of deep brain stimulation (DBS) therapy for epilepsy in adults with treatment-resistant (refractory) epilepsy characterized by partial-onset seizures. The results, which were recently published online by Neurology and will be printed in their March 2015 issue, include safety, efficacy and quality of life outcomes associated with long-term Medtronic DBS Therapy.

SANTE study results at five years include: [i]

- Medtronic DBS Therapy for Epilepsy was associated with a sustained and statistically significant reduction in seizure frequency from baseline that continued to improve over time: 69 percent median seizure reduction from baseline at five years and 41 percent at one year ($p<0.001$ for both time points).
- The percentage of responders (patients with seizure reduction of 50 percent or greater) was 68 percent at five years and 43 percent at one year.
- A seizure-free interval of at least six months during five years of therapy was reported by 16 percent of patients.
- Statistically significant seizure severity and quality of life improvements were observed over baseline at five years and one year as measured by the Liverpool Seizure Severity Scale (LSSS) and Quality of Life measure (QOLIE-31) ($p<0.001$ for both measures).
- The most common serious adverse event through five years was implant site infection, with a rate of 10 percent.
- There were no device-related deaths and no unanticipated adverse device effects. Device-related implantation problems were reversible and as expected with this surgical procedure.

Medtronic DBS Therapy for Epilepsy uses a surgically implanted medical device, similar to a cardiac pacemaker, to deliver electrical stimulation to a target in the brain called the anterior nucleus of the thalamus, which has strong connections to other parts of the brain where seizures begin. Medtronic DBS Therapy is approved in more than 30 countries, including Canada, Australia and countries in the European Union, as adjunctive treatment for partial-onset seizures in adults with medically-refractory epilepsy. This therapy is not approved by the U.S. Food and Drug Administration (FDA) for commercialization in the United States. Medtronic is working to obtain commercial approval of the therapy in the United States.

"The latest SANTE study findings provide important insights into the long-term benefits of DBS therapy, which are encouraging for patients with severe partial epilepsy who are resistant to other treatments and are not candidates for resective epilepsy surgery," said Vicenta Salanova, M.D, Professor of Neurology, Indiana University School of Medicine and lead author of the publication. "Long-term treatment efficacy is critical for people suffering from epilepsy, and it is particularly remarkable that DBS therapy is helping treatment-resistant patients to achieve sustained reduction in seizure frequency and severity over time while also leading to meaningful improvements in quality of life."

Epilepsy is estimated to affect 50 million people worldwide,[ii] including approximately 2.3 million adults in the United States[iii] and 6 million people in Europe.[iv] At least 30 percent of epilepsy is considered refractory, which is generally diagnosed after two anti-epileptic drugs fail to control seizures.[v]

"The SANTE trial continues to provide the medical community with valuable, real-world insight into the benefits of DBS

therapy for people with refractory epilepsy," said Lothar Krinke, Ph.D., vice president and general manager of the Brain Modulation business at Medtronic. "We are committed to providing physicians and researchers worldwide with robust clinical and pre-clinical data, including comprehensive registries, to help appropriate severe epilepsy patients who have not been successful with other treatments. We also continue to work with the FDA to make this therapy available to the right patients in the United States."

About the SANTE Study

The SANTE trial is a prospective, randomized, double-blind pivotal study to evaluate the use of DBS therapy for patients with medically-refractory epilepsy characterized by partial-onset seizures. Five-year data from the study were initially presented as a poster at the American Epilepsy Society meeting in December 2012, and comprehensive results are now being published for the first time in a peer-reviewed journal, Neurology. Previously, two-year data from the study were published in the journal, Epilepsia, in May 2010.[vi]

About Medtronic DBS Therapy

Medtronic DBS Therapy is currently approved in many locations around the world, including Europe and the United States, for the treatment of the disabling symptoms of essential tremor, advanced Parkinson's disease and chronic intractable primary dystonia, for which approval in the United States is under a Humanitarian Device Exemption (HDE). Medtronic DBS Therapy is also approved for the treatment of severe, treatment-resistant obsessive-compulsive disorder in the European Union and Australia, and in the United States under an HDE.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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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References:

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