Medtronic News

Medtronic Receives European CE Mark Approval for Deep Brain Stimulation Therapy for Refractory Epilepsy

Further Clinical Study Required for Application to U.S. Food and Drug Administration

MINNEAPOLIS, Sep 16, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced that the company has received CE (*Conformité Européenne*) Mark approval for Medtronic Deep Brain Stimulation (DBS) Therapy in Europe as adjunctive treatment for partial-onset seizures in adults with medically refractory epilepsy. DBS therapy for epilepsy delivers controlled electrical pulses to a target in the brain called the anterior nucleus of the thalamus, which is part of a circuit involved in seizures.

"Epilepsy that is refractory to current medical treatment is a severe, unsolved problem," said Prof. Eugen Trinka, M.D., M.Sc., head of Neurology at the University Hospital, Christian Doppler Klinik, Salzburg, Austria. "DBS therapy for epilepsy will be an important new treatment option for many patients in Europe with severe epilepsy who are not able to control their seizures with currently available drugs."

The CE Mark approval was based on data collected in Medtronic's clinical trial called SANTÉ(R) (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy). The SANTÉ trial was a prospective, randomized, double-blind pivotal study to evaluate the use of DBS therapy for patients with medically refractory epilepsy with partial-onset seizures. The trial collected data from 110 patients who were implanted with a Medtronic DBS system at 17 U.S. centers. Long-term data from the study were presented at American Epilepsy Society (AES) meetings in December 2008 and 2009, and were published in the journal, *Epilepsia,* in March 2010. Based on the CE Mark, Medtronic will be introducing its DBS Therapy for Epilepsy in expert epilepsy centers across Europe by the end of the year.

Medtronic DBS Therapy for refractory epilepsy is investigational in the United States and is under review by the U.S. Food and Drug Administration (FDA). FDA recently requested additional data to support Medtronic's premarket approval (PMA) application, which will require further clinical study.

"This CE Mark is the first approval by a regulatory agency for the use of DBS therapy in severe epilepsy and provides a new treatment option for patients in Europe who are in need of other options," said Tom Tefft, senior vice president of Medtronic, Inc., and president of the Neuromodulation business unit. "In the United States, we remain committed to working with FDA to determine the most appropriate path forward."

Medtronic DBS therapy is currently approved in Europe and the United States for the treatment of the disabling symptoms of essential tremor and advanced Parkinson's disease. The therapy also is approved in Europe for dystonia and obsessive-compulsive disorder (OCD). In the United States, the use of DBS for dystonia and treatment-resistant OCD is approved under a Humanitarian Device Exemption (HDE). More than 75,000 people worldwide have received Medtronic DBS therapy.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, 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.

SOURCE: Medtronic, Inc.

Medtronic, Inc.
Jon Pike, +44 1923 212213
Public Relations
or
Cindy Resman, 763-526-6248
Public Relations
or
Jeff Warren, 763-505-2696
Investor Relations

---

https://news.medtronic.com/2010-09-16-Medtronic-Receives-European-CE-Mark-Approval-for-Deep-Brain-Stimulation-Therapy-for-Refractory-Epilepsy