



## NEWS RELEASE

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### FOR IMMEDIATE RELEASE

## FDA PANEL RECOMMENDS APPROVAL WITH CONDITIONS OF MEDTRONIC DEEP BRAIN STIMULATION THERAPY FOR PATIENTS WITH REFRACTORY EPILEPSY

**MINNEAPOLIS – MARCH 12, 2010** – The U.S Food and Drug Administration (FDA) Neurological Devices Panel today voted seven to five to recommend approval with conditions of Deep Brain Stimulation (DBS) Therapy for Epilepsy from Medtronic, Inc. (NYSE: MDT) as adjunctive treatment for partial-onset seizures in adults with medically refractory epilepsy. If the FDA follows the recommendation of the panel, the therapy will be approved for the treatment of epilepsy in patients who have continued seizures with inadequate response to currently available epilepsy treatments.

“Epilepsy and its unpredictable seizures can have a major impact on work, school, family life and social functioning, especially for the estimated one-third of individuals who continue to have seizures despite trying a range of treatment options,” said Robert Fisher, M.D., Ph.D., professor of neurology and director of the Stanford Epilepsy Center in Palo Alto, Calif. “Today’s FDA expert panel recommendation affirms that potential benefits outweigh risk for appropriate patients with refractory epilepsy. This new therapy would be a welcome addition to our treatment possibilities.”

The panel recommended approval with conditions, including a post-approval study for long term follow up and labeling requirements. The FDA panel reviewed data from a U.S. clinical trial called SANTE® (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy) involving 110 patients from 17 U.S. trial centers who had severe epilepsy for an average of 22 years prior to study enrollment.

“We are pleased with the FDA panel’s recommendation today and will work closely with the FDA to address the conditions of approval so that we are able to bring expanded DBS Therapy to market in the United States,” said Tom Tefft, senior vice president of Medtronic, Inc., and president of the Neuromodulation business unit.

“We’re proud to partner with leading research centers and physicians to continue the pursuit of appropriate applications for DBS therapy for the benefit of patients.”

### **About Medtronic DBS Therapy**

DBS therapy uses a pacemaker-like device to deliver individualized, targeted and precise electrical stimulation to a specific target in the brain called the anterior nucleus of the thalamus, which is part of a circuit involved in seizures. Small electrical pulses delivered from the neurostimulator can be programmed to automatically provide therapy at specific times for a patient and the settings can be non-invasively adjusted with a physician programmer. The therapy is also reversible and can be turned off or removed at any time.

Medtronic DBS Therapy is currently approved by the FDA for the treatment of the disabling symptoms of essential tremor and advanced Parkinson's disease. The therapy also is approved under a Humanitarian Device Exemption (HDE) for the treatment of dystonia, and chronic, severe, treatment-resistant obsessive-compulsive disorder. More than 75,000 people worldwide have received Medtronic DBS Therapy.

## **About Epilepsy**

According to the Epilepsy Foundation, epilepsy and seizures affect more than three million Americans of all ages, at an estimated annual cost of \$12.5 billion in direct and indirect costs. Despite trying a range of treatment options, about one-third of people with epilepsy cannot adequately control their seizures or tolerate other available therapies. The unpredictability of seizures significantly affects a patient's life and daily activities.

## **About Medtronic**

Medtronic, Inc. ([www.medtronic.com](http://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. Actual results may differ materially from anticipated results.**

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