Medtronic News

Medtronic Announces Japanese Regulatory Approval for Micra(TM) Transcatheter Pacing System (TPS)

DUBLIN - Feb. 17, 2017 - Medtronic plc (NYSE: MDT) today announced Japan regulatory approval for the world's smallest pacemaker, the Micra(TM) Transcatheter Pacing System (TPS). Japan's Pharmaceuticals and Medical Device Agency (PMDA) granted approval for Micra based on positive data from the Medtronic Micra TPS Global Clinical Trial, which enrolled 744 patients and evaluated the safety and efficacy of the device through a single-arm, multi-center study at 56 centers in 19 countries, including Japan.

Approved by the U.S. Food and Drug Administration (FDA) in April 2016 for patients who need a single-chamber pacemaker, the Micra TPS is the first and only leadless pacemaker approved for use in the United States. Micra was recently named at the top of US News & World Report's list of "2016's Biggest Achievements in Medicine." It is approved for both 1.5 and 3 Tesla full-body magnetic resonance imaging (MRI) scans.

"The development of a leadless pacemaker which can be implanted with a less invasive procedure has been eagerly awaited by physicians and patients in Japan," said Kyoko Soejima, M.D., professor of cardiovascular internal medicine at Kyorin University. "The safety and efficacy of the Micra TPS has been confirmed in my hospital as well as in other hospitals across the world that took part in the Micra TPS Global Clinical Trial."

Comparable in size to a large vitamin, the Micra TPS is less than one-tenth the size of traditional pacemakers, yet delivers the most advanced pacing technology to patients via a minimally-invasive approach. During the implant procedure, it is attached to the heart with small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device.

Unlike traditional pacemakers, the Micra TPS does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to such leads and pocket are eliminated - as are any visible signs of the device.

"Medtronic is excited to be the first to offer a miniaturized, leadless pacemaker to patients in Japan," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division. "We look forward to working with Japan's Ministry of Health, Labor and Welfare to gain reimbursement for Micra so patients can gain access to this innovative technology as quickly as possible."

The Micra design incorporates a retrieval feature which can be enabled when possible; however, the device is designed to be left in the body. For patients who need more than one device, the miniaturized Micra TPS can be permanently turned off, allowing it to remain in the body so a new device can be implanted without risk of electrical interaction.

Preliminary results from the Medtronic Micra TPS Global Clinical Trial, published in the*New England Journal of Medicine,* showed the Micra TPS was successfully implanted in 99.2 percent of patients and that the system met its safety and effectiveness endpoints with wide margins. In August 2016, new long-term data presented in a late-breaking clinical trial at the European Society of Cardiology congress continued to reinforce these results, demonstrating consistent and sustained outcomes from early performance through 12-month follow-up.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

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 88,000 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.

-end-

Contacts:
Ryan Mathre
Public Relations
+1-763-514-9625

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2017-02-17-Medtronic-Announces-Japanese-Regulatory-Approval-for-Micra-TM-Transcatheter-Pacing-System-TPS