Medtronic News

Data Reinforce Reduced Complications with Medtronic Micra Transcatheter Pacing System Over Traditional Pacemakers in Real-World Use

Results Presented at Heart Rhythm 2018 Also Show Leadless Pacemaker is Safe Option for Patients with Past Device Infection

DUBLIN and BOSTON - May 9, 2018 - Medtronic plc (NYSE: MDT) today announced that results through 12-months from the Post-Approval Registry (PAR) for the Medtronic Micra(TM) Transcatheter Pacing System (TPS), reinforcing the high implant success rate and low complication rate seen since its U.S. approval two years ago, will be presented on Thursday, May 10 at Heart Rhythm 2018, the Heart Rhythm Society's 39th Annual Scientific Sessions in Boston.

The smallest pacemaker in the world, Micra TPS is the only leadless pacemaker approved in the U.S. New data from the PAR study showed Micra TPS in clinical practice had an implant success rate of 99.1 percent. The PAR study also showed a low major complication rate (2.7 percent) through 12 months post-implant (95 percent CI: 2.0 percent - 3.6 percent), with a 63 percent lower risk for major complication ($P<0.001$) compared to traditional pacing systems. Additionally, the risk for major complication trended lower in the Micra Post-Approval Registry than in the investigational study (HR: 0.71, 95 percent CI: 0.44-1.1; P=0.160).

"The results from the post-approval registry are consistent with the positive outcomes reported with previous Micra TPS data," said Mikhael El-Chami, M.D., director of electrophysiology at Emory Midtown and associate professor of medicine at Emory University School of Medicine in Atlanta. "The high implant success and low major complication rates in a real-world patient population with new Micra implanters reinforce the safety and performance of the Micra TPS."

PAR data also show that Micra TPS is a safe and feasible pacing option for patients with a recent cardiac implantable electronic device (CIED) infection. Among patients in the Micra PAR who previously had a traditional pacemaker explanted due to infection, 98 of 99 patients underwent a successful Micra implant attempt (99 percent implant success rate). No patients who received a Micra device experienced infections that required removal.

"By eliminating the need for leads and a subcutaneous pocket, miniaturized leadless pacemakers are associated with a low-risk of device-related infection," said Dr. El-Chami. "These new data show that this novel technology may provide a safe option for patients with prior device-related infections."

The global Micra PAR is a prospective single-arm observational study designed to assess the safety and effectiveness of the Micra TPS in the post-approval setting. PAR data presented at Heart Rhythm 2018 were from an analysis of 1,817 patients at 179 centers across 23 countries worldwide, which assessed system or procedure-related major complications through 12 months following implant. These rates were then compared to the major complication rates of the Micra IDE and to a reference dataset of 2,667 patients implanted with a transvenous pacemaker.

"Medtronic is committed to providing the most advanced technologies that improve lives of patients around the world," said Rob Kowal, M.D., Ph.D., vice president and chief medical officer of the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. "The leadless Micra pacemaker is an excellent example of one of those technologies, and now we know that it performs well for patients in a real world setting as well as in a clinical trial."

About the Micra Transcatheter Pacing System (TPS)

Approved by the U.S. Food and Drug Administration 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 U.S. 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.

The Micra design incorporates a retrieval feature which can be enabled, if necessary; 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. The Micra TPS is the first and only leadless pacing system to be approved for both 1.5 and 3 Tesla full-body magnetic resonance imaging (MRI) scans.

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. Medtronic 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 84,000 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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