Medtronic News

New Medtronic Study Reinforces Safety and Performance of the World's Smallest Pacemaker in a Real-World Patient Population

HRS Late-Breaking Trial Reveals High Implant Success Rate and Low Early Major Complication Rate for the Medtronic Micra® Transcatheter Pacing System (TPS)

DUBLIN and CHICAGO - May 11, 2017 - Medtronic plc (NYSE: MDT) today announced preliminary results for the Medtronic Micra® Transcatheter Pacing System (TPS) Post-Approval Registry, revealing a 99.6 percent implant success rate and a low rate of major complications (1.51 percent) at 30 days in a diverse, real-world patient population. The study was presented in a late-breaking clinical trial session at Heart Rhythm 2017, the Heart Rhythm Society's 38th Annual Scientific Sessions, and simultaneously published in *Heart Rhythm*.

"It is encouraging to see these strong outcomes with such a novel technology in the hands of new implanting physicians," 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 reinforce the positive results seen in the investigational Micra clinical trial."

The global Micra Post-Approval Registry is an ongoing, prospective single-arm observational study designed to assess the safety and effectiveness of the Micra TPS in the post-approval setting. Data presented at HRS were from an interim analysis of 795 patients treated by 149 physicians at 97 centers across 20 countries worldwide, which assessed system or procedure-related major complications through 30 days following implant. These rates were then compared to the major complication rates of the Micra Investigational Device Exemption study (IDE).

More than 20 percent of patients in the Micra Post-Approval Registry study had at least one condition that did not allow the use of a transvenous pacemaker including history of infection or compromised venous access. Nearly 87 percent of the physicians in the analysis were new implanters with no previous experience with Micra.

Major complications were low, with 1.51 percent of patients experiencing a major complication at 30 days post-implant (95 percent CI: 0.78 percent to 2.62 percent). There were low rates of cardiac perforation or prefusion (0.13 percent), device dislodgement (0.13 percent), and infection (0.13 percent), and no (0 percent) major complications related to battery or telemetry issues. When compared to the IDE study, the rate of major complications in this real-world registry trended lower after adjusting for differences in baseline patient characteristics (1.51 percent vs. 2.89 percent; Odds Ratio=0.59, 95 percent CI: 0.27, 1.27; P=0.18).

"These positive early data in the post-market setting reinforce the careful attention that went into the design of the Micra TPS and the rigorous training program we have put in place for new implanting physicians of the device," said Rob Kowal, M.D., Ph.D., vice president and medical director of the Cardiac Rhythm and Heart Failure Division at Medtronic. "We look forward to sharing additional outcomes as we gain even more experience through this post-market registry."

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 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.

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. It is designed to allow patients to be followed by their physicians and send data remotely via the Medtronic CareLink® Network. Remote monitoring of Micra devices is expected to be available in the U.S. later this year.

Primary results from the Medtronic Micra TPS Global Clinical Trial, published in November 2015 in the*New England Journal of Medicine*, showed the Micra TPS was successfully implanted in 99.2 percent of patients by 94 physicians around the world and that the system met its safety and effectiveness endpoints at six months follow-up with wide margins. Long-term results from the Micra Trial, published in November 2016 in *Heart Rhythm*, reinforced these data, showing the risk of major complications at 12 months for Micra patients was low at four percent, 48 percent lower than for patients with traditional pacemakers (hazard ratio: 0.52, 95 percent CI: 0.35-0.77, P=0.001).

Second Medtronic-Sponsored Late Breaker Presented Today: ADVANCE III

The ADVANCE III (Avoid Delivering Therapies for Non-Sustained Arrhythmias in ICD Patients III) trial evaluated the effects of implantable cardioverter defibrillators (ICDs) waiting to deliver therapy to terminate irregular heart rhythms. Presented by Maurizio Gasparini, M.D., of Milan, Italy, and published simultaneously in the *Journal of the American College of Cardiology: Clinical Electrophysiology*, results showed that optimized device programming, which combined a long-detection setting with ATP During Charging(TM), significantly reduced unnecessary ICD therapies, reduced hospitalizations, and improved survival in patients with single chamber ICDs.

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.

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Contacts:
Ryan Mathre
Public Relations

+1-651-335-2338

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

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