Medtronic News

New Long-Term Data Reinforce Safety Benefits of the World's Smallest Pacemaker

Results Featured at ESC 2016 Demonstrate Consistent, Sustained Safety and Effectiveness for the Medtronic Micra TPS

DUBLIN and ROME - AUGUST 28, 2016 - In the largest and longest clinical evaluation of leadless pacing patients to date, Medtronic plc (NYSE: MDT) today announced new long-term results from the Medtronic Micra® Transcatheter Pacing System (TPS) Global Clinical Trial in a clinical trial update late-breaking session at the 2016 European Society of Cardiology (ESC) Congress in Rome.

The Micra TPS is less than one-tenth the size of traditional pacemakers and is the only leadless pacemaker approved for use in both the U.S. and Europe. Data presented today at ESC showed that the risk for major complications with the Micra TPS remained consistently low, with 96 percent of patients experiencing no major complications through 12 months follow-up (95 percent CI, 94.2 percent-97.2 percent, P<0.0001). The Micra TPS reduced the risk of major complications by nearly half (48 percent; hazard ratio = 0.52, P=0.001) compared to conventional systems and the risk was lower across all patient sub-groups, whether measured by age, sex or comorbidity (all hazard ratios < 1.0).

The overall reduction in major complications with the Micra TPS was associated with a 47 percent decrease (p=0.017) in the risk of hospitalization and 82 percent (p<0.001) reduction in risk of system revisions (meaning extraction, repositioning or replacement) compared to conventional pacing systems. These reductions were largely due to the elimination of complications such as pneumothoraces (air between the lungs and chest wall), the absence of Micra dislodgements and device infections.

"The Micra TPS has consistently demonstrated strong effectiveness and safety benefits in patients with diverse comorbidities," said Philippe Ritter, M.D., principal investigator of the Micra TPS Global Clinical Trial and cardiologist at University Hospital of Bordeaux. "All pre-specified safety and efficacy objectives from the trial were met, with consistent findings from early performance, six-month, and 12-month data."

Micra battery projections continue to perform in-line with conventional pacemaker systems. Based on 644 patients with 12-month device use conditions available, Micra yielded a projected average longevity of more than 12 years.

"The Micra TPS continues to deliver safe and effective pacing, while also providing a less invasive alternative to conventional pacemakers," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division. "The Micra TPS has also shown a significant reduction in healthcare utilization compared to conventional pacemakers, which is promising for clinicians looking to adopt cost-effective therapies to improve patient outcomes."

In November 2015, preliminary results from the Medtronic Micra TPS Global Clinical Trial were published in the *New England Journal of Medicine*, which 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. The 12-month data presented today at ESC continues to reinforce these results, demonstrating consistent and sustained results from early performance through 12-month follow-up.

The Micra TPS is comparable in size to a large vitamin, 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 also incorporates a retrieval feature to enable retrieval 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 was designed with a unique feature that enables it to be permanently turned off so it can remain in the body and a new device can be implanted without risk of electrical interaction.

The Micra TPS was awarded CE Mark in April 2015 and U.S. Food and Drug Administration approval in April 2016. It is intended for use in patients who need a single-chamber pacemaker. The Micra TPS is the first and only leadless pacing system to be approved for both 1.5 and 3 Tesla (T) full-body magnetic resonance imaging (MRI) scans, providing patients with access to the most advanced imaging diagnostic procedures available. The device was 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 available in Europe and expected to be available in the U.S. later this year.

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
+1-651-335-2338

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

---

https://news.medtronic.com/2016-08-28-New-Long-Term-Data-Reinforce-Safety-Benefits-of-the-Worlds-Smallest-Pacemaker