Medtronic News

New Data Further Demonstrate Safety Benefits for World's Smallest Pacemaker

Data Featured In Late-Breaking Trial Session at Cardiostim 2016 Show Micra TPS Safety Benefits Maintained Beyond Six Months

DUBLIN and NICE, FRANCE - JUNE 9, 2016 - Medtronic plc (NYSE:MDT) today announced new results from the Medtronic Micra® Transcatheter Pacing System (TPS) Global Clinical Trial in a late-breaking trial session at CARDIOSTIM / EHRA EUROPACE 2016, the World Congress in Electrophysiology and Cardiac Techniques, in Nice, France.

The new follow-up data on patients enrolled in the pre-market Micra TPS Global Clinical Trial underscore the safety benefits of the Micra TPS, with only 3.7 percent of patients (27 of 726; Kaplan-Meier estimate) experiencing a major complication, and no patients (0) experiencing a device dislodgement, at 7.7 months of follow-up.

The results showed that at 7.7 months, the risk for major complications with Micra is significantly lower - 52 percent lower - than the risk associated with conventional pacing systems (hazard ratio: 0.48; 95 percent CI, 0.32 to 0.72; $P<0.001$). In addition, the risk for major complications was lower for the Micra TPS relative to conventional systems across all patient sub-groups, whether measured by age, sex or comorbidity (all hazard ratios < 1.0).

"Clinicians are extremely pleased that the evidence continues to demonstrate the strong safety profile of the Micra for all patient groups," said Dr. Gabor Duray, head of Clinical Electrophysiology and Pacing, State Health Center, Budapest, Hungary. "These data provide the largest sample and the longest follow-up reported for this technology to date. We look forward to further evaluating this minimally invasive, leadless option in patients across the world."

The Micra TPS is less than one-tenth the size of traditional pacemakers and the only leadless pacemaker approved for use in both the U.S. and Europe. 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.

At 7.7 months, Micra TPS continued to provide low and stable pacing thresholds, yielding projected average longevity for the device of more than 12 years based on device use conditions through six-months on 590 patients. This longevity rate is similar to conventional pacing systems (references Hauser, et al Heart Rhythm 2007 and Senaratne, et al PACE 2006).

In November 2015, preliminary results from the Medtronic Micra TPS Global Clinical Trial were published in the *New England Journal of Medicine* and presented during a late-breaking Special Report at the American Heart Association Scientific Sessions. Data showed the Micra TPS was successfully implanted in 99.2 percent of patients and the system met its safety and effectiveness endpoints with wide margins. Data from beyond six months, presented today at Cardiostim 2016, reinforced these results with no (0) dislodgments, and no (0) systemic infections. These low complication rates were achieved despite the inclusion of high-risk patients in the study worldwide, including patients with chronic obstructive pulmonary disease (COPD).

"The Micra delivers vital pacing therapy to patients, while also providing a less invasive alternative than other pacemaker therapies on the market," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division. "This novel technology continues to demonstrate a low rate of major complications, both during and after implant, in a diverse group of patients. We're pleased these new longer-term data further underscore the safety profile of Micra."

Micra's design 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 (FDA) approval in April 2016. It is intended for use in patients who need a single-chamber pacemaker. Micra 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 expected to be available 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 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 85,000 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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