

World's Smallest Pacemaker, Medtronic Micra TPS, Featured in Late-Breaking Trial Session at EUROPACE 2015

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Global clinical trial finds Medtronic Micra Transcatheter Pacemaker Meets Initial Safety and Performance Measures

DUBLIN and MILAN - June 22, 2015 - Medtronic plc (NYSE: MDT) today reported study results of its Micra® Transcatheter Pacing System (TPS) at a late-breaking clinical trials session at EHRA EUROPACE-CARDIOSTIM 2015 in Milan. The study results demonstrated that the miniaturized pacemaker met initial safety and performance measures in its global clinical trial.

Of the first 140 patients who received the Micra TPS, 100 percent were successfully implanted. At one- and three-month follow ups, all patients had mean electrical pacing measurements within expected ranges.

"The initial results for this novel device are quite promising, and similar to results seen with conventional pacemakers," said Philippe Ritter, M.D., principal investigator of the Micra TPS Global Clinical Trial and cardiologist at University Hospital of Bordeaux. "Patients in this study have fared very well, and if the strong safety and performance profile of the Micra TPS continues with more patients and over the long-term, this transcatheter pacing therapy will prove to be a simpler, less-invasive pacemaker option while maintaining therapy effectiveness."

The first 140 patients in the Medtronic Micra TPS Global Clinical Trial were implanted by 37 physicians at 23 sites across Asia-Pacific, Europe and the United States. They spanned a wide variety of patient profiles such as age (from 21 to 94 years), weight (ranging from 41 to 148 kilograms), and residence (including Asia-Pacific, Europe and the U.S.). Patients considered to be at high risk also participated in the study, including patients with lung disease such as COPD (chronic obstructive pulmonary disease) and pulmonary hypertension.

Of the 140 patients followed for an average of 1.9 months, eight patients experienced a serious adverse event and most of these were easily managed; only two patients (1.4 percent) experienced events which resulted in prolonged hospitalization. This rate is in line with rates observed in studies of traditional pacemakers.¹ Importantly, there were no infections or dislodgments, and no events required surgical re-operation or resulted in death. Further, there were no (0) unanticipated serious adverse device events (assumed <5 percent).

Testing of electrical performance at three months showed the pacing threshold was lower (0.51V at 0.24ms) than the pre-specified performance objective (<2.0V at 0.24ms), resulting in an expected average longevity of at least 10 years.

These initial results from the clinical trial also were published in the *European Heart Journal*, *Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study*.²

At less than one-tenth the size of traditional pacemakers, the Micra TPS provides the most advanced pacing technology available while being cosmetically invisible and small enough to be delivered with minimally invasive techniques through a catheter, and implanted directly into the heart. The small size and short length of the Micra device allows physicians to implant more than one device within the heart, if needed.

Comparable in size to a large vitamin, the Micra TPS does not require the use of wires, known as "leads," to deliver pacing therapy; rather, it is attached to the heart via small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device. Once positioned, the Micra TPS can be repositioned or retrieved, if needed. The device responds to patients' activity levels by automatically adjusting therapy. Micra TPS also is the first transcatheter pacing system to be awarded CE (Conformité Européenne) Mark for 1.5T and 3T full body MRI scanning, providing patients

with access to the most advanced imaging diagnostic procedures.

Unlike traditional pacemakers, the Micra TPS does not require a surgical "pocket" under the skin, so potential sources of complications from this type of implantation are eliminated-as are any visible signs of the device.

The Micra TPS was commercially launched in Europe earlier this month after being awarded CE (Conformité Européenne) Mark based on data from the Medtronic Micra TPS Global Clinical Trial. The trial is ongoing and will continue to evaluate the safety and efficacy of the device through a single-arm, multi-center study that has enrolled more than 700 patients at 56 centers in 19 countries.

In the United States, the Micra TPS is an investigational device and not yet approved for commercial use.

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 the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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1 Udo et al. FOLLOWPACE. *Heart Rhythm* 2012;9:729

2 European Heart Journal, doi:10.1093/eurheartj/ehv214

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