

## Global Clinical Trial Finds Medtronic Micra® Transcatheter Pacemaker Meets Initial Safety and Performance Measures

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*Initial Safety and Performance Data of World's Smallest Pacemaker Featured in Late-Breaking Session at Heart Rhythm 2015*

**DUBLIN and BOSTON - May 15, 2015** - Medtronic plc (NYSE: MDT) today announced study results of its Micra® Transcatheter Pacing System (TPS), which demonstrated that the miniaturized pacemaker has met its initial safety and performance measures. In the largest report to date of a transcatheter pacing system, 100 percent of the first 140 patients who received the Micra TPS experienced a successful implant procedure, and mean electrical pacing measurements at all patient visits (one- and three--month follow up) were within expected ranges. These data, from the Medtronic Micra TPS Global Clinical Trial, were presented today during a Late-Breaking Clinical Trials session at Heart Rhythm 2015, the Heart Rhythm Society's 36th Annual Scientific Sessions in Boston.

"These initial data are quite promising, as patients in this study have fared very well with this novel device," said Philippe Ritter, M.D., principal investigator of the Micra TPS Global Clinical Trial and cardiologist at University Hospital of Bordeaux. "If the strong safety and performance profile of the Micra TPS that we've seen so far persists over the long-term and in more patients, this transcatheter pacing therapy will prove to be an effective but simpler and less-invasive pacemaker option for many patients."

The first 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.

The 140 patients spanned a wide variety of patient profiles, including high-risk 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.<sup>1</sup> 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.

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 are eliminated-as are any visible signs of the device.

The Micra TPS was awarded CE (Conformité Européenne) Mark in April 2015 based on the 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](http://www.medtronic.com)), headquartered in Dublin, 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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<sup>1</sup> : Udo et al. FOLLOWPACE. *Heart Rhythm* 2012;9:729

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