Global Trial Finds Medtronic Micra® Transcatheter Pacemaker Meets Initial Safety Measures in Wide Range of Patients

May 14, 2015 12:30 PM CT

Initial Safety Data on World's Smallest Pacemaker Presented at Heart Rhythm 2015

DUBLIN and BOSTON - May 14, 2015 - Medtronic plc (NYSE: MDT) revealed today the first safety data on its Micra® Transcatheter Pacing System (TPS). In the largest reported sample of a transcatheter pacing system to date, the first 140 patients in the Medtronic Micra TPS Global Clinical Trial showed 100 percent were successfully implanted with the Micra TPS. The data were presented at Heart Rhythm 2015, the Heart Rhythm Society's 36th Annual Scientific Sessions in Boston.

"These initial positive results from the Micra TPS are very encouraging as they demonstrate safe delivery via the femoral vein and placement within the heart in a wide range of patients from diverse geographies," said Dr. L.V.A. Boersma, one of the study's principal investigators and cardiologist at St. Antonius Ziekenhuis Nieuwegein, The Netherlands. "The strong initial safety data show the potential benefits of the pacemaker system's unique design, including secure attachment to the heart wall along with easy and safe deployment."

At less than one-tenth the size of a conventional pacemaker and comparable in size to a large vitamin, the Micra TPS is delivered directly into the heart through a catheter inserted in the femoral vein. The transcatheter pacemaker is attached to the heart wall via small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device. The tines are designed to be easily disengaged without causing trauma to the cardiac tissue if the device needs to be repositioned.

The first 140 patients in the study were enrolled by 37 physicians at 23 sites and spanned a wide variety of patient profiles such as age (from 21 to 94 years), weight (ranging from 41 to 148 kilograms, or 90 to 326 pounds), 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.

Patients were followed for an average of 1.9 months, and up to a maximum of 6.5 months. There were 30 adverse events, most of which were easily managed; only two patients (1.4 percent) experienced events which resulted in prolonged hospitalization, despite the broad inclusion criteria. 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. There were no apparent differences in the risk of adverse events across the various sub-groups of patients such as gender, age, size (body mass index), disease history or other baseline factors. Further, there were no (0) unanticipated serious adverse device events (assumed <5 percent).

Unlike traditional pacemakers, the Micra TPS does not require leads or a surgical 'pocket' under the skin, so potential sources of complications are eliminated-as are any visible signs of the device. Despite its miniaturized size, the Micra TPS provides the most advanced pacing technology available while being cosmetically invisible and small enough to be delivered with minimally invasive techniques.

In a separate presentation today, investigators shared results on the magnetic resonance imaging (MRI) compatibility of the new transcatheter pacemaker. The data showed that patients with one or more Micra TPS devices can safely undergo full body scans in 1.5T and 3T MRI scanners, providing patients with access to the most advanced imaging diagnostic procedures. MRI compatibility was evaluated using methods similar to tests for traditional pacemaker systems, and found the MRI risk with Micra TPS is greatly reduced compared to traditional MR-conditional pacemaker systems because of

the small device size and absence of leads.

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), 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.

- end -

---

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

Contacts:
Kathleen Janasz
Public Relations
+1-763-526-3676

Jeff Warren
Investor Relations
+1-763-505-2696