Medtronic News

New Study Shows Promise in Treating More Patients with World's Smallest Pacemaker

Data Published in JACC: Clinical Electrophysiology and to be Presented at American Heart Association Scientific Sessions Demonstrates the Potential of Investigational Algorithms in Medtronic Micra Pacemaker to Improve Synchrony and Cardiac Function in AV Block Patients

DUBLIN, Nov. 11, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced results from the MARVEL 2 (Micra Atrial Tracking Using A Ventricular accELerometer) study showing that an investigational set of algorithms in the Micra™ Transcatheter Pacing System (TPS) significantly improves synchrony and cardiac function in patients with impaired electrical conduction between the chambers of the heart, called atrioventricular (AV) block. The results from the MARVEL 2 study will be presented Nov. 16 during a Featured Science session at American Heart Association 2019, the AHA Scientific Sessions and were published today in *JACC: Clinical Electrophysiology*.

Based on positive results from both the MARVEL and MARVEL 2 studies, Medtronic submitted a new leadless pacemaker, Micra AV, to expand the indicated population to AV block and normal sinus rhythm. This submission is currently under FDA review. The Micra AV submission is not approved and the product is not currently available for sale in the United States. By federal law, Micra AV is investigational use only.

"While leadless pacing has many advantages compared to traditional pacemakers - including fewer infection-related complications - leadless pacemakers are currently only capable of single-chamber ventricular sensing and pacing," said Larry Chinitz, M.D., MARVEL 2 study co-principal investigator, cardiac electrophysiologist and director of NYU Langone's Heart Rhythm Center in New York City. "Our investigation shows that accelerometer-based atrial-sensing algorithms can sense signals from the atrium in the heart and make calculated adjustments to when ventricular pacing occurs, thus improving coordination between the atrium and ventricle. These results provide further evidence that these novel investigational algorithms added to the Micra TPS may allow more patients, including those with normal sinus rhythm and AV block, to benefit from a leadless pacemaker."

The MARVEL 2 study evaluated 75 patients with a Micra TPS at 12 centers in Hong Kong, Malaysia, Europe and the United States. Investigators evaluated the safety and effectiveness of accelerometer-based atrial sensing algorithms, which were downloaded to the Micra TPS device. Forty patients had complete heart block and normal sinus rhythm and were eligible for inclusion in the primary efficacy analysis while all 75 patients were included in the primary safety objective. Investigators evaluated the ability of the Micra accelerometer to monitor and detect atrial contractions and enable coordinated pacing between the atrium and ventricle, thereby providing AV synchrony.

Using continuous device telemetry and an electrocardiogram Holter monitor, patients' AV synchrony was measured during 20 minutes of rest and during single-chamber ventricular (VVI) pacing. The study's primary efficacy objective was met, with a significantly greater percentage of complete heart block patients with normal sinus rhythm having $\geq$70% AV synchrony during algorithm-mediated AV synchronous pacing (38 of 40 patients, 95%) than VVI pacing (0 patients, $P<0.001$ for proportion of patients with $\geq$70% synchrony). The median percent AV synchrony was 94.3% during AV synchronous pacing compared to 26.9% during VVI pacing.

In addition, blood flow from the left ventricle (velocity time integral, a proxy for stroke volume), increased by 1.7 cm (on an absolute scale, 95% CI: 0.7-2.7cm, $P=0.002$; or 8.8% on a relative scale) during AV synchronous

pacing compared with single-chamber ventricular pacing mode in patients with normal sinus rhythm with complete heart block.

The study's primary safety objective was met, with no pauses or episodes of pacing-induced tachycardia reported during algorithm mediated AV synchronous pacing in any of the 75 patients.

"The results of MARVEL 2 build on the original promising MARVEL results and provide the strongest evidence to date that accelerometer-based atrial sensing with the Micra leadless pacemaker has the potential to provide improved AV synchrony in AV block patients, who make up approximately 40% of the pacemaker population worldwide," said Rob Kowal, M.D., Ph.D., chief medical officer, vice president of medical affairs in the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. "This first-of-its-kind approach to pacing is another example of Medtronic's commitment to meaningful product innovation that will help patients around the world."

About the Micra Transcatheter Pacing System (TPS)

Approved by the U.S. Food and Drug Administration in April 2016 for patients who need a single-chamber pacemaker, the Micra TPS is the first and only leadless pacemaker approved for use in the U.S.

Comparable in size to a large vitamin, the Micra TPS is less than one-tenth the size of traditional pacemakers 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 incorporates a retrieval feature which can be enabled, if necessary; however, the device is designed to be left in the body. For patients who need more than one device, the miniaturized Micra TPS can be permanently turned off, allowing it to remain in the body so a new device can be implanted without risk of electrical interaction. The Micra TPS is the first and only leadless pacing system to be approved for both 1.5 and 3 Tesla full-body magnetic resonance imaging (MRI) scans.

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. Medtronic 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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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-

Ryan Mathre
Public Relations
+1-651-335-2338

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

---

https://news.medtronic.com/2019-11-11-New-Study-Shows-Promise-in-Treating-More-Patients-with-Worlds-Smallest-Pacemaker