Medtronic News

Medtronic Micra™ AV Receives CE Mark

World's Smallest Pacemaker Can Now Treat Patients with AV Block, Allowing More Potential Candidates for Leadless Pacing

DUBLIN, June 15, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced it has received CE (*Conformité Européenne*) Mark for Micra™ AV Transcatheter Pacing System (TPS), the world's smallest pacemaker with atrioventricular (AV) synchrony. Micra AV is indicated for the treatment of patients with AV block, a condition in which the electrical signals between the chambers of the heart (the atria and the ventricle) are impaired. Medtronic now offers the first and only CE Mark approved leadless pacemaker portfolio, expanding the number of potential candidates for this groundbreaking technology throughout the world.

First implants of Micra AV recently occurred in Spain by Dr. José Ramón González Juanatey at the University Hospital in Santiago de Compostela.

"This new device not only stimulates but is also able to recognize the electrical activity of the whole heart. Our ultimate goal is to bring the latest cardiovascular innovation to patients in our area. Now we can extend this wireless technology to other patients who require dual chamber stimulation and in whom traditional stimulation cannot be performed or is conditioned by previous infections, occlusions of the vessels of the upper extremities, etc.," said Dr. José Ramón González Juanatey, director, Cardiology and Intensive Cardiac Care Department, full professor of Cardiology, University Hospital, Santiago de Compostela, Spain (past-president, Spanish Society of Cardiology).

Historically, patients with AV block have been treated with traditional dual-chamber pacemakers which are implanted in the upper chest, under the skin below the collar bone, and connected to the heart using thin wires called "leads." Identical in size and shape to the original Micra TPS, Micra AV has several additional internal atrial sensing algorithms which detect cardiac movement, allowing the device to adjust pacing in the ventricle to coordinate with the atrium, providing "AV synchronous" pacing therapy to patients with AV block.

The Micra AV approval is based on data from the MARVEL 2 (Micra Atrial Tracking Using A Ventricular accELerometer) study, which evaluated the safety and effectiveness of accelerometer-based atrial sensing algorithms. The study evaluated the ability of the Micra's internal sensor to monitor and detect atrial contractions and enable coordinated pacing between the atrium and ventricle, thereby providing AV synchrony. Results from the study, presented at the American Heart Association 2019 Scientific Sessions and published simultaneously in *JACC: Clinical Electrophysiology*, showed the primary efficacy objective was met, with a significantly greater percentage of complete heart block patients with normal sinus rhythm having ≥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 ≥70% synchrony). The study's primary safety objective was also met, with no pauses or episodes of pacing-induced tachycardia reported during algorithm mediated AV synchronous pacing.

"From the first battery-operated external pacemaker in 1957 to the innovative Micra leadless pacemaker portfolio, Medtronic continues to provide pioneering pacing solutions to physicians and their patients," said Alphons Vincent, M.D., medical director for Europe, the Middle East & Africa of the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic.

About the Micra Transcatheter Pacing Systems (TPS)

Micra TPS is a leadless pacemaker option for patients who only require pacing in the right ventricle. Micra TPS received CE Mark in April 2015. Comparable in size to a large vitamin, Micra is less than one-tenth the size of traditional pacemakers yet delivers advanced pacing technology to patients via a minimally invasive approach. During the implant procedure, the device 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, Micra does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to leads and pockets are eliminated - as are any visible signs of the device.

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.

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