Medtronic News

New Data Unveiled at Heart Rhythm 2020 Demonstrate Effectiveness of App-Based Remote Monitoring of Medtronic Cardiac Devices, Significant Reduction in Complications with Micra Leadless Pacemaker

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DUBLIN, May 08, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced results from late-breaking clinical trials evaluating the MyCareLink Heart™ mobile app and the Micra® Transcatheter Pacing System (TPS), products that provide needed care for patients and optimal management of their symptoms – while reducing potential exposure between patients and their clinicians. During the current COVID-19 pandemic, procedures and therapies that reduce exposure to other people are important because that also reduces the potential for spreading the virus. The results were presented at the annual Heart Rhythm Society Scientific Sessions, held virtually for the first time.

Results from the BlueSync™ Evaluation study demonstrated that patients who used the Medtronic MyCareLink Heart mobile app (MCLH), a remote monitoring application on a patient's phone or tablet, were more likely to adhere to their pacemaker remote monitoring schedule than patients who used traditional bedside monitors.

The study found that patients using the MCLH technology successfully completed 94.6% of scheduled transmissions, which was superior to all three Medtronic bedside monitor control groups (whose results ranged from 56.3% to 87.1%).

Higher patient adherence to scheduled transmissions of remote monitoring suggests that patients who use the MCLH app are more likely to benefit from remote monitoring than those with low or no adherence to remote monitoring.

Numerous peer-reviewed, published studies have demonstrated the benefits of remote monitoring; it has been shown to:

- provide earlier detection and evaluation of patient clinical and device related events1-4,
- reduce in-person clinic visits with no change in patient safety5-8,
- improve patient quality of life 9-11 and
- be associated with improved long-term patient survival12-14.

Medtronic introduced the world's first remote cardiac monitoring system in 2002, and it has been embraced by two million patients worldwide. Because remote monitoring helps limit in-person contact between patients, caregivers and physicians, it potentially reduces exposure to bacteria and viruses, including the virus that causes COVID-19.

"Remote monitoring for cardiac health is associated with better patient outcomes and is playing an important role in the care of patients during the COVID-19 pandemic as in-person clinic visits are restricted, " said Rob Kowal, M.D., Ph.D., chief medical officer of the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. "These findings are very promising for this first-of-its-kind technology, suggesting patients using this app-based approach are more likely to successfully transmit the important remote cardiac device data that physicians need to manage their patients."

Micra TPS CED Study

Results from the Micra Coverage with Evidence Development (CED) Study showed that patients implanted with a Micra TPS experienced a 66% reduction in chronic complications at six months compared with patients who received a traditional transvenous VVI pacemaker (TV-VVI). These results provide the first insight into the real-world comparative effectiveness of Micra TPS in the Medicare population, and represent the largest evaluation of leadless pacemakers to date.

"These results show that Micra's lower likelihood of complications in earlier clinical trials is being maintained in real-world practice," said Jonathan P. Piccini, M.D., associate professor of medicine and director of cardiac electrophysiology at Duke University Medical Center.

Approved by the FDA in 2016, the Micra TPS is the first and only leadless pacemaker option available globally. Micra does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to leads and pockets are eliminated – which may reduce in-office or hospital visits, an important consideration during this pandemic.

FDA Approves Cobalt and Crome Portfolio

Medtronic has received FDA approval for its Cobalt™ and Crome™ implantable cardioverter-defibrillators (ICD) and cardiac resynchronization therapy-defibrillators (CRT-D), the first Medtronic “high power” devices to offer connected health, including the ability for clinicians to program devices from a physical distance, thereby reducing potential exposure to the virus that causes COVID-19. The devices use the MyCareLinkHeart mobile app, along with other exclusive features including:

- TriageHF™ Heart Failure Risk Status: TriageHF automatically provides patients’ heart failure risk assessments to clinicians and identifies changes that may lead to worsening heart failure. It evaluates multiple factors that can lead to hospitalization such as heart rate variability, atrial fibrillation and fluid status, and it is compatible with all Medtronic ICDs and CRT-Ds with the Medtronic OptiVol™ fluid status monitoring feature, including those currently implanted in patients.
- CareAlerts™: New CareAlert notifications help physicians manage clinically relevant events and direct their attention to patients who need it most, potentially before patients need in-office care. Clinicians can opt to receive CareAlerts via text, email and/or voicemail.
- Intrinsic ATP™: Intrinsic ATP (anti-tachycardia pacing) gives patients individualized therapy in real-time, with devices automatically adapting to a patient’s abnormally fast heart rhythms (ventricular tachycardia) and attempting to terminate them with painless pacing therapy, possibly avoiding the need for shocks and their associated hospitalizations.

About the Studies

The full recorded late-breaking presentations on the BlueSync Evaluation and Micra CED studies can be accessed at Heart Rhythm 365.

The BlueSync Field Evaluation was a prospective, multicenter study measuring the success rate of scheduled transmissions in pacemaker patients using the MCLH mobile app for 12 months. Scheduled transmission success was compared to 3 distinct groups of bedside monitor device users from the Medtronic de-identified CareLink™ database.

Compatible with Medtronic BlueSync technology-enabled cardiac devices, the MCLH mobile app is designed to securely and wirelessly send cardiac device data to the Medtronic CareLink™ network via a patient-owned phone or tablet, eliminating the need for a dedicated bedside monitor or other remote monitoring hardware.

The Micra Coverage with Evidence Development Study evaluated device performance in 5,746 Medicare patients implanted with a Micra TPS and 9,662 Medicare patients implanted with a traditional pacemaker (TV-VVI, regardless of manufacturer) using claims data from the Centers for Medicare & Medicaid Services.

Along with a significant reduction in complication rates, Micra TPS patients also had a reduction in the rate of device revision compared to patients implanted with a TV-VVI device. While event rates are low, cardiac effusion and/or perforation within 30 days was higher among Micra TPS patients than transvenous patients in both unadjusted and adjusted models (unadjusted, 0.8% vs. 0.4%, P<0.001; adjusted, 0.8% vs. 0.4%, P=0.002); however, results were consistent with findings from the Micra TPS investigational device exemption (IDE) study and post approval registry.

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.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties, including risks related to the impact of COVID-19 on our business, operations and production, as well as demand for our offerings, competitive factors, difficulties and delays inherent in the development, manufacturing, marketing and sale of medical products, government regulation and general economic conditions and other risks and uncertainties described in the Company's periodic reports on file with the U.S. Securities and Exchange Commission including the most recent Annual Report on Form 10-K of the Company, as filed with the U.S. Securities and Exchange Commission. In some cases, you can identify these statements by forward-looking words, such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "looking ahead," "may," "plan," "possible," "potential," "project," "should," "will," and similar words or expressions, the negative or plural of such words or expressions and other comparable terminology. Actual results may differ materially from anticipated results. Medtronic does not undertake to update its forward-looking statements or any of the information contained in this press release, including to reflect future events or circumstances.

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