Medtronic News

Medtronic Evaluates Insertable Cardiac Monitor in Identifying Patients at High Risk of Worsening Heart Failure

DUBLIN, Sept. 23, 2020 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced first enrollments in the ALLEVIATE-HF clinical trial which will evaluate the ability of its Reveal LINQ™ Insertable Cardiac Monitor (ICM) in identifying patients at high-risk of worsening heart failure. The trial will determine if early information provided by the LINQ devices enable clinicians to take action before patients' conditions worsen. The LINQ device will alert clinicians if a patient is at high risk for a heart failure event, allowing time for a physician to adjust medications to enhance patient health.

The Reveal LINQ ICM allows physicians to continuously and wirelessly monitor a patient's heart for arrhythmia disorders. With a proprietary algorithm added to the Reveal LINQ system for this study, clinicians will be alerted to signs of worsening heart failure. They will receive the information via nightly transmissions delivered to the Medtronic CareLink® Network from patients' bedside monitors. Patient data will be stratified by risk level, providing physicians remote access to patient data and allowing them to intervene earlier than possible without this system.

The first patients were enrolled at Cardiology Associates ofNorth Mississippi by Dr. Barry Bertolet, and Florida Heart Center by Dr. Prasad Chalasani. The trial is a prospective, randomized, multisite, interventional, investigational device exemption (IDE) study that will enroll up to 300 patients at up to 30 sites across the United States. Patients will be followed a minimum of seven months and up to three years. With the commencement of the ALLEVIATE-HF trial, Medtronic is the first to study the use of an ICM to manage heart failure in a remote setting.

Heart failure affects approximately 6.2 million Americans and causes or contributes to an estimated 380,000 deaths per year in the United States alone.[1] The condition occurs when the heart isn't pumping enough blood to meet the body's needs. As a result, fluid may build up in the legs, lungs, and in other tissues throughout the body, leaving patients feeling tired or experiencing shortness of breath. Therapeutic options for those with heart failure may include medication, cardiac resynchronization therapy (CRT) or an implantable cardioverter-defibrillator (ICD).

"It's vital that clinicians know about the early warning signs of worsening heart failure, and this study will help us determine if the new LINQ algorithm will identify that information so we can take action," said Javed Butler, M.D., chairman of the Department of Medicine at the University of Mississippi, and chair of ALLEVIATE-HF Steering Committee. "Remote monitoring may transform treatment and personalize the ongoing management of patients, and we look forward to having more evidence to help physicians proactively manage their patients, even without a face-to-face visit."

The Reveal LINQ ICM is approximately one-third the size of a AAA battery (~1 cc) and is placed just beneath the skin through a small incision of less than 1 cm in the upper left side of the chest, using a minimally invasive procedure. The device communicates wirelessly with a patient bedside monitor that uploads device data to the CareLink Network; it is MR-Conditional, allowing patients to undergo magnetic resonance imaging (MRI), if needed. The remote monitoring feature of the LINQ device could potentially reduce unnecessary in-office visits since physicians have remote access to patient data. Medtronic introduced the world's first remote cardiac monitoring system in 2002, and it has been implanted in 1.3 million patients worldwide ever since.

"For two decades, Medtronic has been an innovator in cardiac monitoring, allowing for diagnosis and management in the home rather than the hospital environment," 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. "Heart failure management is a critical element in extending the capabilities of the LINQ platform beyond arrhythmia management to reach more patients with the right

interventions before heart failure progresses. By initiating the ALLEVIATE-HF trial, Medtronic endeavors to help improve how clinicians receive actionable insights to better treat higher-risk patient populations."

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, 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.

[1] Virani SS, Alonso A, Benjamin EJ, Bittencourt MS,Callaway CW, Carson AP, et al. Heart disease and stroke statistics—2020 update: a report from the American Heart Associationexternal icon. *Circulation.* 2020;141(9):e139-596.

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