Medtronic News

Medtronic Clinical Trial to Evaluate ECG Belt for Optimizing Heart Failure Therapy

(GLOBE NEWSWIRE via COMTEX) --DUBLIN - July 19, 2018 - Medtronic plc (NYSE: MDT) today announced first enrollments in a new clinical trial evaluating the ECG (electrocardiography) Belt Research System (ECG Belt) as a diagnostic tool for optimizing cardiac resynchronization therapy (CRT) for patients with heart failure. The first patient enrolled in the ECG Belt for CRT Response trial was at Mercy Medical Center - West Lakes in Des Moines, Iowa, by Troy Hounshell, D.O., Iowa Heart Center. The ECG Belt is investigational and not approved for sale in the United States.

ECG Belt for CRT Response is a prospective, randomized, interventional, investigational study that will initially enroll patients in 10 centers across the U.S. The trial will compare patients treated with CRT and ECG Belt diagnostics to patients treated with standard CRT. The study will expand to additional sites worldwide to ensure a total of 400 randomized patients.

CRT is an established treatment option for indicated patients with heart failure in which an implantable device sends low levels of energy through thin wires, called leads, to stimulate the lower chambers of the heart to improve its pumping efficiency. The therapy has been demonstrated to improve survival and quality of life, and to reduce hospitalizations.

"The aim of this technology is to give physicians immediate feedback that may impact clinical decision making at the time of implant and also during follow-up visits," said Dr. Hounshell, electrophysiologist at Iowa Heart Center, and the site's principal investigator in the study. "By pairing CRT with the ECG Belt, we have the potential to provide a more personalized and noninvasive approach to help heart failure patients."

Using the ECG Belt during the trial, clinicians will assess the heart's electrical activity through real-time synchronization measurements. At the time of CRT device implant, the ECG Belt will be applied externally to patients' bodies, wrapped around the chest and back, to help physicians guide placement of the left ventricular lead. The ECG Belt will be used again at follow-up visits to further optimize the device's programmed settings.

"Our goal for this study is to give clinicians real-time insights to address each patient's needs, and to help optimize CRT for heart failure patients," said Kweli P. Thompson, M.D., M.P.H., vice president and general manager of the Cardiac Resynchronization Therapy business, which is part of the Cardiac Rhythm and Heart Failure division at Medtronic.

The Medtronic portfolio of therapies, diagnostic tools and services for patients suffering from heart failure includes CRT devices, including MR-conditional CRT-Ds and CRT-Ps; mechanical circulatory support therapy for advanced heart failure patients; heart failure diagnostics; and meaningful expert analysis through Medtronic Care Management Services.

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 86,000 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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