Medtronic News

Medtronic Announces FDA Approval of Attain Ability(R) Plus and Attain Ability(R) Straight Left-Heart Leads for Cardiac Resynchronization Therapy (CRT) Devices

New Leads Add to Company's Expansive Portfolio of Innovative CRT-Related Technology Proven to Treat Heart Failure Patients

MINNEAPOLIS & SAN FRANCISCO, May 05, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) approval and launch of the Attain Ability(R) Plus and the Attain Ability(R) Straight left-heart leads for use with cardiac resynchronization therapy (CRT) devices in treating heart failure patients. The two new dual-electrode leads are the latest offering in a line of advanced left-heart lead options that fit through the Attain Select(R) II sub-selection catheter delivery system and navigate a variety of patient vein anatomies to enhance success during the CRT implant procedure.

A pooled data analysis from several Medtronic left-heart lead studies for 1,307 patients presented today at Heart Rhythm 2011, the Heart Rhythm Society's 32nd Annual Scientific Sessions, shows a CRT retention rate of 95 percent at 18 months for Medtronic's Attain family of left heart leads. In this analysis, CRT retention rate was defined as 18-month survival rate from loss of CRT due to any left ventricle (LV) lead-related events that required operative intervention or termination of CRT. The observed events were LV lead dislodgement, phrenic nerve stimulation (PNS) (electrical stimulation of the nerve that facilitates breathing), and other LV lead failures such as elevated thresholds, loss of capture and lead fracture. Clinically acceptable performance was achieved in the majority of patients in this analysis using a variety of Medtronic left-ventricle leads to accommodate varying anatomies.

"The varying left-heart lead designs that are now available allow physicians to provide their patients with a more individualized approach to CRT delivery and more consistent, effective delivery of this therapy," said Derek V. Exner, M.D., M.P.H., F.R.C.P.C., F.A.C.C., F.H.R.S. Professor, Libin Cardiovascular Institute of Alberta, AHFMR Clinical Scholar Director, CON-ECT Clinical Coordinating Centre Medical Director, Cardiac Device Program, Calgary Region.

Attain Ability Plus enables physicians to reach and maintain the target vein, providing stability in medium-to-large venous anatomies, while Attain Ability Straight allows physicians to maneuver through small cardiac veins. These leads are part of the only portfolio of medical technology to incorporate NASA-developed insulation material that was previously evaluated for space applications, high-performance engines and harsh environments.

"With the availability of Attain Ability Plus and Attain Ability Straight, I now have access to a comprehensive family of left-heart leads designed to address the needs of a range of heart failure patients and have a proven track record of successful delivery of CRT," said George H. Crossley, M.D., F.A.C.C., Saint Thomas Research Institute and Saint Thomas Heart at Baptist Hospital in Nashville, TN.

An important factor associated with achieving effective delivery of CRT in patients with heart failure is the position of the left ventricular lead. Navigating the lead through the heart's anatomy is a complex process and placing the lead in the ideal location on the left ventricle proves challenging. The design of the Attain Ability Plus and Attain Ability Straight left-heart leads, combined with their capacity to be delivered via the Attain Select II, a sub-selection catheter (in leads greater-than or equal to 88 cm in length), assists physicians in placing the lead directly in difficult to reach locations in the heart.

According to clinical studies conducted on these leads, approximately 94 percent of physicians positively rated the ability to position the Attain Ability Plus lead to the desired cardiac veins, with a one-month complication-free rate of 98.5 percent. Additionally, 96.8 percent of physicians positively rated the handling of the Attain Ability Straight and the ability to maneuver it to

the appropriate veins, with a low lead-dislodgement rate of 3.2 percent. Both left-heart leads offer multiple pacing vectors, which may help address PNS and help prevent the need to reposition the lead invasively.

"The Attain Ability Plus and Attain Ability Straight left-heart leads add to our extensive portfolio of innovative product offerings that are developed using cutting-edge technology to address the complex challenges associated with CRT response in heart failure patients," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "We are committed to offering physicians an array of innovative medical solutions across the continuum of care, including a broad selection of left-ventricular leads."

In addition to the United States, the Attain Ability family of left-heart leads is available in Australia, Canada, Europe, Greece, Israel, Japan, Malaysia, New Zealand and the Middle East. Attain Ability Plus and Attain Ability Straight are compatible with the Attain family of exclusive delivery tools including the Attain Select II, the Attain Hybrid(R) Guide Wires and Attain Command(TM). As part of Medtronic's fully integrated CRT systems, the entire Attain portfolio, can be used with both the Protecta(TM) and Vision 3D(TM) portfolios of CRT-Ds and CRT-Ps.

About Cardiac Resynchronization Therapy

In CRT, a stopwatch-sized device is implanted into the chest and connected by leads to the heart's left and right ventricles. Through electrical impulses, the device resynchronizes heartbeats, allowing blood to be pumped more effectively through the body. CRT defibrillators (CRT-D) incorporate additional lifesaving therapy to quickly terminate an abnormally fast, life-threatening heart rhythm. CRT and CRT-D have become increasingly important therapeutic options for patients with moderate and severe heart failure since Medtronic first began clinical evaluation of its CRT systems in 1997.

About Heart Failure

Heart failure is a chronic and progressive condition that affects more than 5 million Americans and more than 22 million worldwide. Heart failure occurs when the heart muscle is unable to pump effectively to meet the body's need for blood and oxygen. In the late stages of heart failure, the heart cannot keep up with the body's demand for oxygen-rich blood and its ability to pump blood significantly deteriorates, creating a backup of blood flowing into the heart. This extra blood pools in the pulmonary veins and causes fluid to build in the lungs and other tissues. Additionally, when the heart is not pumping properly, even mild activity can cause shortness of breath or difficulty breathing. Cardiac resynchronization therapy is designed to coordinate the contraction of the heart's two lower chambers and improve the heart's efficiency to increase blood flow to the body.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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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