Medtronic News

Medtronic HeartWare(TM) HVAD(TM) System Approved for Destination Therapy

Patients with End-Stage Heart Failure Now Have New Options for Care

DUBLIN - September 27, 2017 - Medtronic plc (NYSE: MDT) has received U.S. Food and Drug Administration (FDA) approval for its HeartWare(TM) HVAD(TM) System as a destination therapy for patients with advanced heart failure who are not candidates for heart transplants. The HVAD System, a left ventricular assist device or LVAD, helps the heart pump and increases the amount of blood that flows through the body.

"LVADs are an effective and well-established treatment for patients who have progressed to advanced heart failure," said Joseph Rogers, M.D., interim chair of the Department of Medicine at Duke University, and a co-principal investigator for the ENDURANCE and ENDURANCE Supplemental trials. "In addition to its use as a bridge to heart transplantation, the HVAD System offers a promising option for a growing number of patients who are ineligible for transplant."

FDA approval is based on results from the ENDURANCE and ENDURANCE Supplemental trials, which enrolled nearly 1,000 destination therapy patients. The data support the safety and effectiveness of the HeartWare HVAD System for patients with advanced, refractory left ventricular heart failure as a bridge to cardiac transplantation (BTT), or myocardial recovery, or as destination therapy (DT) in patients for whom subsequent transplantation is not planned.

"We have been impressed with the overall clinical profile of the HVAD System, as evidenced by the ENDURANCE and ENDURANCE Supplemental trials, which affirmed its safety and effectiveness as a life-saving therapy for patients," said Francis D. Pagani, M.D., Ph.D., surgical director of the Adult Heart Transplant Program and director of the Center for Circulatory Support at the University of Michigan Health System, and a co-principal investigator for the ENDURANCE and ENDURANCE Supplemental trials. "The new indication is extremely important for patients with end-stage heart failure as the HVAD System offers significant survival and quality-of-life benefits."

Heart failure occurs when the heart is unable to pump enough blood to meet the body's needs. It is a progressive condition, affecting more than 6.5 million people in the United States alone,1 a number expected to rise to 8.5 million by 2030.2 A mechanical, centrifugal flow pump, the HVAD System supports heart function and blood flow, continuously drawing oxygen-rich blood from the left ventricle to deliver to the rest of the body.

The HVAD System received FDA approval in 2012 as a bridge to transplant in patients eligible for heart transplants. It also received European CE Mark that same year for patients at risk of death from refractory, end-stage heart failure, and it previously had received CE Mark for the bridge to transplant indication in 2009.

"Heart failure continues to be a growing burden to millions of patients, caregivers and the healthcare system," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business, which is part of the Cardiac and Vascular Group at Medtronic. "Medtronic strives every day to advance the field of mechanical circulatory support so we can offer physicians more solutions for patients who are living with this debilitating disease."

About the HVAD System

The HVAD(TM) System features the world's smallest centrifugal-flow VAD and is designed to reduce surgical invasiveness, improve patient recovery times and enhance patient outcomes. Weighing only 160 grams, the HVAD System's continuous flow pump is 30 percent thinner and has 38 percent less volume than other centrifugal devices.3,4 The pump features a unique integrated inflow cannula that is designed to treat more complex patients while maintaining stable inflow position and eliminating the need for abdominal surgery and device pockets.5-12

About the ENDURANCE Supplemental and ENDURANCE Trials

The ENDURANCE Supplemental trial was a prospective, randomized, controlled, multicenter evaluation of the incidence of neurologic events in patients receiving the HVAD System as destination therapy who received improved blood pressure management. Between October 2013 and August 2015, 465 patients were randomly selected to receive either the HVAD System or, as part of a control group, an alternative LVAD approved by the FDA for destination therapy, in a two-to-one ratio. Patients will be followed long term, up to five years.

This trial was a follow-up to the ENDURANCE Destination Therapy trial that implanted 445 patients between 2010-2012 who received either the HVAD System or an alternative LVAD approved by FDA for destination therapy in a two-to-one ratio. The ENDURANCE trial met its primary endpoint, demonstrating non-inferiority of the HVAD System to the control device; results were published in *The New England Journal of Medicine*.

The Medtronic portfolio of therapies, diagnostic tools and services for patients suffering from heart failure includes the industry's leading cardiac resynchronization therapy devices, including MR-conditional CRT-defibrillators and -pacemakers; mechanical circulatory support therapy for advanced heart failure patients; heart failure diagnostics; and meaningful expert analysis through Medtronic Care Management Services, including the Beacon Heart Failure Management Service.

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 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 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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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