Medtronic News

Clinical Trial of Medtronic Heart Pump Delivers Positive Results with Less-Invasive Implant Procedure

HVAD(TM) System is a Mechanical Pump that Circulates Blood Throughout the Body in Patients with Advanced Heart Failure.

DUBLIN and SAN DIEGO - April 6, 2017 - Preliminary results from the Medtronic plc (NYSE:MDT)-sponsored HVAD LATERAL(TM) study were presented today as a late breaking clinical trial during the 2017 International Society for Heart and Lung Transplantation (ISHLT) Scientific Meeting in San Diego. Patients with end-stage heart failure, who have not responded to standard medical management and are eligible for heart transplantation, received the HVAD(TM) System - a mechanical pump that delivers blood to the body - through a less-invasive thoracotomy procedure. The HVAD System is not approved in the United States for implantation via the thoracotomy procedure.

Results showed that, at six months, 87.6 percent of patients remained alive on the original device and free from disabling stroke, or received a heart transplant, or were explanted due to recovery. Since the percentage of patients exceeded the pre-specified performance goal of 77.5 percent, the trial successfully met its primary endpoint (p-value = 0.002). Simon Maltais, M.D., Ph.D., chair of clinical practice, Department of Cardiovascular Surgery, Mayo Clinic, Rochester, Minn., presented the data.

LATERAL is the largest, prospective clinical trial of a full-support ventricular assist device (VAD) to evaluate the thoracotomy implant technique (study group). A thoracotomy is a small, lateral, surgical incision between the patient's ribs on the left side of the chest, while the more commonly used median sternotomy (the currently approved implant technique in the U.S.) is a surgical procedure in which a vertical incision is made down the middle of the chest, after which the sternum (or breastbone) is divided. Implanting a left ventricular assist device (LVAD) with the thoracotomy technique - instead of through a median sternotomy - preserves the chest for a subsequent sternotomy, such as that occurring at the time of heart transplantation.

The LATERAL study, involving 30 centers in the United States and Canada, enrolled 145 patients with end-stage heart failure who have not responded to standard medical management and who are eligible for heart transplantation. Patients were followed for six months post-implant. Adverse events (AEs) observed in the study at 30 days included cardiac arrhythmia (22.1 percent); right heart failure (22.1 percent); bleeding requiring reoperation (3.4 percent); and stroke (4.1 percent). Overall survival among patients receiving an HVAD via the thoracotomy procedure was 91.8 percent at six months. FDA submission of the data is planned for later this year.

"The LATERAL trial demonstrates overall positive outcomes for patients who received the HVAD System via a thoracotomy procedure," said Edwin McGee, Jr., M.D., professor and director, Heart Transplant & Ventricular Assist Device Program, Loyola University Medical Center, Maywood, Ill. "While we only have an early snapshot of adverse event rates at 30 days, we are encouraged by the preliminary data. We look forward to reviewing longer-term patient data, as well as getting a more complete picture of the average length of hospital stay, another meaningful measure for VAD patients."

"The LATERAL trial represents positive, contemporary results with the HVAD System, with overall survival rates of nearly 92 percent at six months," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business at Medtronic. "This innovative technique was pioneered by clinicians whose contributions

have helped to significantly advance the field of mechanical circulatory support. The data presented today support this less-invasive surgical approach."

The HVAD System is the only full-support, centrifugal LVAD approved for implantation via the thoracotomy procedure in the European Union. The HVAD System features the HVAD(TM) pump, which is smaller than other commercially available devices, more easily enabling implantation through a thoracotomy approach. In the United States, the HVAD System is approved for implantation via a median sternotomy in patients with end-stage heart failure who are eligible for a heart transplant.

In the same session today at ISHLT, Salpy Pamboukian, M.D., MSPH, of the University of Alabama at Birmingham, presented a subset of data from the ENDURANCE trial, which evaluated the safety and efficacy of the HVAD system as destination (long-term) therapy. The data showed that very sick patients - those classified as INTERMACS level 1 or 2 (95 patients) - did not have worse outcomes than those considered less sick [INTERMACS level 3 (121 patients), and levels 4-7 (80 patients)]. Previous studies of VADs have shown that sicker patients have worse outcomes. Primary results from the ENDURANCE study were recently published in *The New England Journal of Medicine*. The HVAD System is not approved in the United States for destination therapy.

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 88,000 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.

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