Medtronic News

New Data Show Encouraging Economic Outcomes for Medtronic HeartWare(TM) HVAD(TM) System

Positive HVAD LATERALTM Study Results Also Now Published in The Journal of Heart and Lung Transplantation

DUBLIN and ORLANDO, Fla. - April 8, 2019 - Medtronic plc (NYSE:MDT) today announced data showing promising economic outcomes for the Medtronic HeartWare(TM) HVAD(TM) System after analyzing multiple clinical studies. The economic analyses of the HVAD System - a left ventricular assist device (LVAD) that helps a failing heart pump and increases the amount of blood that circulates through the body - were presented at the 2019 International Society for Heart and Lung Transplantation (ISHLT) Scientific Sessions.

The first analysis showed that heart failure patients who received the HVAD System through a less-invasive thoracotomy procedure in the LATERAL study incurred lower hospitalization and medical supply costs than patients who received a ventricular assist device (VAD) through the traditional sternotomy implant procedure. The average total cost per patient in the thoracotomy (LATERAL) study was $204,107 compared to $260,492 for (non-study) traditional median sternotomy VAD cases ($p<0.001$).

A second analysis demonstrated substantially improved cost-effectiveness of the HVAD System when used as a bridge to heart transplant (BTT) or as a longer-term destination therapy (DT) in patients with advanced heart failure who are not candidates for heart transplants, as compared to previously published U.S. cost-effectiveness analyses.

In the BTT population, the HVAD System showed nearly a two-thirds reduction in the incremental cost effectiveness ratio (ICER), from $226,300 in a 2014 analysis1 to $69,561 in the current analysis (per Quality-Adjusted Life Year, or QALY, gained over a patient's lifetime). Similarly, in the DT population, the current analysis demonstrated an ICER of $102,499 for the HVAD System, a dramatic reduction from four prior, U.S.-based economic analyses (conducted 2004-16) of predominantly competitive LVADs, that estimated the ICER from $209,400-$802,700.1-4 (ICER is a statistical summary of a healthcare intervention's cost effectiveness, and QALY is a measure of the quantity and quality of life.) The current analysis was conducted using HVAD patient data from the ADVANCE-BTT + CAP5, ENDURANCE4 and ENDURANCE Supplemental6 clinical trials, Medicare cost data, and Seattle Heart Failure Model estimates.

"These studies help us understand the cost effectiveness and economic value of the HVAD System, demonstrating a greater level of cost effectiveness than previously reported for LVAD therapy," said Scott Silvestry, M.D., surgical director of thoracic transplant, AdventHealth Transplant Institute, Orlando, Fla. "The progress toward greater cost effectiveness is an important advance that will support wider adoption of LVAD therapy for indicated patients."

In addition to these cost analyses, the LATERAL trial results were recently published in The Journal of Heart and Lung Transplantation,7 demonstrating 87 percent survival at two years, and a 30 percent reduction in hospital length of stay for patients who received the HVAD System via thoracotomy, compared to patients who received their HVAD System via a sternotomy.

"These economic analyses illustrate the value of the HeartWare HVAD System for patients with advanced heart failure," said Rob Kowal, M.D., Ph.D., vice president and chief medical officer of the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. "Most important are the patient benefits - shorter hospital stays and improved survival - with the less-invasive thoracotomy approach, but there

are also healthcare system benefits tied to patients spending fewer days in the hospital and their related supply costs."

The HVAD System is currently available in 47 countries, and has the broadest base of clinical evidence of any centrifugal-flow LVAD with more than 2,000 clinical trial patients and 18,000 worldwide implants to date.

In 2018, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved the HVAD System as a bridge to heart transplant (BTT) in patients with advanced heart failure, and in February 2019, Health Canada licensed the HVAD System for implantation via the thoracotomy approach. The HVAD System is now approved in the United States, Canada and in CE Marked countries for BTT and DT patients, both via sternotomy and thoracotomy implant techniques.

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 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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