Medtronic News

Medtronic HeartWare(TM) HVAD(TM) System Demonstrates Reduction in Total Strokes, Disabling Strokes and Stroke-Related Mortality with Blood Pressure Management

Company Has Initiated a Post-Approval Study of Heart Failure Management Best Practices to Further Demonstrate Improved Patient Outcomes

DUBLIN and ORLANDO, Fla. - April 5, 2019 - Medtronic plc (NYSE:MDT) today announced the results of an analysis on the impact of stroke severity in patients receiving its HeartWare(TM) HVAD(TM) System as destination therapy, showing that targeted blood pressure management helped reduce serious strokes. The HVAD System is a left ventricular assist device (LVAD) that helps increase the amount of blood that circulates through the body in patients with advanced heart failure; the destination therapy indication (also known as DT) refers to patients who are not candidates for heart transplants.

The retrospective analysis used data from both the ENDURANCE1 and ENDURANCE Supplemental2randomized trials. In the latter trial patients received optimal blood pressure management. Presented at the 2019 International Society for Heart and Lung Transplantation (ISHLT) Scientific Sessions, the researchers found that:

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- Freedom from disabling stroke at two years was 91 percent in the HVAD cohort.
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- Survival was significantly higher for HVAD patients who experienced a non-disabling stroke compared to patients who had a disabling stroke (76 percent vs. 29 percent, p<0.0001; one-year post-stroke event).
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- For patients receiving the control device, survival was also greater in patients with non-disabling compared to disabling strokes (71 percent vs. 17 percent, p<0.0001).
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- In patients who experienced a stroke of any severity, those receiving the HVAD pump tended to have a lower stroke-related mortality rate than patients receiving the control device (17 percent vs. 27 percent, p=NS).
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- The current analysis demonstrated a 23 percent reduction in total strokes, a 36 percent reduction in disabling strokes, and a 39 percent reduction in stroke-related mortality in patients in the ENDURANCE Supplemental HVAD arm compared to those in the original ENDURANCE trial HVAD arm.

In the ENDURANCE Supplemental Trial, a total of 465 patients were randomized in a two-to-one ratio to receive the HVAD System or a control device, i.e., an alternative LVAD approved by the FDA for destination therapy. A pre-specified blood pressure management strategy was applied to patients in the HVAD arm, in an effort to reduce the stroke rate seen in earlier trials.

"This analysis shows that stroke severity is an important determinant of outcomes, and the use of the HVAD System with a guidelines-based blood pressure management strategy can, in addition to reducing overall stroke rates, reduce the occurrence of disabling stroke and improve survival in patients who experience strokes," said Jeffrey Teuteberg, M.D., section chief of Heart Failure, Cardiac Transplantation, and Mechanical Circulatory Support, and associate professor of medicine at Stanford University. "We also found that patients with a stroke in the HVAD cohort had better survival than those who received the control device. These results reinforce the importance of blood pressure management with the HVAD for end-stage heart failure patients."

To further confirm the safety and effectiveness of the HVAD System in "real-world" clinical practice, Medtronic has initiated two studies: The Destination Therapy Post Approval Study (DT PAS) and the Apogee Study, which will look at how to improve

patient outcomes through best practices in blood pressure management, anticoagulation/antiplatelet therapy, and implant procedure.

The DT PAS is a prospective, observational study of 300 newly implanted DT patients at approximately 50 U.S. sites, that will follow patients up to five years. The primary objective is long-term, complication-free survival over two years.

Apogee is a prospective, observational, multisite study involving DT PAS patients who consent to an additional heart failure management protocol and data collection for one year. The primary objective is to understand how blood pressure management, anticoagulation/antiplatelet therapy and implant procedures affect the 12-month rate of overall major adverse events, including infection, bleeding, device malfunction, stroke or death.

The studies are led by co-principal investigators Nader Moazami, M.D., surgical director of Heart Transplantation and Mechanical Circulatory Support at NYU Langone in New York, and Jennifer Cowger, M.D., cardiologist and transplant specialist who directs the Mechanical Circulatory Support Program at Henry Ford Health System in Detroit.

"Medtronic aims to advance the field of mechanical circulatory support and, consequently, the overall management of heart failure patients who can benefit from the therapy," 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. "Continuing to define and drive best practices that reduce pump-related adverse events in a real-world setting is central to this patient-first strategy."

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 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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1 Rogers JG, et al. Intrapericardial Left Ventricular Assist Device for Advanced Heart Failure. N Engl J Med 2017;376:451-60. DOI: 10.1056/NEJMoa1602954

2 Milano CA, et al. HVAD: The ENDURANCE Supplemental Trial. JACC: Heart Failure Sep 2018, 6 (9) 792-802; DOI:10.1016/j.jchf.2018.05.012

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