Medtronic News

Study Shows Medtronic Left Ventricular Assist Devices Have Positive Results at One Year in Patients Seeking Long-Term LVAD Therapy

GLOBE NEWSWIRE via COMTEX) --Data Presented in Late-Breaking Presentation at ISHLT 2017

DUBLIN and SAN DIEGO - April 5, 2017 - Medtronic plc (NYSE:MDT) today announced results of the ENDURANCE Supplemental trial in a late-breaking clinical trial session of the 2017 International Society for Heart and Lung Transplantation (ISHLT) Scientific Meeting in San Diego. The study evaluated the company's HVAD(TM) System as a destination (long-term) therapy for patients needing heart pumps (left ventricular assist devices, or LVAD) who received improved blood pressure management. The HVAD System is not approved in the United States for destination therapy.

While the trial did not meet its primary endpoint (all neurologic events at 12 months), secondary results showed that 76.4 percent of patients receiving the HVAD System were alive on the originally implanted device and free of disabling stroke, compared to 66.9 percent of patients in the control arm (non-inferiority p-value < 0.0001; superiority p-value = 0.0354). This prespecified secondary endpoint analysis showed the HVAD System was superior to the control group (absolute difference 9.2 percent), as evaluated by the composite endpoint used in most clinical trials of LVAD therapies.

"In the ENDURANCE trial, we were concerned about the higher rate of stroke in the HVAD group compared to the control. In the ENDURANCE Supplemental trial, that gap closed and the stroke rates are comparable: there was no statistically significant difference between the HVAD and HeartMate II(TM). We believe the narrowing of those rates was most likely due to blood pressure management," said Carmelo Milano, M.D., co-principal investigator, and surgical director of cardiac transplantation and left ventricular assist device programs for the Division of Cardiothoracic Surgery at Duke University Medical Center in Durham, N.C.

Device exchange was not included in the primary endpoint, but transient ischemic attacks were: 14.7 percent of patients who received the HVAD System experienced a neurologic event within 12 months of implantation, compared to 12.1 percent of patients in the control arm (p =0.14). Post-hoc analysis revealed a rate of disabling stroke or death of 18.8 percent at 12 months among patients receiving the HVAD System, compared to 21.6 percent of patients receiving the control device.

Additional post-hoc analyses comparing data from the ENDURANCE Supplemental trial to data from the original ENDURANCE Destination Therapy trial show:

- The pre-specified blood pressure management protocol in the ENDURANCE Supplemental trial was effective in reducing the mean arterial blood pressure (MAP) by a clinically meaningful amount when compared to HVAD patients from the original ENDURANCE trial (as well as when compared to the control group in ENDURANCE Supplemental).

- A 24.7 percent reduction of overall stroke and transient ischemic attack (TIA) incidence - and a 50 percent reduction in hemorrhagic strokes - in patients receiving support from the HVAD System.

"We are pleased with the overall results of the ENDURANCE Supplemental trial, particularly the reduced rates of disabling stroke and the promising effects of optimal blood pressure management," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business at Medtronic. "We hope to be able to offer this therapy to the very sick population of patients in the U.S. who are ineligible for a heart transplant and rely upon mechanical circulatory support as long-term destination therapy."

ENDURANCE Supplemental Destination Therapy Trial Design

The ENDURANCE Supplemental clinical 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 optimal 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, any alternative LVAD approved by the U.S. Food and Drug Administration (FDA) for destination therapy, in a two-to-one ratio. The HVAD pump was implanted in 308 patients ineligible for a heart transplant, while 157 patients received the control device for the same destination therapy indication.

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 any 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 recently published in The New England Journal of Medicine.

LVAD therapy is an effective treatment for indicated patients. The HVAD System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. Medtronic has submitted its PMA application to the FDA for a destination (long-term) therapy indication for the HVAD System based on the ENDURANCE and ENDURANCE Supplemental trial datasets.

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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