Medtronic News

Medtronic HeartWare(TM) HVAD(TM) Implanted via Less Invasive Thoracotomy Shows 95 Percent Freedom from Disabling Stroke at Two Years

Company Plans Global Registry of HVAD Thoracotomy Implants to Advance Therapy Knowledge

DUBLIN, July 08, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced two-year outcomes from the LATERAL clinical trial evaluating the use of its HeartWare™ HVAD™ System in patients who received the system via a less-invasive, thoracotomy implant approach. The HVAD System is a heart pump, called a left ventricular assist device (LVAD), that helps increase the amount of blood that circulates through the body in patients with advanced heart failure.

Presented at the ASAIO (American Society for Artificial Internal Organs) 65th Annual Conference, the data showed that after two years of follow up, 95 percent of HVAD patients implanted via thoracotomy were free from disabling stroke (Modified Rankin Score, or mRS, greater than 3). Additionally:

- A review of adverse events occurring in the LATERAL trial revealed that adverse events were more likely to occur during the first 30 days after implant, with a significant decline in bleeding (1.53 vs. 0.51 events per patient year, or EPPY; $p<0.001$), arrhythmias (3.22 vs. 0.26 EPPY; $p<0.001$) and strokes (0.51 vs. 0.12 EPPY; $p=0.01$) in the later time periods (>30 days -180 days) that patients are on LVAD support. Overall adverse event rates were meaningfully reduced one to six months post implant.
- The late risk of stroke was very low, with total strokes occurring at only 0.05 EPPY in years one to two post-implant.
- And previously published data from the LATERAL trial showed 87 percent survival at two years.1

"Remembering my earliest experiences with the very first HVAD System implant in patient more than 15 years ago, I've seen both the significant benefits and also the risks for patients who receive a ventricular assist device. These new data are impressive," saidGeorg Wieselthaler, M.D., director of the Heart Transplant and Mechanical Circulatory Support programs at UC San Francisco, and an investigator in the LATERAL trial."Many of us have dedicated our lives' work to improving this therapy, including minimizing adverse events. The HVAD Pump's small size lends itself to the less-invasive surgical approach, and to see 95 percent freedom from disabling stroke at two years with the HVAD System implanted via thoracotomy reinforces that we are making dramatic strides in this therapy."

The HVAD Pump is the world's smallest, commercially available, full-support, centrifugal LVAD, and the only full-support LVAD with clinical evidence demonstrating its safety and effectiveness when implanted via the less-invasive thoracotomy approach. The HVAD System is approved in the U.S. and in CE Marked countries for implant via thoracotomy or median sternotomy. An HVAD thoracotomy implant involves a small lateral, surgical incision between the ribs on the left side of the chest to insert the pump, and a second small incision to attach the outflow graft. The traditional median sternotomy approach requires a vertical incision down the middle of the chest to divide the sternum (or breastbone).

"These data give us more comprehensive information showing low adverse event and stroke rates for end-stage heart failure patients who receive the HVAD System," 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.

In addition to ongoing follow up of patients from the LATERAL trial,Medtronic plans to launch a global registry to collect additional clinical evidence to further characterize survival, adverse events, and economic benefits of the HVAD System when implanted via a lateral thoracotomy in bridge-to-transplant (BTT) or destination therapy (DT) patient populations. Together with the HVAD Destination Therapy Post Approval Study (DT PAS) and Apogee Study, both of which are prospective, observational, multisite HVAD studies, Medtronic aims to advance physician knowledge and patient access to pump therapy.

The HVAD System is currently available in 56 countries, and hasthe 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 90,000 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 inMedtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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1 McGee E, Danter M, Strueber M, et al. Evaluation of a lateral thoracotomy implant approach for a centrifugal-flow left ventricular assist device: The LATERAL clinical trial. Journal of Heart and Lung Transplantation. 38:4, 344-351. https://doi.org/10.1016/j.healun.2019.02.002.

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