Medtronic News

Medtronic Initiates Clinical Study of Recapturable CoreValve Evolut R

Thomson Reuters ONE via COMTEX) --First Patients Successfully Treated With Novel 'CoreValve Evolut R' Transcatheter Valve

MINNEAPOLIS - Oct. 22, 2013 - Medtronic, Inc. (NYSE: MDT) today announced the first implants in the CoreValve Evolut R Clinical Study, which will evaluate the safety and effectiveness of the new Medtronic CoreValve® Evolut(TM) R Recapturable System. This recapture-enabled valve and delivery system offers new capabilities that are designed to advance deliverability and valve performance while providing the option to recapture and reposition the CoreValve Evolut R valve during deployment, if needed, while performing transcatheter aortic valve implantation (TAVI).

"CoreValve has set a high bar for rates of procedural success, which have been confirmed in both real-world use and clinical studies such as CoreValve ADVANCE. We are studying this recapture-enabled valve and low profile delivery system to provide design enhancements that further increase procedural confidence and, ultimately, improve patient care," said Ian Meredith, M.D., of Monash Medical Centre - Southern Health, Melbourne, Australia, who is a principal investigator and implanted the first devices in the study.

In addition to Monash Medical Centre, the prospective CoreValve Evolut R Clinical Study will enroll up to 60 patients with severe symptomatic aortic stenosis who are considered at high risk for open-heart surgical aortic valve replacement at University Hospital Bonn in Bonn, Germany, St. George's Hospital in London, and Royal Victoria Hospital in Belfast, Northern Ireland. The primary endpoints are all-cause mortality and stroke at 30 days, as well as device success rate at 24 hours to seven days. Secondary endpoints include recapture success rate, when attempted, and hemodynamic performance.

The new system consists of the CoreValve Evolut R transcatheter valve and the EnVeo(TM) R Recapturable Delivery System. The new valve is anatomically designed to provide conformability at the annulus for optimal annular fit and sealing, while maintaining supra-annular valve function for strong hemodynamic performance. The EnVeo R delivery system offers a new InLine Sheath, significantly reducing the profile of the catheter required to access the patient vessel, and its 1:1 delivery response is designed to provide first-time valve placement accuracy during deployment. The new system builds on experience from more than 45,000 CoreValve System implants worldwide.

The CoreValve Evolut R and EnVeo R Recapturable System are not currently approved for commercial use. The CoreValve System is not currently approved for commercial use in the United States, where it is currently undergoing clinical trials.

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 that deliver clinical and economic value to healthcare consumers and providers around the world.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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