New Data Reinforce Positive Clinical Outcomes for Direct Aortic Implants Using the Medtronic CoreValve System

The Associated Press

Medtronic Launches New European Clinical Study to Further Evaluate Direct Aortic Surgical Approach

MINNEAPOLIS - October 2, 2012 - Medtronic, Inc. (NYSE: MDT) today reported two clinical research updates related to the Medtronic CoreValve® System direct aortic implantation approach, which received CE (Conformité Européenne) Mark in November 2011 for patients with severe aortic stenosis.

New data presented at the PCR London Valves 2012 Meeting confirm that direct aortic implantation of the CoreValve System is a feasible option for patients: The data from 151 patients showed 97 percent procedural success in implants at 15 centers across Europe and Israel. There were no procedural deaths, the overall 30-day mortality rate was 8.6 percent, and the incidence of stroke was 3.9 percent.

Medtronic also announced the start of its international CoreValve ADVANCE Direct Aortic Study. The direct aortic approach also is being evaluated in the Medtronic CoreValve U.S. Pivotal Trial. The CoreValve System is currently limited to investigational use in the United States.

"The growing base of evidence for direct aortic implantation with the CoreValve System shows it is a highly successful and reliable approach for many patients who have a challenging peripheral vascular system and are at high risk for open-heart surgery," said Giuseppe Bruschi, M.D., cardiac surgeon at A De Gasperis Cardiology & Cardiac Surgery Department, Niguarda Ca' Granda Hospital, Milan, Italy, an early contributor to the development of the direct aortic approach, and co-primary investigator in the ADVANCE Direct Aortic Study. "These studies are enabling heart teams to collect important information about direct aortic access for the benefit of patients who need aortic valve replacement and are best suited for this increasingly common delivery option."

In the multicenter experience reported at PCR London Valves, approximately 62 percent of the patients received the replacement valve through a minithoracotomy (an opening between two ribs), and other patients received the valve through a ministernotomy (an opening through the sternum); both procedures are minimally-invasive and are performed without stopping the heart or penetrating the heart's ventricular wall. Most patients (86 percent) in the study had peripheral vascular disease, and the mean logistic EuroSCORE was 26.6 ± 16.

About the CoreValve ADVANCE Direct Aortic Study Dr. Bruschi recently conducted the first procedure in the CoreValve ADVANCE Direct Aortic Study, the first prospective clinical study in the world to exclusively explore the safety and efficacy of the direct aortic access approach to transcatheter aortic valve implantation (TAVI). It is a prospective, interventional, single-arm, post-market, multicenter study enrolling and following 100 patients for 12 months at up to 15 investigational sites in Europe. The primary study objective is to evaluate the safety and performance of the CoreValve System in patients via direct aortic access, with a primary endpoint of all-cause mortality at 30 days. The secondary objective includes assessments of quality of life, therapy clinical benefit and cost-effectiveness.

Since receiving CE (Conformite Europeenne) Mark in 2007, the CoreValve System has been implanted in more than 30,000 patients in more than 60 countries outside of the U.S. Medtronic now offers TAVI in four valve sizes (23mm, 26mm, 29mm and 31mm), each deliverable via transfemoral, subclavian and direct aortic access through a low-profile, 18Fr delivery catheter.

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.

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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