Medtronic News

Medtronic CoreValve(R) System Shows Long-Term Efficacy and Durability in Pivotal Trial

Medtronic CoreValve(R) System Shows Long-Term Efficacy and Durability in Pivotal Trial

PARIS, May 26, 2010 (BUSINESS WIRE) --New clinical data presented today at EuroPCR demonstrate positive long-term performance and durability for the CoreValve transcatheter aortic valve replacement system from Medtronic, Inc. (NYSE: MDT). Two-year results from the pivotal 18-French CoreValve multicenter prospective study provide important additional evidence supporting wider use of the world's market-leading transcatheter aortic valve.

The CoreValve system received CE (Conformité Européenne) Mark in March 2007. It is not yet available in the United States for clinical trial or commercial sale or use.

The CoreValve system, designed to replace a diseased aortic valve without open-heart surgery or surgical removal of the native valve, has now been implanted in more than 10,000 patients worldwide in 32 countries outside the United States. Typically delivered through the femoral artery, CoreValve is used in 75 percent of transarterial transcatheter valve replacement procedures.

"These pivotal trial results provide important evidence and confidence to physicians that CoreValve is an effective long-term treatment alternative for many patients with severe aortic stenosis who are considered at high surgical risk or inoperable," said Ulrich Gerckens, M.D., HELIOS Heart Center Siegburg, Siegburg, Germany. "Without valve treatment this patient population faces a 50 percent chance of survival from cardiovascular events at two years. In contrast, patients who received CoreValve have a greater chance of survival and overall better heart function."

The study evaluated 126 patients at nine centers in Europe and Canada who were implanted with the currently marketed 18F CoreValve system. Investigators reported the following study results:

- *Two-year effectiveness data*: About three quarters (73 percent) of patients saw their heart failure symptoms improve substantially (one or more NYHA class improvement). Valve opening area increased 2.5 times from baseline on average and remained stable at two years. Resistance to forward flow through the valve (peak and mean valve gradient) was decreased by 75 to 80 percent.
- *Two-year survival data*: Two-year cardiac survival was 74 percent.
- *Two-year valve performance*: Over two years, no valve migrations or valve deterioration occurred.

"These trial results reinforce the significance of Medtronic's strong commitment to help many of the 300,000 people worldwide who suffer from severe aortic stenosis," said cardiac surgeon Dr. John Liddicoat, vice president and general manager of the Structural Heart division, part of the CardioVascular business, at Medtronic. "We are proud of these long-term performance results - and to have reached the milestone of 10,000 CoreValve procedures. We look forward to bringing this therapy to many more patients in need."

Medtronic is committed to advancing the treatment of cardiovascular disease through collaboration with leading clinicians, researchers and scientists worldwide.

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.

SOURCE: Medtronic, Inc.

Medtronic, Inc.
Public Relations:
Joe McGrath, 612-819-6421
or
Investor Relations:
Jeff Warren, 763-505-2696

---

https://news.medtronic.com/2010-05-26-Medtronic-CoreValve-R-System-Shows-Long-Term-Efficacy-and-Durability-in-Pivotal-Trial