Medtronic News

Medtronic Gains CE Mark for 31mm CoreValve(R) Percutaneous Aortic Valve

New Offering Provides Therapy Option to Previously Unserved Patients with Larger Aortic Valves

MINNEAPOLIS, Aug 18, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced it has received CE (*Conformité Européenne*) Mark for its 31mm Medtronic CoreValve(R) System, the only transcatheter aortic valve available in the world that can treat- without surgery - patients with larger valve openings (up to 29mm). It is the largest transcatheter valve available and, because it can be compressed into a small delivery system, is deployed through the same 18Fr (less than ¼-inch or approximately 6mm in diameter) delivery system as smaller CoreValve sizes.

Medtronic's CoreValve portfolio now includes 26mm, 29mm and 31mm valves - all based on the self-expanding platform that received CE Mark in 2007. Individual sizing is critical to achieving optimal patient blood flow (hemodynamic function) and reducing adverse events, making the availability of an additional size an important offering to physicians and patients. The Medtronic CoreValve System is currently limited to investigational use in the United States.

"The 31mm CoreValve size allows us to provide a lifesaving treatment option for more patients with severe aortic stenosis," said Prof. Ulrich Schäfer, M.D., Ph.D., from Asklepios Klinik St. Georg Hamburg. "We have seen positive clinical outcomes with the CoreValve System and are pleased to offer it to individuals who, until now, have been denied transcatheter aortic valve implantation due to their larger native valve size."

The CoreValve System is designed to provide a minimally invasive treatment option - without open-heart surgery - for patients with symptomatic, severe aortic stenosis who are at high risk, or are ineligible, for open-heart surgery. Worldwide, approximately 300,000 people have been diagnosed with this condition, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery1. Since 2007, the Medtronic CoreValve System has been implanted in more than 15,000 people in more than 40 countries.

"We are pleased to introduce the 31mm CoreValve System to expand our CoreValve portfolio and meet the needs of more patients in markets where the lifesaving therapy is approved," said John Liddicoat, M.D., vice president and general manager of the Medtronic Structural Heart Business. "The new CoreValve size may afford many patients with severe aortic stenosis their first chance at a treatment alternative beyond optimal medical management or open-heart surgery."

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.

1*Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?* Bernard Iung et al. Eur Heart J (December 2005) 26(24): 2714-2720.

SOURCE: Medtronic, Inc.

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https://news.medtronic.com/2018-12-28-Medtronic-Chairman-and-CEO-Omar-Ishrak-to-Speak-at-J-P-Morgan-Healthcare-Conference2011-08-18-Medtronic-Gains-CE-Mark-for-31mm-CoreValve-R-Percutaneous-Aortic-Valve