Medtronic News

# Medtronic Announces FDA Approval of New Recaptureable TAVR System Available for Severe Aortic Stenosis Patients with Large Anatomies

*Launch of 34 mm Self-Expanding Evolut R Device Expands TAVR Treatment to Patients Who Could Not be Treated Previously*

DUBLIN - Oct. 26, 2016 - Medtronic plc (NYSE:MDT) today announced the U.S. Food and Drug Administration (FDA) approval and U.S. launch of the CoreValve(TM) Evolut(TM) R 34 mm valve-the largest sized transcatheter aortic valve replacement (TAVR) system available in the U.S. The new Evolut R 34 mm valve is approved for severe aortic stenosis patients who are at high or extreme risk for surgery with an annulus size ranging from 26-30 mm. This large valve segment is estimated to account for approximately 25-30 percent of the eligible global TAVR patient population. Previously, some of these patients were unable to receive a TAVR due to the larger size of their native diseased aortic valve.

"We're pleased to have more options to offer patients suffering from severe aortic stenosis who are at high risk or unable to have open-heart surgery," said Mathew Williams, M.D., co-primary investigator for the Evolut 34mm Clinical Study, and chief of Adult Cardiac Surgery and director of Interventional Cardiology and the Heart Valve Program at the NYU Langone Medical Center in New York City. "This new, larger valve offers patients with larger anatomical structures access to TAVR. For physicians, the recapturable and repositionable Evolut R can lead to increased accuracy in placement and control during the procedure."

The Evolut R 34mm valve is delivered through the EnVeo(TM) R Delivery Catheter System, which features an InLine Sheath. The system delivers the lowest, true delivery profile currently on the market (16 Fr equivalent, approximately 1/5 inch), which provides a greater opportunity to treat patients with smaller vessels through the preferred transfemoral access route. The Evolut R System, with its self-expanding nitinol frame, is designed to fit within the native aortic valve, using its supra-annular valve position to help achieve excellent hemodynamic performance.

"Heart teams can now use the Evolut R platform to treat the broadest annulus range in the U.S. market. The approval of the 34mm valve expands the patient population that can now receive this minimally invasive treatment alternative to open heart surgery," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group. "We look forward to working with physicians and heart teams across the U.S. to provide this valve to the many patients who need it."

The CoreValve Evolut R 34 mm valve is only approved in the United States and not approved in Europe and other countries.

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 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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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 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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