Medtronic Announces Clinical Study of Transcatheter Aortic Valve Replacement in Aortic Stenosis Patients with Bicuspid Valves

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(GLOBE NEWSWIRE via COMTEX) --Medtronic Receives FDA Approval for Revised TAVR Labeling and Begins Investigational Study of Low Risk Patients with Bicuspid Valves

DUBLIN - September 18, 2018 - Medtronic plc (NYSE:MDT) today announced that the U.S. Food and Drug Administration (FDA) has approved an investigational device exemption (IDE) to initiate a single-arm study to evaluate the CoreValve Evolut(TM)TAVR system in patients with bicuspid aortic valves who are at low risk of surgical mortality. Medtronic separately received FDA approval for revised commercial labeling for the CoreValve Evolut TAVR system that removed a precaution for the treatment of bicuspid severe aortic stenosis patients deemed at intermediate or greater risk for surgical aortic valve replacement.

"Real-world data suggests that TAVR with the self-expanding Evolut can be a suitable treatment option for many patients with bicuspid aortic valve disease," said Jeffrey J. Popma, M.D., director of Interventional Cardiology at the Beth Israel Deaconess Medical Center in Boston, Mass. "In fact, data from the TVT Registry has shown near-parity in certain outcomes between bicuspid and tricuspid patients using the Evolut self-expanding platform."

Estimated to affect 1 in 5 patients undergoing surgical aortic valve replacement (SAVR), bicuspid valve patients are born with two aortic valve leaflets instead of the more common three leaflets (tricuspid). While the revised labeling approval pertains to patients deemed at Intermediate Risk or greater for SAVR, Medtronic is studying bicuspid patients within a separate single-arm study of the Low Risk TAVR Trial. In the U.S., use for treatment with bicuspid aortic valves in patients who are at low risk of surgical mortality is investigational use only.

"As a leader in heart valve solutions, this label revision enables us to provide proactive training and education on procedural TAVR sizing and placement in this patient population," said Pieter Kappetein, M.D., vice president, medical affairs for Structural Heart business, which is part of the Cardiac and Vascular Group at Medtronic. "The bicuspid study, in addition to new studies on TAVR efficiencies and leaflet mobility, will provide important insights as we look to further refine TAVR therapy."

Medtronic is a leading innovator of heart valve therapies, including the first transcatheter pulmonic valve, the first self-expanding and recapturable transcatheter aortic valve, and the first transcatheter mitral valve replacement technology to be studied in a global pivotal trial. Following the launch of the self-expanding CoreValve System in 2014, and the Evolut(TM) R system in 2015, the third-generation Evolut(TM) PRO TAVR system was approved in the U.S. and Europe for extreme-, high-, and intermediate-risk patients in 2017.

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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Contacts:
Joey Lomicky
Public Relations
+1-763-526-2494

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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