Medtronic News

Medtronic Evolut Low Risk Trial Meets Primary Endpoint

Less Invasive Evolut™ Transcatheter Aortic Valve Replacement (TAVR) System Successful in Clinical Trial When Compared to Open Heart Surgery in Healthier Aortic Stenosis Patients

DUBLIN and NEW ORLEANS – March 16, 2019 – Medtronic plc (NYSE:MDT) today announced first-ever clinical data from the landmark Evolut Low Risk Trial comparing the minimally invasive Evolut™ transcatheter aortic valve replacement (TAVR) system to the gold standard of open-heart surgery in characteristically younger, healthier aortic stenosis patients. The randomized trial, which met its primary non-inferiority endpoint of all-cause mortality or disabling stroke at two years compared to surgery (5.3 percent versus 6.7 percent; *posterior probability of non-inferiority* >0.999), was presented today at the American College of Cardiology 68th Annual Scientific Session (ACC.19) and published simultaneously in *TheNew England Journal of Medicine (NEJM)*[i].

Key Data Highlights:

- The prespecified 30-day safety composite of all-cause mortality, disabling stroke, life-threatening bleeding, major vascular complications or acute kidney injury was significantly lower for TAVR as compared to open heart surgery (5.3 percent versus 10.7 percent), as was the rate of the composite endpoint of all-cause mortality or disabling stroke at 30 days (0.8 percent versus 2.6 percent). The pacemaker rate was greater in the TAVR treatment arm.
- TAVR demonstrated excellent hemodynamic (blood flow) performance with significantly lower mean aortic valve gradients (8.6 mm Hg versus 11.2 mm Hg) and larger EOAs (effective orifice area) than surgery (2.3 vs. 2.0) at 12 months.
- The TAVR treatment arm also showed statistically lower rates of heart failure hospitalizations (3.2 percent versus 6.5 percent) and disabling stroke (0.8 percent versus 2.4 percent) compared to surgery at 12 months.

“Low-risk aortic stenosis patients have unique characteristics due to their tendency to be younger and more active than their higher-risk counterparts,” said Michael Reardon, M.D., cardiothoracic surgeon at Houston Methodist DeBakey Heart & Vascular Center, principal investigator and senior author of the Evolut Low Risk Trial. “These data suggest that not only did TAVR match the gold standard of surgery, but it demonstrated statistical superiority across several key endpoints, including quality of life and hemodynamics – important considerations for severe aortic stenosis patients who may be more active.”

The Evolut TAVR system is not approved in any geography for use in patients considered to be at a low risk of surgical mortality. These new data will need to be submitted to government regulators to support the safety and effectiveness of this device for this use.

It is estimated that 165,000 low risk patients suffer from severe aortic stenosis per year in the U.S., Western Europe and Japan. If left untreated, it can cause heart failure in as little as two years.

“Technological advances in the Evolut TAVR platform, including recapturability and repositionability coupled with its supra-annular valve design, have contributed to positive hemodynamic outcomes, which we continue to see with the Evolut platform across large-scale, randomized clinical trials,” said Pieter Kappetein, M.D., Ph.D., vice president and chief medical officer for the Structural Heart and Cardiac Surgery businesses, which are part of the Cardiac and Vascular Group at Medtronic.

The global, prospective, multi-center, randomized Evolut Low Risk Trial evaluated three valve generations (CoreValve™, Evolut™ R and Evolut™ PRO valves) across a variety of valve sizes in more than 1,400 low risk severe aortic stenosis patients deemed to

have a low mortality risk with surgery with a predicted risk of mortality of less than three percent.

“These groundbreaking clinical trial results are positive for patients and heart teams alike and add to the growing body of clinical evidence that will help define the future of TAVR,” said Nina Goodheart, vice president and general manager of the Structural Heart business at Medtronic. “We now have positive results from a wide range of patients with severe aortic stenosis across the surgical risk spectrum, and we hope to see that more patients will have the opportunity to receive this therapy option down the road.”

Following the launch of the self-expanding CoreValve System in the U. S. in 2014, the CoreValve Evolut R System became the first-and-only recapturable and repositionable TAVR device approved in the U.S. for severe aortic stenosis patients at a high or extreme risk for surgery in 2015. The Evolut R system received CE (*Conformité Européene*) Mark for intermediate risk severe aortic stenosis patients in 2016. In 2017, the third-generation Evolut PRO TAVR system was approved in the U.S. and Europe for extreme-, high- and intermediate-risk patients. The Evolut PRO valve features an outer tissue wrap that adds surface area contact between the valve and the native aortic annulus to further advance valve sealing.

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.

Analyst and Investor Briefing
Medtronic will host a webcast to highlight its Cardiac and Vascular Group from 2:30-3:30 p.m. CDT, Sunday, March 17. The webcast will feature remarks from Medtronic management, including comments on Medtronic's clinical data and product pipelines. The live audio webcast can be accessed by clicking on the Investor Events link at http://investorrelations.medtronic.com on March 17. Within 24 hours of the webcast, a replay will be available on the same webpage. This event is not part of the official ACC Scientific Sessions.

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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[i] Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. DOI: 10.1056/NEJMoa1816885.

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