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Medtronic Evolut™ TAVR platform shows excellent valve performance and durability in low-risk aortic stenosis patients

ACC.23/WCC Late-Breaking Clinical Trial: Evolut™ is only TAVR to show excellent outcomes in low-risk patients at 3 years

Medtronic today announced three-year data from the Evolut Low Risk Trial, demonstrating the Medtronic Evolut™ transcatheter aortic valve replacement (TAVR) System had numerically better clinical outcomes and significantly better hemodynamic valve performance than surgical aortic valve replacement (SAVR) in low-risk aortic stenosis (AS) patients. The data was presented as late-breaking clinical data at the American College of Cardiology's 72nd Annual Scientific Session Together with World Heart Federation's World Congress of Cardiology and simultaneously published in the *Journal of the American College of Cardiology*.

"With an increasing number of younger, low risk patients undergoing TAVR, there is a critical need to better understand the intermediate and longer-term durability of TAVR to aid in the shared decision making between patients and providers," said Dr. John Forrest, MD, FACC, FSCAI, Associate Professor of Medicine, Director of Interventional Cardiology, Cardiovascular Medicine; Director of Structural Heart Disease, Yale Medicine; Director, Structural Heart Disease Program, Cardiovascular Medicine. "These positive mid-term results from the Evolut Low Risk Trial add to the growing body of clinical evidence demonstrating the benefits of Evolut TAVR for a broad set of patients."

The Evolut™ Low Risk Trial was a prospective, randomized, multicenter, noninferiority study to assess the safety and efficacy of the Evolut™ TAVR system compared to SAVR in patients with a low predictive risk of 30-day surgical mortality. Low risk patients, defined in the trial as a predicted risk of 30-day mortality <3% per multidisciplinary local heart team assessment, were randomized to TAVR with a self-expanding, supra-annular CoreValve, Evolut R, or PRO bioprosthesis or SAVR. A total of 1414 patients underwent attempted implant (730 TAVR; 684 SAVR). Patients had a baseline mean age of 74 years and STS score of 2.0 and 1.9 in the TAVR and SAVR groups, respectively.

In the trial, Evolut™ TAVR demonstrated a numerical benefit compared to surgery in the primary end point of all-cause mortality or disabling stroke at three years (7.4% Evolut TAVR, 10.4% SAVR; $p=0.051$). Evolut™ TAVR patients had less moderate or greater prosthesis-patient mismatch (PPM) at 3 years compared to SAVR (10.6% Evolut™ TAVR, 25.1% SAVR; $p<0.001$), which occurs when the valve is too small for the patient's body size. These findings support the two-year data



published in JACC¹ demonstrating the improved hemodynamic valve performance of supra-annular, self-expanding TAVR compared with surgery.

“As Medtronic works to expand the benefits of TAVR to a broader patient population and empower physicians to deliver individualized lifetime care, the results of the Evolut Low Risk Trial are an important milestone for our TAVR platform,” said Nina Goodheart, senior vice president and president of the Structural Heart & Aortic business within the Cardiovascular portfolio at Medtronic. “These data add to the robust body of evidence demonstrating that the Evolut platform offers excellent valve performance and remains hemodynamically stable for years to come in younger, healthier patients.”

The Medtronic CoreValve™ and next generation Evolut™ systems are TAVR devices used in a procedure that is less invasive than traditional open-heart surgery for patients with symptomatic severe aortic stenosis.

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.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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¹ J Am Coll Cardiol 2022;79:882-896

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