

## Medtronic AVALUS(TM) Surgical Aortic Valve Shows Positive Outcomes in One-Year Clinical Trial Results

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*Presented at EACTS, First Data of New Pericardial  
Heart Valve Finds High Survival and Excellent Hemodynamics*

**DUBLIN and BARCELONA - Oct. 3, 2016** - Medtronic plc (NYSE: MDT) today announced positive clinical data for its investigational AVALUS(TM) pericardial aortic surgical valve, intended for the treatment of aortic valve disease. Presented at the 30th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting for the first time, results from the PERIGON (PERIcardial SurGical AOrtic Valve ReplacemeNt) Pivotal Trial showed low rates of adverse valve-related events, high survival and improved hemodynamic performance at one year.

One of the largest, most comprehensive and modern data sets of surgical aortic valve replacement (SAVR) patients, the PERIGON Pivotal Trial is a single arm, non-randomized, prospective study of approximately 1,300 patients from 40 clinical sites across Europe, Canada, Japan and the United States. In the cohort presented at EACTS, outcomes of 270 patients were analyzed at the one-year endpoint. The vast majority (91 percent) of patients were at low mortality risk for open heart surgery (STS≤4 percent), with the remaining 8 percent at intermediate risk (STS=4 to 8 percent) and <1 percent at high risk (STS>=8 percent). At one year, all patients showed low rates of all-cause mortality (3.6 percent) and cardiac death (1.1 percent).

"As surgical aortic valve replacement remains one of the most important treatment options for patients, the one-year outcomes from the PERIGON trial demonstrate how the advanced design elements of AVALUS contribute to positive valve performance and clinical outcomes," said Robert Klautz, M.D., cardiothoracic surgeon, head of the department of cardiothoracic surgery at the Leiden University Medical Center in The Netherlands, and co-primary investigator of the PERIGON trial and presenter of the one-year results at EACTS. "The value of this large, contemporary dataset is that it allows surgeons to better understand treatment for today's SAVR patients, as opposed to data from older studies that may not be as representative."

The primary analysis demonstrated positive clinical outcomes at one year, with low linearized rates of thromboembolism (2.2 percent), endocarditis (1.0 percent), all paravalvular leaks (0.5 percent), all hemorrhages (3.7 percent) and major hemorrhages (2.7 percent). No thrombosis, hemolysis, severe paravalvular leaks or structural valve deterioration were observed at one year.

Additionally, patients treated with the supra-annular design of the AVALUS valve also experienced improved hemodynamic (blood flow) performance with mean aortic gradients improving from 42.3 mmHg at baseline to 12.6 mmHg at one year. Additionally, nearly three-fourths of patients improved one or two NYHA Functional Classes from baseline to one year across all valve sizes.

"With more than 25 years of experience in the surgical valve space, we have designed the AVALUS valve through close collaboration with expert surgeons. The valve design concepts and contemporary features are designed to help facilitate procedural ease of use while enabling the lifetime management of the patient," said Rhonda Robb, vice president and general manager of the heart valve therapies business, a part of Medtronic's Cardiac and Vascular Group. "We are very pleased to see the initial positive outcomes from this trial and intend to report on the growing body of evidence at future congresses."

The AVALUS valve is not approved for commercial use in the United States or Europe.

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](http://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 more than 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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