Medtronic News

# Medtronic Resolute® Stent Shows Strong Performance in Heart Disease Patients With and Without Diabetes

*Study Results Slated for Presentation in Late-Breaking Clinical Trials Session at Endocrinology Meeting Include Low Event Rates Through Two Years of Follow-Up*

MINNEAPOLIS--(BUSINESS WIRE)--May. 25, 2012-- According to study results to be featured in Sunday's late-breaking clinical trials session at the American Association of Clinical Endocrinologists (AACE) 21st Annual Scientific and Clinical Congress in Philadelphia, the Resolute® drug-eluting stent (DES) from Medtronic, Inc. (NYSE:MDT) yields strong performance in coronary artery disease (CAD) patients both with and without diabetes through two years of follow-up.

The Resolute Integrity DES was approved by the U.S. Food and Drug Administration (FDA) in February 2012 with a first-of-its-kind indication for CAD patients who also have diabetes.

Research shows that people with diabetes have a two- to three-fold increased risk for CAD and two- to four-fold higher CAD morbidity and mortality rates.1 Historically it's been difficult to treat CAD patients with diabetes because they tend to have smaller coronary arteries and persistently elevated blood-sugar levels, which can increase the rate of procedural complications and long-term safety risks. As a result, CAD patients with diabetes have commonly undergone open heart surgery, which is more invasive and requires longer hospital stays and recovery time compared with stent procedures.

Within the RESOLUTE clinical program, roughly 30 percent of the patients had diabetes — a proportion that mirrors current clinical practice. The late-breaking diabetes analysis will compare the clinical outcomes associated with the Resolute DES in 878 standard risk2 diabetes patients to 1,903 patients without diabetes enrolled in the clinical program.

The analysis will show consistently low event rates out to two years for both groups, despite the higher-risk nature of the diabetes patient population. At two years of follow-up, rates of target lesion failure (TLF) — defined as cardiac death, target vessel myocardial infarction (heart attack due to a blockage in the stented vessel) and target lesion revascularization (a repeat procedure) — are 7.1 percent for the patients without diabetes and 9.6 percent for patients with diabetes.

"Clinically-validated and minimally-invasive treatment options for patients with both coronary artery disease and diabetes has represented a significant unmet clinical need for the diabetes community for quite some time," said Dr. Scott W. Lee, M.D., clinical professor of medicine at Loma Linda University Medical Center near Los Angeles and medical director of global clinical research for Medtronic Diabetes in Northridge, Calif., who will present the results of the diabetes analysis. "Considering the challenges that are presented when treating diabetes patients with CAD, physicians can have confidence in the consistently low event rates in both patients with and without diabetes when using this device."

The analysis will also feature additional outcomes for important safety measures, comparing insulin-dependent- and non-insulin-dependent diabetes patients to patients without diabetes. Rates are similar among non-insulin-dependent diabetes patients and patients without diabetes.

RESOLUTE Pooled Diabetes Analysis: Two-Year Outcomes

| Endpoint* | Insulin-Dependent Diabetes Patients | Non-Insulin Dependent Diabetes Patients | Patients Without Diabetes |
|---|---|---|---|
| | N=250 | N=628 | N=1,903 |
| TLR | 6.5% | 4.3% | 3.4% |
| CD/TVMI | 8.6% | 3.9% | 4.1% |
| Def/Prob ST | 0.80% | 0.16% | 0.43% |

** Endpoint Key*

• TLR = target lesion revascularization (a repeat procedure to treat the same arterial segment)

• CD/TVMI = cardiac death/target vessel myocardial infarction

• Def/Prob ST = definite/probable stent thrombosis as defined by the Academic Research Consortium (ARC)

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.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health and extending life for millions of people around the world.

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.

1 Tan, Meng Hee. From Research to Practice Diabetes and Coronary Heart Disease. Diabetes Spectrum1999; 12: 80-83. http://journal.diabetes.org/diabetesspectrum/99v12n2/pg81.htm

2 Standard risk was defined as excluding the following characteristics: bifurcation, saphenous vein graft (SVG), in-stent restenosis (ISR), acute myocardial infarction (AMI) within 72 hours, left ventricular ejection fraction (LVEF) of less than 30%, unprotected left main disease, atherosclerosis in three or more vessels, renal impairment, total lesion length per vessel of greater than 27 mm, two or more lesions per vessel, lesion with thrombus, or lesion with total occlusion.

Source: Medtronic, Inc.

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