Cordis Corporation Announces Two-Year Results from the STROLL Trial

The Associated Press

BRIDGEWATER, N.J.--(BUSINESS WIRE)--Jan 21, 2013--Cordis Corporation today announced the presentation of the two-year STROLL study results at the Abstracts and Late Breaking Clinical Trials session at ISET 2013.

William A. Gray, MD, Director of Endovascular Services, Cardiovascular Research Foundation, New York, presented the results of the STROLL study (S.M.A.R.T.® Vascular Stent Systems in the TR eatment of O bstructive Superficia L Femora L Artery Disease) on behalf of the study investigators. The STROLL study assessed the safety and efficacy of the S.M.A.R.T.® Vascular Stent Systems (S.M.A.R.T.® Stent) in treating patients with obstructive superficial femoral artery (SFA) disease.

"The two-year data from the pivotal STROLL trial highlight not only the durability of the clinical outcomes such as patency and target lesion revascularization using the S.M.A.R.T. ® Stent in the femoro-popliteal vessels, but also the associated patient outcomes such as Rutherford classification," said Dr. Gray.

In the study, the average lesion length was 77 mm, 23.6% of patients presented with total occlusions and 47% of patients were diabetic. Freedom from clinically driven target lesion revascularization (TLR) at two years was 80.3%. The 24-month primary patency rate for the S.M.A.R.T.® Stent was 74.9% by Kaplan Meier estimate. The primary duplex patency rate (PSVR>/=2.5) was 83.5%. There were no major adverse events at 30 days after the initial index procedure. There was also a low rate of stent fractures noted at 12 months (2.0%) with no additional fractures reported out to 24 months. All stent fractures were Type I, least severe, and there were no incidents of more severe stent fractures (Type II-V).

In addition to the excellent clinical outcomes in the STROLL study, the clinical data showed an improvement in patient outcomes. This included minimal or no signs of PAD* in more than 80% of patients (as measured using Rutherford-Becker classification), and normal Ankle Brachial Index (ABI) in 4 of 5 patients at 2 years. 1 "The exceptional two-year results in the STROLL Study confirm the long-term efficacy of the S.M.A.R.T.® Vascular Stent Systems in the treatment of Peripheral Arterial Disease (PAD)," said Shlomi Nachman, Worldwide President, Cordis Corporation. "Beyond the clinical results, the excellent patient outcomes observed at one year were sustained through the second year. The unique design of the S.M.A.R.T.® Vascular Stent contributed to these results and we look forward to continuing to build on its legacy." STROLL is a multicenter, non-randomized, single-arm, prospective trial comparing the safety and efficacy of the S.M.A.R.T.® Stent with a previously published objective performance goal. Patients ≥30 years of age with de novo or restenotic native SFA lesion(s) or total occlusions with length ≥ 4.0 cm to ≤ 15.0 cm, and reference vessel diameters of ≥ 4.0 mm to ≤ 6.0 mm were

included in the study. The 12-month primary patency endpoint was defined as no relevant flow reduction by duplex ultrasonography (DUS) determined by independent core lab, and no interim clinically driven TLR. The primary safety endpoint was 30-day freedom from major adverse events, a composite of all-cause death, index limb amputation and clinically driven TLR. Secondary endpoints cover a variety of morphological, clinical and hemodynamic outcomes. The STROLL Study will follow patients out to three years with mandatory X-Ray and DUS at all key follow-up points.

The STROLL study represents the latest commitment by Cordis to continue its groundbreaking work in the fight against vascular disease. Late last year, the U.S. Food and Drug Administration (FDA) approved the S.M.A.R.T.® CONTROL® Vascular Stent Systems for use in the superficial femoral artery (SFA) and/or the proximal popliteal artery (PPA). The S.M.A.R.T.® Stent, which has been approved for peripheral indication in international markets since 1999, is now the first stent in the United States with both Iliac and SFA indications.

Dr. Gray is compensated for his services as a member of the company’s scientific advisory board and provides other consulting services.

About Cordis Corporation Cordis Corporation, part of the Johnson & Johnson family of companies, is a worldwide leader in the development and manufacture of interventional vascular technology. Through the company's innovation, research and development, Cordis partners with interventional cardiologists worldwide to treat millions of patients who suffer from vascular disease. More information about Cordis Corporation can be found at www.cordis.com.

*Defined as Rutherford-Becker classification 0 or 1.

Reference: 1. Data on file, Cordis Corporation.

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