



CYPHER(R) Sirolimus-eluting Coronary Stent Demonstrates Sustained Benefits Compared to Bare-Metal Stents in Six-Year Randomized Clinical Trial

WASHINGTON, Mar 05, 2009 (BUSINESS WIRE) -- In the first six-year follow-up of a pivotal study of any drug-eluting stent, the clinical benefits of the [CYPHER\(R\)](#) Sirolimus-eluting Coronary Stent compared to a bare-metal stent (BMS) were sustained according to data presented here at the [Cardiovascular Revascularization Therapies](#) conference. In addition, no differences were observed between the CYPHER(R) Stent and the BMS in the safety measures of myocardial infarction (heart attack), death or stent thrombosis (blood clots).

At six-year follow-up, patients in the CYPHER(R) Stent arm of the SIRIUS trial experienced significantly lower rates of target vessel failure (TVF), the primary endpoint of the trial, than those who received the BMS (26.1 percent for the CYPHER(R) Stent versus 39.9 percent for the BMS; $p < 0.0001$). TVF was defined as a composite of cardiac death, myocardial infarction and target vessel revascularization (TVR, or re-treatment of the blocked vessel).

"The six-year results of the SIRIUS trial demonstrate that the treatment benefits and safety of the CYPHER(R) Stent are preserved in longer-term follow-up," said Sidney Cohen, M.D., Vice President, Clinical, [Cordis Corporation](#). "The CYPHER(R) Stent remains the most proven and studied drug-eluting stent in its class and physicians can trust in the long-term safety profile and sustained patient benefits associated with the CYPHER(R) Stent."

In this long-term six-year follow-up, the CYPHER(R) Stent also demonstrated lower rates of target lesion revascularization (TLR, or re-treatment at the same arterial site) and major adverse cardiac events (MACE), which include myocardial infarction and death, compared to the BMS. The TLR rate for the CYPHER(R) Stent was 11.9 percent versus 27.9 percent for the BMS ($p < 0.0001$), and the MACE rate for the CYPHER(R) Stent was 22.6 percent versus 37.2 percent for the BMS ($p < 0.0001$). These six-year outcomes support the previously reported results of the trial and showed no signs of late 'catch-up.'

Dr. Cohen added, "It is important to note that both the absolute reduction in key endpoints between the CYPHER(R) Stent and the control, and the increment in these numbers due to underlying cardiovascular disease progression, remains consistent over the six-year time frame. This demonstrates there is no 'late catch up' in the patients receiving the CYPHER(R) Stent."

In addition, there was no significant difference in the mortality or the myocardial infarction rates between the CYPHER(R) Stent and the BMS at six-year follow-up. The mortality rate was 8.9 percent for those receiving the CYPHER(R) Stent compared to 9.4 percent for those receiving BMS ($p = 0.974$). The myocardial infarction rate for the CYPHER(R) Stent was 6.4 percent, compared to 7.0 percent for the BMS ($p = 0.774$).

There was no significant difference in the overall rate of stent thrombosis between the CYPHER(R) Stent and the BMS, regardless of the definition of stent thrombosis employed. The definitions include the original SIRIUS Trial protocol definition and the Academic Research Consortium (ARC) definition. At six years, the protocol definition identified a rate of 1.2 percent stent thrombosis for the CYPHER(R) Stent versus 0.8 percent for the BMS ($p = 0.536$). The definite/probable ARC definition identified a stent thrombosis rate of 1.2 percent for the CYPHER(R) Stent versus 2.1 percent for the BMS ($p = 0.304$). There was no trend for an increase in ARC-defined definite or probable very late stent thrombosis rates between 1 and 6 years (0.8 percent in CYPHER(R) Stent arm vs. 1.0 percent in the bare-metal stent arm).

The SIRIUS (Sirolimus-coated BX VELOCITY(R) Balloon-Expandable Stent in Treatment of Patients with De Novo Coronary Artery Lesions) Trial, sponsored by Cordis Corporation, served as a pivotal study for the U.S. approval of the CYPHER(R) Stent in 2003 and is the longest running U.S.-based study for a drug-eluting stent. In the double-blinded, multi-center randomized trial, patients were divided into two treatment groups: 533 patients received the CYPHER(R) Stent and 525 patients received a BMS. Of the original 1,058 participants, approximately 50 percent of patients (271 patients receiving the CYPHER(R) Stent and 255 patients receiving a BMS) participated in the six-year follow up.

About the CYPHER(R) Stent

The CYPHER^(R) Stent has been chosen by cardiologists worldwide to treat approximately three million patients with coronary artery disease. The safety and efficacy of the device is supported by a robust clinical trial program that includes more than 70 studies that examine the performance of the CYPHER^(R) Stent in a broad range of patients.

Developed and manufactured by Cordis Corporation, the CYPHER^(R) Stent is currently available in more than 80 countries and has the broadest clinical experience and longest-term clinical follow-up of any drug-eluting stent. The next version of sirolimus-eluting stent, the CYPHER^(R) SELECT^(TM) Sirolimus-eluting Coronary Stent, was launched in Europe, Asia Pacific, Latin America and Canada in 2003. The CYPHER^(R) SELECT^(TM) Plus Stent, the third version of a sirolimus-eluting coronary stent, received CE Mark in 2006 and is currently available in many markets outside the United States.

For more complete information on indications, contraindications, warnings and precautions, see the Instructions for Use available at www.cypherstent.com.

About [Cordis Corporation](#)

For 50 years, Cordis Corporation, a Johnson & Johnson company, has been a recognized 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.

**Cordis Corporation has entered into an exclusive worldwide license with Wyeth for the localized delivery of sirolimus in certain fields of use, including delivery via vascular stenting. Sirolimus, the active drug released for the stent, is marketed by Wyeth Pharmaceuticals, a division of Wyeth, under the name Rapamune(R). Rapamune is a trademark of Wyeth Pharmaceuticals.*

SOURCE: Cordis Corporation

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