



Three Year Follow-up Data Suggest Better Outcomes Were Maintained with the CYPHER(R) Sirolimus-Eluting Coronary Stent Compared to Brachytherapy in Patients with In-Stent Reblockage

CHICAGO, Mar 30, 2008 (BUSINESS WIRE) -- Long-term, follow-up data presented today suggest that patients who received the CYPHER(R) Sirolimus-eluting Coronary Stent for blockage of a bare metal stent were significantly less likely to need another procedure (target lesion revascularization or TLR) at three years compared to patients who received brachytherapy. In addition, there were no significant differences in safety endpoints, such as the rates of death, myocardial infarction (MI), or stent thrombosis between the two treatment arms of this study.

These data were presented at the Society for Cardiovascular Angiography and Interventions (SCAI) Annual Scientific Sessions in Partnership with American College of Cardiology (ACC) i2 Summit during the 57th Annual Scientific Sessions.

The SISR Trial (A Randomized Trial Comparing Sirolimus-Eluting Stent with Vascular Brachytherapy for the Treatment of In-Stent Restenosis Within Bare Metal Stents) is a multi-center, randomized study of 384 patients from 26 academic and community health centers in the United States. The original trial was designed for follow-up at nine months. This longer-term, follow-up analysis focused on pre-specified safety endpoints, namely death, MI and stent thrombosis, as well as target lesion revascularization (TLR), an efficacy endpoint, to determine whether any new safety issues emerged and whether the major benefit of the CYPHER(R) Stent, namely reduction in TLR, was maintained. Cordis Corporation sponsored the trial.

"These data continue to favor the CYPHER(R) Stent compared to radiation therapy in these patients with complex coronary artery disease," said David R. Holmes Jr., M.D., Principal Investigator and Professor of Medicine, The Mayo Clinic College of Medicine, Rochester, MN. "Neither treatment modality in this study was associated with any new safety issues or concerns." Dr. Holmes also serves as an advisory board member to the company's e-SELECT registry, which is being conducted outside the United States.

At three years, 81 percent of patients who received the CYPHER(R) Stent were free from a TLR compared to 71.6 percent of patients receiving brachytherapy ($p=0.018$). For target vessel revascularization, the survival free rates were 78.2 percent for the CYPHER(R) Stent and 68.8 percent for the brachytherapy arm ($p=0.022$).

The stent thrombosis rates, as defined as definite and probable per the Academic Research Consortium (ARC) definitions, were not significantly different (3.7 percent for the CYPHER(R) Stent vs. 2.6 percent for brachytherapy; $p=0.606$).

Although three year rates of target vessel failure (the CYPHER(R) Stent, 75.1 percent; brachytherapy, 67.9 percent; $p=0.067$) and major adverse cardiac events, also known as MACE, were both improved with the CYPHER(R) Stent, this did not reach statistical significance, likely reflecting progression of coronary artery disease at sites other than the original location of bare metal stent restenosis. Rates of MACE were 75.5 percent for the CYPHER(R) Stent and 70.5 percent for brachytherapy ($p=0.186$).

The CYPHER(R) Stent does not have an approved indication for the treatment of in-stent restenosis in the United States.

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.

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

About Cordis Corporation

Cordis Corporation, a Johnson & Johnson company, 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.

*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

Cordis Cardiology
Christopher Allman, 305-586-6024
or
Edelman
Todd Ringler, 617-872-1235

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