



## New Clinical Data at ACC09 Show the CYPHER(R) Sirolimus-eluting Coronary Stent Outperformed TAXUS(R) LIBERTE(R) and ENDEAVOR(R) Stents in Key Outcome Measures

### Data Presented Also Show Importance of Optimal Stent Deployment

BRIDGEWATER, N.J., Apr 09, 2009 (BUSINESS WIRE) -- As this year's [American College of Cardiology](#) Annual Scientific Sessions conclude, interventional cardiologists from around the world are returning to their catheterization labs with new information from clinical trials about how the [CYPHER<sup>\(R\)</sup> Sirolimus-eluting Coronary Stent](#), from [Cordis Corporation](#), compares with other drug-eluting stents.

On Sunday, March 29<sup>th</sup>, the results of the ZEST randomized controlled trial showed that the CYPHER<sup>(R)</sup> Stent significantly outperformed the ENDEAVOR<sup>(R)</sup> Stent and the TAXUS<sup>(R)</sup> LIBERTE<sup>(R)</sup> Stent in the key clinical outcomes of ischemia-driven target lesion revascularization (TLR) and stent thrombosis through one year. TLR is the need for another interventional procedure to open a blockage in the previously stented area.

The rates of ischemia-driven TLR and target vessel revascularization (TVR) were lowest in the CYPHER<sup>(R)</sup> Stent group compared to the ENDEAVOR<sup>(R)</sup> Stent arm (TLR=1.4 percent vs. 4.9 percent;  $p<0.001$  and TVR=1.9 percent vs. 5.2 percent;  $p<0.001$ ) and the TAXUS<sup>(R)</sup> LIBERTE<sup>(R)</sup> Stent (TLR = 1.4 percent vs. 7.6 percent;  $p<0.001$  and TVR = 1.9 percent vs. 7.7 percent ( $p <0.001$ )).

"ZEST is the largest randomized controlled trial comparing three drug-eluting stents, and as we saw in previous trials, like SORT OUT III, the CYPHER<sup>(R)</sup> Stent outperformed both the ENDEAVOR<sup>(R)</sup> Stent and the TAXUS<sup>(R)</sup> LIBERTE<sup>(R)</sup> Stent in terms of key clinical outcomes like TLR and TVR," said Campbell Rogers, M.D., F.A.C.C., Chief Scientific Officer and Global Head, Research & Development, [Cordis Corporation](#).

In terms of the safety parameters, the [CYPHER<sup>\(R\)</sup> Stent](#) had a trend for lower MACE (major adverse cardiovascular events, such as death and heart attack and repeat revascularization) rates at one year --the primary endpoint in the study--than the ENDEAVOR<sup>(R)</sup> Stent (8.3 percent vs. 10.1 percent, respectively,  $p=0.25$ ), and significantly lower rates of MACE than the TAXUS<sup>(R)</sup> LIBERTE<sup>(R)</sup> Stent (14.2 percent;  $p<0.001$ ). The CYPHER<sup>(R)</sup> Stent also had significantly lower rates of stent thrombosis at one year compared to the ENDEAVOR<sup>(R)</sup> Stent (0.0 percent vs. 0.7 percent;  $p=0.02$ ) and the TAXUS<sup>(R)</sup> LIBERTE<sup>(R)</sup> Stent (0.8 percent;  $p=0.008$ ).

"The results of the ZEST trial add to the body of clinical data that has shown better performance with the CYPHER<sup>(R)</sup> Stent than both the ENDEAVOR<sup>(R)</sup> Stent and the TAXUS<sup>(R)</sup> Stent in clinical and safety endpoints," said Dr. Rogers. "In addition, the CYPHER<sup>(R)</sup> Stent also has the distinct position of being the only drug-eluting stent with data on long-term sustained patient outcomes out to six years."

ZEST was a multicenter, randomized trial of 2,640 patients designed to assess the safety and efficacy of the ENDEAVOR<sup>(R)</sup> Stent as compared to the CYPHER<sup>(R)</sup> Stent and the TAXUS<sup>(R)</sup> LIBERTE<sup>(R)</sup> Stent in 'real world' patients. Each treatment arm included approximately 880 patients. The trial was supported by research grants from the CardioVascular Research Foundation, Seoul, Korea, the Korean Ministry of Health and Welfare, and Medtronic Vascular.

"The sustained patient outcomes delivered by the CYPHER<sup>(R)</sup> Stent, now demonstrated out to six years, give us confidence in the potential for our NEVO<sup>(TM)</sup> Sirolimus-eluting Coronary Stent, which contains the same drug as the CYPHER<sup>(R)</sup> Stent," Dr. Rogers continued.

Blinded 30-day pooled data from the NEVO-RES I trial were shared at ACC. NEVO-RES I is a randomized trial of 394 patients comparing NEVO<sup>(TM)</sup> to the TAXUS<sup>(R)</sup> Stent. Six-month data from NEVO RES I will be presented at the EuroPCR conference in Barcelona, Spain in May. Results from this trial will support a design dossier submission for CE Mark approval in Europe and in other countries that accept CE mark designation.

In March, Cordis announced plans to initiate a new trial - called NEVO II - which is planned as an approximately 2,000-patient,

randomized, non-inferiority, head-to-head global trial comparing NEVO<sup>(TM)</sup> to the XIENCE<sup>(TM)</sup> Stent. Data from this trial will support Cordis' initial Pre-marketing Application (PMA) submission for NEVO<sup>(TM)</sup> in the U.S. and will help the company secure additional indications.

## **Optimal Stent Deployment**

The importance of optimal stent deployment was also a key topic of data presentations at ACC09. Marco Costa, M.D., Ph.D., from the Harrington McLaughlin Heart and Vascular Institute of at the University Hospitals Case Medical Center in Cleveland, Ohio, presented data showing that optimal deployment of the CYPHER<sup>(R)</sup> Stent, especially in patients with diabetes, is important to maximize the therapeutic potential of the device.

Dr. Costa's data stemmed from the STLLR trial (Stent Deployment Techniques on Clinical Outcomes of Patients Treated with the CYPHER<sup>(R)</sup> Stent), the first prospective, randomized study to evaluate clinical outcomes associated with optimal stent deployment of the CYPHER<sup>(R)</sup> Stent. The STLLR trial was sponsored by Cordis Corporation.

In data presented at ACC09, Dr. Costa reported that there were no significant differences in the rates of TLR between the CYPHER<sup>(R)</sup> Stent-treated patients with and without diabetes through 1-year of follow-up (4.7% vs. 2.8% respectively;  $p = 0.091$ ). However, Dr. Costa reported that longitudinal geographic miss, especially balloon injury during stent implantation, was associated with higher rates of TLR in patients with diabetes compared to patients without diabetes (8.0 percent in patients with diabetes vs. 3.8 percent in patients without diabetes;  $p=0.03$ ).

"I am pleased that data from the STLLR trial continue to be relevant in today's real-world setting of interventional cardiology," said Dr. Costa. "Although this trial included only the CYPHER<sup>(R)</sup> Stent, the result can be extrapolated to the importance of proper stent deployment when treating patients with a DES. The technique one uses can be as important as the product that is chosen." Dr. Costa receives compensation from Cordis Corporation for his role as lead investigator for the STLLR trial. The CYPHER<sup>(R)</sup> Stent does not have an approved indication for use in patients with diabetes in the United States.

"This year's scientific sessions at ACC once again help to expand our understanding of the important role of primary coronary interventions with stenting, especially the CYPHER<sup>(R)</sup> Stent, in our collective drive to fight cardiovascular disease," said Dr. Rogers.

"With its sustained patient outcomes, now out to six years, the CYPHER<sup>(R)</sup> Stent continues to bring evidence to life through an unmatched body of randomized clinical data supporting the safety and efficacy of its unique Sirolimus-stent combination. This body of clinical evidence is completely unmatched by any other anti-restenotic stent," Dr. Rogers concluded.

## **About the CYPHER<sup>(R)</sup> Stent**

The CYPHER<sup>(R)</sup> 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<sup>(R)</sup> Stent in a broad range of patients.

Developed and manufactured by Cordis Corporation, the CYPHER<sup>(R)</sup> 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<sup>(R)</sup> SELECT<sup>(TM)</sup> Sirolimus-eluting Coronary Stent, was launched in Europe, Asia Pacific, Latin America and Canada in 2003. The CYPHER<sup>(R)</sup> SELECT<sup>(TM)</sup> 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](http://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.

For more information about Cordis Corporation, visit [www.cordis.com](http://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.*

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=5936858&lang=en>

SOURCE: Cordis Corporation

For Cordis Corporation

**Media:**

Christopher Allman

(m) 305-586-6024

(o) 908-541-4807

Copyright Business Wire 2009