



**THE REALITY TRIAL AND ACCOMPANYING EDITORIAL APPEAR IN
PRESTIGIOUS MEDICAL JOURNAL**

***Editorial and Study Authors Say Results Must Be Viewed In Broader Context of Other
Available Data Comparing Drug-eluting Stents***

MIAMI, FL – February 21, 2006 – The REALITY Trial, a randomized clinical trial comparing the CYPHER[®] Sirolimus-Eluting Coronary Stent to the Taxus Stent, appeared today in the *Journal of the American Medical Association (JAMA)* with an accompanying editorial.

The REALITY Trial is a one-year, prospective trial of 1,386 moderately complex patients from 90 hospitals in Europe, Latin America and Asia. The primary endpoint of in-lesion binary restenosis rate at eight months was 9.6 percent in the CYPHER[®] Stent group compared to 11.1 percent in the Taxus Stent arm (P=0.31).

“While there was not a significant difference in terms of binary restenosis between the CYPHER[®] Stent and Taxus Stent in this trial of moderately complex patients, these trial results, especially when combined with other head-to-head randomized clinical trials, do provide a more comprehensive assessment of how these two products compare,” said Dennis Donohoe, M.D., Worldwide Vice President, Clinical and Regulatory Affairs, Cordis Corporation.

“In two meta-analyses of randomized clinical trials, both of which include the REALITY data, the CYPHER[®] Stent outperformed the Taxus Stent in key efficacy and safety parameters. These rigorously conducted meta-analyses establish the highest level of scientific evidence relative to the performance of these two drug-eluting stents and put all published data for these two products into a proper perspective. The REALITY Trial results add to our comprehensive body of clinical knowledge for the CYPHER[®] Stent,” Dr. Donohoe added.

Meta-Analyses Results Echoed by Editorial and Study Authors

An accompanying editorial in today’s *JAMA* about the REALITY Trial discusses the results of a meta-analysis published in *JAMA* in August 2005 and serves to put the REALITY Trial data into a broader context.

This meta-analysis entitled “Meta-analysis of Randomized Trials: Sirolimus-eluting Stents versus Paclitaxel-eluting Stents in Patients with Coronary Artery Disease” by Adnan Kastrati, M.D., examined six randomized, head-to-head trials comparing the CYPHER[®] Stent and the Taxus Stent. This analysis included the REALITY Trial results and five additional independent, randomized controlled, head-to-

head studies including: SIRTAX (*New England Journal of Medicine/NEJM*); ISAR Diabetes (*NEJM*); ISAR Desire (*JAMA*); CORPAL (*Journal of the American College of Cardiology/JACC*); and TAXi (*JACC*).

The meta-analysis analysis looked at 3,669 patients with coronary artery disease and concluded that patients receiving the CYPHER[®] Stent had a significantly lower risk of restenosis (9.3 percent versus 13.1 percent; p=0.001) resulting in a significantly lower incidence of target vessel revascularization (5.1 percent versus 7.8 percent; p=0.001) compared with patients receiving the Taxus Stent. Rates of death or myocardial infarction (heart attack) and stent thrombosis (blood clots) were similar.

Separately, a second and more comprehensive meta-analysis of seven randomized clinical trials comparing the CYPHER[®] Stent to the Taxus Stent in more than 4,200 patients showed that the CYPHER[®] Stent reduced the need for re-treatment and target lesion revascularization by 36 percent (odds ratio 0.64; $p < 0.001$) more than the Taxus Stent. Data in this analysis included: SIRTAX (*New England Journal of Medicine/NEJM*); ISAR Diabetes (*NEJM*); ISAR Desire (*JAMA*); CORPAL (*Journal of the American College of Cardiology/JACC*); and TAXi (*JACC*), REALITY (*JAMA*) and BASKET (*Lancet*). These data were presented at the 17th Annual Transcatheter Cardiovascular Therapeutics meeting in October 2005.

The authors of the REALITY Trial acknowledge that the results of their trial need to be considered in light of results from these other clinical trials involving more complex patients.

According to the study authors, “Unlike REALITY, these studies [ISAR-Desire, ISAR-Diabetes and SIRTAX] showed a clear and statistically significant superiority of the CYPHER[®] Stent in the primary endpoints, namely in-segment restenosis, in-segment late loss, and in the composite of death, myocardial infarction and target vessel revascularization respectively.”

The authors continued, “Importantly, these trials differ from REALITY by having enrolled patients with higher lesion complexity (exclusively in-stent restenosis in ISAR-Desire), patients with specific and pro-restenotic co-morbidity (exclusively diabetics in ISAR-Diabetes), or by enrollment unlimited by exclusion criteria (SIRTAX).”

The CYPHER[®] Stent and Inhibition of Tissue Proliferation

Data from the REALITY Trial also suggested the CYPHER[®] Stent inhibited tissue proliferation more effectively than the Taxus Stent (in-stent late loss 0.09mm for the CYPHER[®] Stent arm vs. 0.31mm for the Taxus Stent; $p < 0.0001$) resulting in a significantly larger vessel diameter at follow-up with the CYPHER[®] Stent (2.00mm for the CYPHER[®] Stent versus 1.85mm for the Taxus Stent; $p < 0.001$). This is important because the primary objective of coronary stenting is to improve blood flow to the heart muscle by eliminating a blockage in the coronary artery and ensuring the largest vessel diameter long-term.

Blood Clots (Thrombosis) and Heart Attack Results

In terms of safety, the REALITY Trial data suggested that the incidence of blood clots (stent thrombosis) was higher with the Taxus Stent compared to the CYPHER[®] Stent (1.9 percent vs. 0.7 percent respectively; $p = 0.06$). In addition, the incidence of heart attack (Q-wave myocardial infarction) was significantly higher in those patients receiving the Taxus Stent compared to those receiving the CYPHER[®] Stent (1.2 percent vs. 0.1 percent respectively; $p = 0.02$). Again, the authors indicate that the results from the REALITY Trial need to be evaluated in the context of other available data from studies comparing the two drug-eluting stents.

About the CYPHER[®] Stent

The CYPHER[®] Stent has been chosen by cardiologists worldwide to treat more than 1.7 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 40 Cordis sponsored clinical trials, in addition to many independent clinical trials, that examine the performance of the CYPHER[®] Stent in a broad range of patients. Developed and manufactured by Cordis Corporation, the CYPHER[®] Stent is currently available in more than 80 countries and has the longest-term clinical follow-up of any drug-eluting stent. The CYPHER SELECT[™] Sirolimus-eluting Coronary Stent, which is the first next generation drug-eluting stent, was launched in Europe, Asia Pacific, Latin America and Canada in 2003. More information about the CYPHER[®] Stent can be found at www.cypherusa.com.

About Cordis Corporation

Cordis Corporation, a Johnson & Johnson company, is a worldwide leader in developing and manufacturing interventional vascular technology. Through the company's innovation, research and development, physicians worldwide are better able to treat the millions of patients who suffer from vascular disease.

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**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®. Rapamune is a trademark of Wyeth Pharmaceuticals.*