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DRUG-ELUTING AND BARE-METAL STENTS EQUAL IN RISK OF BLOOD CLOTS, HEART ATTACKS AND DEATH

NEW ORLEANS, La. (March 25, 2007) – Although the use of stents to treat coronary artery disease has soared during the past decade thanks to novel equipment and new implant techniques, clinical data has recently raised concerns around the safety of drug-eluting stents (DES) and their risk of post-procedure complications. A study presented today at the American College of Cardiology's *Innovation in Intervention: i2 Summit* compared rates of complications in thousands of patients who received bare-metal stents (BMS) or DES. *Innovation in Intervention: i2 Summit* is an annual meeting for practicing cardiovascular interventionalists sponsored by the American College of Cardiology in partnership with the Society for Cardiovascular Angiography and Interventions.

Researchers from three University Hospitals in Western Denmark studied 12,395 stent patients; 11,730 coronary lesions were treated with BMS, and 5,422 lesions were treated with DES (Cypher™ or Taxus™). Both BMS and DES patients were treated with two types of blood-thinning medicines for 12 months following stent implantation, as recently recommended by the Food and Drug Administration (FDA). Researchers followed the patients for 15 months after stent implantation and assessed the rates of stent thrombosis, MI (myocardial infarction, or heart attack), mortality and revascularization (repeat procedure or bypass surgery to treat the target lesion).

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2 – 2 – 2 DES and BMS Equal

Overall, results were similar between the two groups. They showed that rates of stent thrombosis were similarly low over the 15 months following implantation, occurring in 2.2 percent of BMS patients compared to 1.9 percent of DES patients. MI rates were also found to be low after 15 months in both groups (3.2% in DES vs 3.0% in BMS). However, while the rates of angiographically-confirmed stent thrombosis and MI were similar in the two groups up to 12 months, there was a small but statistically significant increased risk of stent thrombosis and MI between 12 and 15 months in the DES group. Mortality was similar in the two groups and a 43 percent reduction of target lesion revascularization was found in the DES group as compared to the BMS group.

"While the minor risk of very late stent thrombosis and heart attack after 12 months warrants further research over an extended period of time, these results do not outweigh the benefits of drug-eluting stents at the 15-month follow up," said Michael Maeng, M.D., Aarhus University Hospital, Skejby, Denmark on behalf of the Western Denmark Heart Registry Study Group and an author on the study. "Future studies following this same group of patients for a longer period of time will allow us to determine if the very small excess of stent thrombosis and heart attack in the 12 to 15 month time period will continue to increase."

Dr. Michael Maeng will present the results of "Stent Thrombosis After Implantation of Drug Eluting Stent and Bare Metal Coronary Stents in Western Denmark" on Saturday, March 24, at 11:15 a.m. in room La Nouvelle Orleans C.

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