

STENTYS Self-Apposing Stent performs well in new coronary indications

Two studies assessing STENTYS in indications outside of heart attacks presented at TCT 2013

PRINCETON, N.J. and PARIS – October 30, 2013 - STENTYS (FR0010949404 – STNT), a medical technology company commercializing in Europe the world's first and only Self-Apposing[®] Stent to treat acute myocardial infarction (AMI), announced new data this week in indications outside of myocardial infarction. Results from the OPEN II study and a series from the Amsterdam Medical Center were presented during the TCT (Transcatheter Cardiovascular Therapeutics) conference in San Francisco.

OPEN II is a prospective, single-arm trial that enrolled 217 patients treated for chest pain due to a narrowing at a coronary artery bifurcation with the STENTYS paclitaxel-eluting stent in 21 hospitals in 6 European countries. The primary endpoint of MACE (composite of cardiac death, myocardial infarction, emergent by-pass surgery and target lesion revascularization) at 6 months was 10.1% for the whole study group, with a rate of 6.9% in patients with simple lesions. These results were presented by Christoph K. Naber, M.D., Ph.D. of Contilia Heart and Vascular Center (Essen, Germany), Principal Investigator of the study, and fare favorably compared to the landmark trials in this area.

"This large study in a highly complex group of patients with challenging lesions confirms that the STENTYS stent can be used in routine practice, and leads to very good results compared to those published historically," said Dr. Naber.

Huangling Lu, M.D., from Amsterdam Medical Center (Amsterdam, the Netherlands) also presented a series of 87 patients treated with STENTYS at her institution. This series enrolled primarily patients with atypical anatomy: 53% had aneurysmatic or ectatic (dilated) vessels, 31% had tapered vessels, 23% had large vessels (above 4.5mm) and 10% had by-pass grafts. At 12 months, the MACE rate was 4.7%.

"The Self-Apposing stent is the only available product that can conform to complex, non-cylindrical vessel anatomy, as detailed on its recently extended CE Mark label," said Gonzague Issenmann, CEO and co-founder of STENTYS. *"These data will further support the marketing of our product in these indications in Europe and the Middle East."*

Coronary arteries generally have cylindrical shape and uniform diameters, but can vary greatly in some patients. In these cases, conventional stents often cannot maintain contact to the artery wall, resulting in inadequate implantation called malapposition which can lead to adverse clinical events and heart attacks. The STENTYS Self-Apposing Stent is engineered to solve the dilemma of artery diameter discrepancy. Its flexible, self expanding design takes the shape of the patient's unique vessel anatomy and perfectly apposes to the irregular contours of a blood vessel.

About the STENTYS Self-Apposing[®] Stent

The STENTYS Self-Apposing[®] Stent addresses the stent-sizing dilemma that cardiologists are confronted with when treating heart attack patients or patients with atypical artery anatomy. Its flexible, self expanding design takes the shape of the patient's unique vessel anatomy and apposes to the irregular contours of a blood vessel, in particular after an AMI as the vessel dilates and the clot dissolves. It reduces the risk of malapposition and complications associated with conventional stents in this setting. The STENTYS Self-Apposing Stent has been marketed in Europe since receiving CE Mark in 2010. The STENTYS Sirolimus-eluting stent is expected to receive CE Mark in H2 2014.

About STENTYS

STENTYS is developing and commercializing innovative solutions for the treatment of patients with acute myocardial infarction (AMI, or heart attack) and complex coronary artery disease. STENTYS's Self-Apposing® Stents are designed to adapt to vessels with ambiguous or fluctuating diameters, particularly in the post-infarction phase, in order to prevent the malapposition problems associated with conventional stents. In the APPOSITION III clinical trial, STENTYS stents demonstrated a very low one year mortality rate among 1,000 high-risk AMI patients when compared to recent studies with conventional stents.

More information is available at www.stentys.com.

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