



STENTYS clinical study demonstrating superiority of Self-Apposing[®] stents over conventional stents published in American College of Cardiology journal

APPOSITION II randomized study showed 28% malapposition in conventional stents versus 0% in STENTYS stents

PRINCETON, N.J. and PARIS – January 3, 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 today that results from the foundational APPOSITION II clinical trial were published in the December issue of the American College of Cardiology's journal, *JACC Cardiovascular Interventions*. The manuscript, also available online is titled, "[Self-Expanding Versus Balloon-Expandable Stents in Acute Myocardial Infarction: Results from the APPOSITION II Study](#)".

The study, conducted between December 2009 and June 2010, compared the accurate implantation of the STENTYS Self-Apposing stent vs. a conventional balloon-expandable stent in 80 patients treated for a severe form of heart attack, called ST-segment elevation myocardial infarction (STEMI). Placement accuracy was measured by high-definition imaging inside the artery (OCT) three days after treatment. The study results showed that 28% of the patients treated with conventional stents had a gap between the stent mesh and the artery wall (also called malapposition) whereas 0% of the patients with STENTYS stents had malapposed stents. This result was statistically significant ($p < 0.001$).

"The results of this study remind us that malapposition, which increases the risk of heart attack recurrence, is very common when treating AMI with conventional stents. They also demonstrate that malapposition can be eliminated with the use of a STENTYS stent," said Robert-Jan van Geuns, MD, PhD of Erasmus Hospital, Rotterdam, the Netherlands, investigator of the study and lead author of the publication. "This successful study was an important building block for the on-going APPOSITION clinical program designed to demonstrate optimal clinical outcomes with the Self-Apposing stent technology."

STENTYS received Investigational Device Exemption (IDE) approval from the Food and Drug Administration (FDA) in October 2012 to conduct a pivotal clinical trial in the United States which, if successfully completed, will enable the Company to apply for marketing approval of the STENTYS Self-Apposing stent. Patient enrollment into the trial, APPOSITION V, is expected to begin in early 2013. The Company expects to report full results for the ongoing APPOSITION III Study in H1 2013.

About the APPOSITION II Study

APPOSITION II was a prospective, multi-center, two arm randomized trial designed to demonstrate the superiority of the STENTYS Self-Apposing[®] stent over conventional stents in artery apposition in 80 patients suffering from ST-Elevation Myocardial infarction (STEMI). The trial's primary endpoint was stent strut apposition at 3 days under Optical Coherence Tomography (OCT). Secondary endpoints were Major Adverse Cardiac Events (MACE) in hospital, at 30 days and at 12 months. At 3 days after implantation, the rate of malapposed stent struts was ten-times lower in the STENTYS group than in the balloon-expandable group (0.58% vs. 5.46%, $p < 0.001$). On a per-patient basis, none of the patients in the STENTYS group versus 28% in the balloon-expandable group presented $\geq 5\%$ malapposed struts ($p < 0.001$). At 6 months, MACE rate was statistically equivalent in both groups (2.3% vs. 0%, $p = NS$).

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. It fits into the contour of a blood vessel, and its shape and diameter adapt as the vessel dilates and the initial clot dissolves during the post-AMI phase, thus reducing 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. It is not approved for marketing in the United States; however, the U.S. Food and Drug Administration recently approved an Investigational Device Exemption (IDE) to conduct a pivotal clinical study that will enroll up to 880 heart attack patients at 50 sites in the U.S. and worldwide.

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 30-day 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.*

This press release contains forward looking statements about the Company's business. Such forward looking statements are based on numerous assumptions regarding the Company's present and future business strategies and the environment in which it will operate in the future which may not be accurate. Such forward-looking statements involve known and unknown risks which may cause the Company's actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the final outcome of the APPOSITION trials and other clinical trials, market acceptance of the Company's products, its ability to enforce and protect its patents and proprietary rights, and other factors, including those described in the Section 4 "Risk Factors" of the Company's 2011 Registration Document (*document de référence*) filed with the *Autorité des marchés financiers* in France on June 25, 2012 under number R.12-033 as such section may be updated from time to time.

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STENTYS is listed on Compartment C of the NYSE Euronext Paris
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