

# STENTYS Sirolimus-Eluting Stent Demonstrates Best in Class Efficacy for Heart Attack Patients

## Final Results from APPOSITION IV Study Presented at EuroPCR:

- No late loss and perfect strut coverage at 9-months
- Faster arterial healing compared to conventional drug-eluting stents

PRINCETON, N.J. and PARIS – May 20, 2014 - STENTYS (FR0010949404 – STNT), a medical technology company commercializing in Europe the world's first and only Self-Apposing<sup>®</sup> Stent to treat acute myocardial infarction (AMI), today presented final results from the APPOSITION IV study of its new Self-Apposing sirolimus-eluting stent (SES) during the Hotline session at the EuroPCR conference in Paris.

APPOSITION IV enrolled 152 patients experiencing ST-elevation myocardial infarction (STEMI) and was the first clinical trial to evaluate the novel Self-Apposing sirolimus-eluting stent, which was compared to Medtronic's Resolute<sup>®</sup> zotarolimus-eluting stent at two different time points, 4 and 9 months. The evaluation was based on two imaging modalities: Quantitative Coronary Angiography (QCA) to measure the difference in artery diameters between implantation and follow-up, and Optical Coherence Tomography (OCT) to quantify the number of stent struts apposed and "covered" by tissue, an indication that the endothelial cells lining the artery wall have grown around the stent and that the vessel has healed.

At 9 months, the STENTYS SES showed no reduction in artery lumen diameter (Late Lumen Loss of 0.04mm  $\pm$  0.43 under QCA) with a near perfect arterial healing (99% covered struts at 9 months under OCT), demonstrating stent efficacy and safety.

Stent apposition was statistically better in the STENTYS group than the balloon-expandable group at 4 months (0.07% malapposed struts vs 1.16%, p=0.005), and a greater percentage of STENTYS stents were fully covered (33% vs 4%, p=0.02). At 9 months, strut apposition and coverage were similar in both groups. The results confirm that arteries with STENTYS SES healed faster than with balloon-expandable drug-eluting stents.

"In the APPOSITION IV trial, we found that the addition of sirolimus elution to the STENTYS platform brings the best of both worlds together for heart attack patients," said Robert-Jan van Geuns, M.D., Ph.D., Erasmus Medical Center (Rotterdam, the Netherlands), co-Principal investigator. "An efficacious drug with a perfectly apposed stent over time ensures fast healing and an open vessel in the long run."

"We are thrilled with the results and very grateful to the APPOSITION IV study investigators for further advancing the knowledge and clinical experience of the Self-Apposing technology," said Gonzague Issenmann, CEO and co-founder of STENTYS. "With these study results, our sirolimus-eluting stent could receive CE Mark as soon as the second half of this year."

### About the STENTYS Self-Apposing<sup>®</sup> Stent

The STENTYS Self-Apposing<sup>®</sup> 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 should receive the CE Mark during the second half of 2014.

### About the APPOSITION IV Study

APPOSITION IV is a prospective, randomized, four-arm, multi-center study designed to compare the STENTYS Sirolimus eluting stent (90 patients) with Medtronic Resolute<sup>®</sup> (62 patients) in the treatment of ST-elevation Myocardial Infarction. Patients were followed up at either 4 months (63 patients) or 9 months (89 patients). The endpoints are strut apposition and coverage under OCT at 4 and 9 months.





#### **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' Self-Apposing<sup>®</sup> 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.* 

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, risks associated with the development and commercialization of the Company's products, market acceptance of the Company's products, its ability to manage growth, the competitive environment in relation to its business area and markets, its ability to enforce and protect its patents and proprietary rights, uncertainties related to the U.S. FDA approval process, including with respect to a pre-market approval for the Company's BMS, slower than expected rates of patient recruitment for clinical trials, the outcome of clinical trials, 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 French *Autorité des Marchés Financiers* on August 27, 2013 under number R.13-040 as such section may be updated from time to time.

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