

# STENTYS Sirolimus-Eluting Stent Confirms Best-in-Class Performance at 3 Years

## Follow-up imaging data from APPOSITION IV study to be presented at TCT conference in San Francisco

PRINCETON, N.J. and PARIS – October 12, 2015 – STENTYS (FR0010949404 — STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announces that three-year follow-up imaging data from the STENTYS arm of the APPOSITION IV clinical study confirms the long-term performance of the sirolimus-eluting Self-Apposing stent. The data will be presented at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Francisco, CA.

The data were obtained by Quantitative Coronary Angiography (QCA) and Optical Coherence Tomography (OCT) from a group of patients that were examined three years post-treatment for ST-elevation Myocardial Infarction with the STENTYS stent. The in-stent Late Lumen Loss was 0.08mm ( $\pm 0.43$ ), while the rate of well-apposed struts was 99.3% and the rate of strut covered by tissue was 99.7%.

**Robert-Jan van Geuns, M.D., Ph.D., from Erasmus Medical Center (Rotterdam, the Netherlands)**, who will present these results today at TCT, said: "These images reinforce our confidence that the STENTYS Sirolimus-eluting stent performs very well, not only in the short-term, as previously demonstrated, but also at a much later time point."

**Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS**, stated: "We expect that these exciting long-term results for our Sirolimus-eluting Self-Apposing stent, which is now commercially available in Europe with a new balloon delivery system under the brand Xposition®, will further drive adoption as cardiologists recognize the potential to optimally treat their patients without the risk of severe malapposition observed with conventional stents."

### **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). Stent apposition was statistically better in the STENTYS group than the balloon-expandable group at 4 months, and a greater percentage of STENTYS stents were fully covered by vessel tissue (33% vs 4%, p=0.02), a marker for healing. 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).

#### **About STENTYS**

STENTYS is developing and commercializing innovative solutions for the treatment of patients with complex coronary artery disease. STENTYS' Self-Apposing® Stents are designed to adapt to vessels with ambiguous or fluctuating diameters in order to prevent the malapposition problems associated with conventional stents. The APPOSITION clinical trials in the treatment of acute myocardial infarction showed a very low one year mortality rate and a faster arterial healing compared to conventional stents. The company's product portfolio also includes MiStent SES®, a coronary DES whose new drug delivery mechanism is designed to match vessel response, and is marketed through STENTYS' commercial network in Europe, the Middle East, Asia and Latin America. *More information is available at* <a href="https://www.stentys.com">www.stentys.com</a>.

### **Safe Harbor Statements**

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, 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 2014 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers on July 29, 2015 under number D.15-0807 as such section may be updated from time to time.





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