

STENTYS Sirolimus-eluting stent demonstrates faster arterial healing than conventional drug-eluting stent

4-month results of APPOSITION IV Study presented at TCT 2013

PRINCETON, N.J. and PARIS – October 29, 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 results from the 4-month arm of the APPOSITION IV study of its new Self-Apposing Sirolimus-eluting stent during the TCT (Transcatheter Cardiovascular Therapeutics) conference.

The APPOSITION IV trial enrolled 152 patients suffering from ST-elevation Myocardial Infarction (STEMI) in a double-randomized trial to compare the STENTYS Sirolimus-eluting stent to Medtronic's Resolute[®] zotarolimus-eluting stent at two different time points, 4 and 9 months, evaluating stent apposition and strut coverage under intra-vascular OCT imaging (optical coherence tomography).

Among the 62 patients enrolled in the 4-month group, those treated with a STENTYS stent had better apposition than the control stent (p=0.006). The imaging analysis also quantified the number of stent struts "covered" by tissue, an indication that the endothelium cells lining the artery wall have grown around the stent and that the vessel has healed. At 4 months, 32% of the STENTYS stents had all struts already covered compared to 4% for the Resolute (p=0.03).

"Long-term malapposition and partial strut coverage of drug-eluting stents have been associated with late stent thrombosis, so the early healing of vessels treated with STENTYS DES is very good news for our patients," said Dr. Robert Jan van Geuns, M.D., Ph.D., Erasmus Medical Center (Rotterdam, the Netherlands), co-Principal Investigator of the study, who presented the data.

"These data provide further evidence of the significant benefits that the Self-Apposing technology can bring to heart attack patients," said Gonzague Issenmann, CEO and co-founder of STENTYS. "The Self-Apposing Sirolimus-eluting stent remains on track for CE Marking and commercial launch in the second half of 2014."

The full presentation of results will be available on the **STENTYS website**.

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 the APPOSITION IV Study

APPOSITION IV is a prospective, randomized, two-arm, multi-center study designed to compare the apposition of the STENTYS Sirolimus eluting stent with Medtronic Resolute[®] in 150 patients suffering from ST-elevation Myocardial Infarction. Patients will be followed up at either 4 or 9 months (double randomization). The powered primary endpoint is strut apposition at 9 months under OCT. The secondary endpoints are strut apposition at 4 months under OCT and strut coverage at 4 and 9 months. The final results are expected to be announced in Q2 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.

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 *Autorité des Marchés Financiers* in France on August 27, 2013 under number R.13-040 as such section may be updated from time to time.

STENTYS

Stanislas Piot, CFO Tel.: +33 (0)1 44 53 99 42 stan.p@stentys.com

STENTYS is listed on Comp. C of the NYSE Euronext Paris ISIN: FR0010949404 – Ticker: STNT **Europe: NewCap.** Dusan Oresansky / Pierre Laurent Tel.: +33 (0)1 44 71 94 92 <u>stentys@newcap.fr</u>

US: MacDougall Biomedical Communications Charles Liles, Tel.: 781 235 3060 Christine Labaree or Hunter Marshall, Tel.: 650 339 7533 stentys@macbiocom.com

