STENTYS: First Clinical Experience with Xposition shows 100% implantation success, Confirms Ease of Use

Results of SETUP Trial presented at EuroPCR and Published on-line in EuroIntervention

PRINCETON, N.J. and PARIS — May 19, 2015 — STENTYS (FR0010949404 — STNT), a medical technology company commercializing the world’s first and only Self-Apposing® coronary stent, today announced that the findings of the first Xposition® clinical experience, as part of the SETUP trial, were presented at the EuroPCR conference. The results of this study were also published today in the online edition of EuroIntervention.

Xposition S is STENTYS’ next-generation sirolimus-eluting Self-Apposing stent. It is delivered by a unique stent delivery system that closely replicates conventional stent implantation techniques: a small balloon peels the sheath containing the stent to release it precisely at the intended location.

The SETUP study was a prospective, single-arm first-in-man study performed in two Dutch centers (Academic Medical Center, Amsterdam, and Albert Schweitzer Hospital, Dordrecht) to evaluate the feasibility of the use of the novel STENTYS Xposition S in de novo coronary lesions. The study enrolled 25 patients and demonstrated 100% technical and angiographic success rates without longitudinal geographical miss on quantitative coronary angiography (QCA). Stent strut malapposition as assessed by optical coherence tomography (OCT) was very low (0.6%) at the end of the procedure.

Principal Investigator Karel Koch, MD, PhD from AMC hospital (Amsterdam, the Netherlands), stated, “STENTYS’ novel balloon delivery system allowed for easy and accurate deployment of all stents at the target lesions, which of note, were performed with real-world lesion complexities, including ostial lesions, highly calcified lesions and lesions with high thrombus burden. We noticed significant improvement over the previous system and see how Xposition S could advance the quality of treatment for heart attack patients or patients with variable artery anatomy.”

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, concluded: “We are extremely pleased by these clinical results, which are published concurrently to our launch today of Xposition S and prove that Xposition S represents a quantum leap in terms of product design that will lead to faster adoption of the Self-Apposing technology by interventional cardiologists.”

About STENTYS
STENTYS is developing and commercializing innovative solutions for the treatment of patients with complex artery disease. STENTYS’ Self-Apposing® drug-eluting 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 www.stentys.com.

Safe Harbor Statements
This press release contains forward-looking statements about the Company that 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 2013 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers on October 29, 2014 under number D.14-1026 as such section may be updated from time to time.