STENTYS Completes Enrollment in the Study Assessing the Safety and Efficacy of Xposition S in Left Main Artery Lesions

200 patients enrolled in the TRUNC clinical trial

PARIS – July 27, 2017 – 6.15 pm CEST – STENTYS (FR0010949404 – STNT), a medical technology company commercializing the Xposition S Sirolimus-eluting self-apposing coronary stent, today announces that the enrollment of the 200 patients for the TRUNC trial has been completed as scheduled.

Carried out in 18 European clinical sites, the aim of the TRUNC trial is to evaluate the long-term safety and efficacy of the Xposition S stent for the treatment of the unprotected left main artery (the heart’s main artery). Patients will be monitored for up to 2 years following the initial procedure, with the results of the primary endpoint - Target Vessel Failure at 12 months - expected before the end of 2018.

Left main artery lesions, especially within the setting of a heart attack, are characterized by a large artery diameter followed by a substantial tapering on this segment, and also involving a bifurcation in most cases, which makes it very difficult to use conventional balloon-expandable DES. The Xposition S stent is an optimal solution to this issue, thanks to its self-apposing profile that allows the stent to adapt to vessels with varying diameters and perfectly fit even the broadest vessel walls.

Christophe Lottin, Chief Executive Officer of STENTYS, comments: “I would like to thank all the centers taking part in this trial for meeting this key step of the study as scheduled. Left main artery lesions represent an excellent opportunity to demonstrate that the Xposition S DES is capable of treating particularly complex pathologies and to strengthen our positioning on this segment, which accounts for approximately 10% of all coronary surgical operations worldwide.”

About the TRUNC study
TRUNC is a prospective, single-arm multi-center trial to evaluate the long-term safety and efficacy of the Xposition S stent in the treatment of unprotected left main lesions in routine clinical practice. It is scheduled to include 200 patients in approximately 10 European clinical sites. The primary endpoint is Target Lesion Failure at 12 months. The trial’s steering committee is composed of Dr. Baumbach (UK), Dr. Briguori (Italy) and Prof. Tamburino (Italy).

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

Upcoming financial publication
Publication of the first half 2017 financial results on October 2, 2017, before market open.

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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 2015 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers (AMF) on August 30, 2016 under number D.16-804.