STENTYS Announces the CE Marking of the Self-Apposing Stent for Left Main Coronary Artery Disease

PRINCETON, N.J. and PARIS – March 21, 2016 – STENTYS (FR0010949404 — STNT), a medical technology company commercializing the world’s first and only Self-Apposing® coronary stent, today announced that Xposition S, the Sirolimus-eluting Self-Apposing stent, received CE Marking for the treatment of Unprotected Left Main Coronary artery disease on the basis of the results from a study published last year in the peer-reviewed journal Catheterization and Cardiovascular Interventions (CCI).

When treating patients with left main coronary artery disease, the large diameter of the left main artery and the significant vessel tapering at that location represents serious challenges for conventional balloon-expandable DES that often result in important stent structural deformations. The STENTYS Self-Apposing stent can adapt to vessels with varying diameters and ensure optimal fit to the vessel wall along the entire stented length. Xposition S new delivery catheter also enables very accurate stent positioning, a key feature when the lesion is close to the aorta.

The single center, retrospective, two-arm, controlled study, conducted by Carlo Briguori, MD, PhD, (Clinica Mediterranea, Italy), included 75 consecutive patients with tapered distal unprotected left main coronary artery lesions treated with STENTYS DES. The authors concluded that the STENTYS stent offers a valid treatment alternative for this indication.

Gonzague Issenmann, co-founder and Chief Executive Officer of STENTYS commented: “This CE Marking confirms the adequacy of our technology in this complex setting and now allows us to quickly start the multicentric study that will evaluate the efficacy of Xposition S in 200 patients in this indication.”

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.

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 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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STENTYS is listed on Comp. B of the NYSE Euronext Paris
ISIN: FR0010949404 – Ticker: STNT