Latest TRUNC study clinical data demonstrates the safety and efficacy of Self-Apposing stents in unprotected Left Main

Paris – September 26, 2018 – 5.45 pm CEST – STENTYS (FR0010949404 — STNT), a French group specialized in medical technologies for interventional cardiology, today announced that it has reported 12-month results of the Clinical Study to Evaluate the STENTYS Xposition S for the Treatment of Unprotected Left Main Coronary Artery Disease (TRUNC) at the Trans Catheter Technologies (TCT) Congress held in San Diego, United States.

During a poster presentation session, Professor Corrado Tamburino (Ferrarotto Hospital, University of Catania, Catania, Italy) gave a presentation entitled “Prospective Evaluation of Drug Eluting Self-Apposing Stent for the Treatment of Unprotected Left Main Coronary Artery Disease: 1-Year Results of the TRUNC Study”.

The TRUNC study is a prospective, non-randomized, multi-centre study assessing the long-term safety and efficacy of the self-expandable sirolimus eluting Xposition S stent in the treatment of unprotected left main coronary artery disease. The 12-month results confirmed the safety and efficacy of the Xposition S self-apposing stent technology in unprotected left main stenting, with a high procedural success rate and a low rate of Target Lesion Failure at 12 months of 8.3%. The study included an IVUS study, which confirmed the very high rate of completed stent apposition with 98% of stents being completely apposed.

Professor Corrado Tamburino commented: “The results of the TRUNC study are very promising, demonstrating both safety and efficacy of the self-apposing stent technology in this challenging indication, the unique features of the Xposition S stent are well adapted for Left Main stenting particularly when there is a large variance in vessel diameters.”

Professor Christian Spaulding, Georges-Pompidou European Hospital, Paris, France, President of the STENTYS scientific committee, further commented: “The positive results of the TRUNC study coupled with the reduced need for additional stent optimisation techniques often required by conventional drug eluting stents puts the Xposition S stent amongst the forefront of devices for Left Main stenting.”

Christophe Lottin, Chief Executive Officer of STENTYS, added: “We would like to thank all the physicians and their patients that participated in the study. We are delighted that the 12-month results of the TRUNC study have met a keen interest from the scientific community during the TCT conference in San Diego. The presented data confirm the advantages of the self-apposing technology for the treatment of unprotected left main disease, an indication which represents nearly 10% of all percutaneous coronary interventions. It also supports our growth strategy based on the Xposition S stent and its targeted indications. We firmly believe that our Xposition S stent will be used in a growing number of indications, and its unrivalled technical characteristics will establish it as a benchmark.”

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 included 205 patients in 18 European clinical sites. The primary endpoint is Target Lesion Failure at 12 months. The trial’s steering committee is composed of Prof. Tamburino and Dr. Briguori (Italy) and Dr. Baumbach (UK).

About STENTYS

The STENTYS group develops and markets minimally-invasive cardiovascular solutions for the needs of interventional cardiology. Its extensive range of innovative products, including drug-eluting stents, coronary and drug-eluting balloons as well as cardiovascular accessories, is marketed in over 60 countries. Thanks to its flagship product, Xposition S, the self-apposing stent that adapts to vessels with variable diameters and enables the treatment of complex arterial disorders, and to its portfolio of balloons and accessories, STENTYS covers all coronary indications.

Additional information is available at www.stentys.com
Forward-looking 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 2016 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers (AMF) on November 29, 2017 under number D.17-1084.