STENTYS' Sirolimus-Eluting Stent Receives CE Marking

PRINCETON, N.J. and PARIS – October 27, 2014 – STENTYS (FR0010949404 — STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announces it received CE Marking for its Sirolimus-Eluting Stent (SES). The CE Marking will allow the Company to market its SES in Europe immediately and, starting in 2015, in the many other countries where the Company has commercial activity.

The CE marking approval was based on the excellent outcomes of the APPOSITION IV clinical study, in which the STENTYS SES demonstrated best-in-class efficacy and faster healing compared to balloon-expandable stents in patients treated for a severe heart attack.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, stated: *"STENTYS finally has a drug-eluting stent from the 'limus' family of compounds as requested by the interventional cardiology community."*

"In a global coronary stent market that has seen renewed growth and will reach $7 billion by the end of the decade, unmet patient needs are driving the market towards specialty stent solutions. STENTYS Sirolimus-eluting Self-Apposing stent is the only product that can guarantee complete and continuous apposition in patients with varying vessel anatomy, including in the acute setting, for a safer and more efficacious treatment. This clear competitive advantage will fuel the company's growth worldwide," **added Mr. Issenmann.**

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 varying 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. More than 10,000 STENTYS Self-Apposing stents have been implanted since receiving CE Mark in 2010.

About the APPOSITION IV study

APPOSITION IV is a prospective, randomized, four-arm, multi-center study designed to compare the STENTYS Sirolimus eluting stent (90 patients) with Medtronic Resolute® (62 patients) in the treatment of ST-elevation Myocardial Infarction. Patients were followed up at either 4 months (63 patients) or 9 months (89 patients). Stent apposition was statistically better in the STENTYS group than the balloon-expandable group at 4 months, and a greater percentage of STENTYS stents were fully covered by vessel tissue (33% vs 4%, p=0.02), a marker for healing. At 9 months, the STENTYS SES showed no reduction in artery lumen diameter (Late Lumen Loss of 0.04mm ±0.43 under QCA) with a near perfect arterial healing (99% covered struts at 9 months under OCT).

About STENTYS

STENTYS is developing and commercializing innovative solutions for the treatment of patients with complex coronary artery disease. STENTYS' Self-Apposing® Stents are designed to adapt to vessels with ambiguous or fluctuating diameters 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.

Safe Harbor Statements

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, 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 French Autorité des Marchés Financiers 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

NewCap
Investor Relations / Strategic Communications
Dusan Oresansky / Pierre Laurent
Tel.: +33 (0)1 44 71 94 93
stentys@newcap.fr

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ISIN: FR0010949404 – Ticker: STNT

LifeSci Advisors LLC
Andrew McDonald
Tel: +1.646.597.6987
andrew@lifesciadvisors.com