STENTYS Reallocates Resources to focus on its Advanced Drug-Eluting Stent Program

PRINCETON, N.J. and PARIS – July 31, 2014 – STENTYS (FR0010949404 — STNT), a medical technology company commercializing in Europe the world's first and only Self-Apposing® stent to treat acute myocardial infarction (AMI), today announces that it has discontinued enrollment of the APPOSITION V trial evaluating its bare metal stent (BMS) and that the Company will instead direct those financial resources towards developing its next-generation Sirolimus-eluting stents (SES) on a new delivery catheter.

The APPOSITION V study was designed to compare the clinical outcome of patients suffering from STEMI treated with the bare metal STENTYS Self-Apposing® Stent versus a conventional balloon-expandable BMS, at 12 months after the procedure. However, recently published articles have accelerated the market trend of treating STEMI patients with a drug-eluting stent (DES) rather than a BMS, and this trend is particularly pronounced in the U.S. As a result, the Company has experienced slower enrollment in the U.S. portion of the APPOSITION V trial. Of the 297 patients enrolled to date, only 20% were enrolled in the U.S. STENTYS recognized that slower than expected enrollment rates could result in both a significant delay of final study results and that the final APPOSITION V population may not capture enough U.S patients to adequately satisfy the FDA for a PMA approval.

This strategic decision was reinforced by the recent clinical results obtained from the APPOSITION IV study, where the STENTYS Sirolimus-eluting stent demonstrated excellent efficacy compared to market leading stents and faster healing compared to balloon-expandable stents. With these final results, the STENTYS SES could receive CE Mark before the end of this year.

With a cash position of €23 million at June 2014, STENTYS intends to focus on the commercialization of its new sirolimus-eluting stent worldwide.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, stated: “This decision to terminate enrollment in the study was made in close collaboration with the study’s Steering Committee. We are affirming our plan to invest the Company’s financial resources where we can make the greatest positive impact on a patient’s health in the future and be best positioned to take a leading share of this dynamic market.”

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 atypical 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. The STENTYS Self-Apposing Stent has been marketed in Europe since receiving CE Mark in 2010. The STENTYS Sirolimus-eluting stent should receive the CE Mark during the second half of 2014.

About STENTYS
STENTYS is developing and commercializing innovative solutions for the treatment of patients with acute myocardial infarction (AMI, or heart attack) and complex coronary artery disease. STENTYS’ Self-Apposing® Stents are designed to adapt to vessels with ambiguous or fluctuating diameters, particularly in the post-infarction phase, 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.
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, including with respect to a pre-market approval for the Company’s BMS, 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

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

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

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