STENTYS Self-Apposing® Stent continues to demonstrate low mortality at one year in APPOSITION III trial

Interim results to be reported at TCT 2012

PRINCETON, N.J. and PARIS – October 22, 2012 - 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), announced today the interim results of the APPOSITION III clinical trial for the first 600 patients at one year post treatment of a severe heart attack.

The APPOSITION III trial was designed to assess the long term performance of STENTYS Self-Apposing® Stents in routine clinical practice in 1,000 patients suffering from ST-elevation myocardial infarction (STEMI) in Europe. The interim analysis was conducted on the first 600 patients at the one-year time point and showed a death rate of 1.7% where conventional stents average 3.9% (pooled analysis from ACTION Study Group, Prof. G. Montalescot at Pitie-Salpetriere Hospital), thus maintaining the early clinical gain that was reported in May 2012 for the one-month time point.

“In addition to the favorable MACE and mortality results, we noticed a very low rate of revascularization (TLR) at 5.8% (6.2% for BMS, 3.8% for DES), which confirms that the Self-Apposing Stents have a restenosis rate in line with or better than the best conventional balloon-expandable stents,” commented Prof. Harald Mudra, M.D., Ph.D. of Klinikum Neuperlach (Munich, Germany) and investigator of the study.

“The new positive clinical data that is coming in provides further evidence that the Self-Apposing Stent is well suited for AMI and can provide better clinical outcomes for heart attack patients,” said Gonzague Issenmann, CEO and co-founder of STENTYS.

The data will be featured at the Transcatheter Cardiovascular Therapeutics (TCT) conference in Miami during a presentation entitled “Primary PCI for STEMI: Drugs, Devices, and Technique Controversies,” by Prof. Mudra on Thursday, October 25, 2012 at 9:58 a.m., as well as a satellite symposium chaired by Maurice Buchbinder, M.D., of the Foundation of Cardiovascular Medicine (San Diego), scheduled for Wednesday, October 24, 2012 from 12:15 p.m. to 1:15 p.m.

In its latest guidelines on AMI treatment, the European Society of Cardiology (ESC) calls attention to the importance of selecting the appropriate stent size. During a heart attack treatment procedure, the presence of a thrombus (clot) and the natural vessel contraction prevent cardiologists from determining the artery diameter with certainty. When selecting a conventional stent size, there is a risk of under sizing, causing malapposition, or oversizing, causing vessel wall injury; either leads to increased risk of heart attack recurrence. The STENTYS Self-Apposing Stent solves that “stent-sizing dilemma”: it fits into the contour of a blood vessel, and its shape and diameter adapt as the vessel dilates and the initial clot dissolves during the post-AMI phase.

About the APPOSITION III Study

APPOSITION III is a prospective, single-arm, multi-center (50 hospitals across Europe) post-market trial to assess the long term performance of STENTYS Self-Apposing® Stents in routine clinical practice in 1,000 patients suffering from ST-elevation myocardial infarction (STEMI). The trial’s primary endpoint is major adverse cardiac events (MACE) at 12 months. MACE is defined as cardiac death, target vessel re-MI, emergent by-pass, or clinically-driven TVR by percutaneous or surgical methods at 12 months. The trial’s secondary endpoints are MACE at 30 days and 24 months post-procedure. The study completed enrollment in January 2012. Results at the 30-day time point were announced in May 2012, which included a MACE rate of 3.5%, where conventional stents averaged 6% in the pooled analysis; the death rate at 30 days was 1.2% compared to 3.5% with conventional stents in the pooled analysis. STENTYS expects to release the full primary endpoint results on 1,000 patients in H1 2013.
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. It fits into the contour of a blood vessel, and its shape and diameter adapt as the vessel dilates and the initial clot dissolves during the post-AMI phase, thus reducing 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. It is not approved for marketing in the United States; however, the U.S. Food and Drug Administration recently approved an Investigational Device Exemption (IDE) to conduct a pivotal clinical study that will enroll up to 880 heart attack patients at 50 sites in the U.S. and worldwide.

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 30-day 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, the final outcome of the APPOSITION III and other clinical trials, market acceptance of the Company's products, its ability to enforce and protect its patents and proprietary rights, and other factors, including those described in the Section 4 “Risk Factors” of the Company’s 2011 Registration Document (document de reference) filed with the Autorité des marches financiers in France on June 25, 2012 under number R.12-033 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

Europe: NewCap.
Axelle Vuillermet / Pierre Laurent
Tel.: +33 (0)1 44 71 94 93
stentys@newcap.fr

US: MacDougall Biomedical Communications
Kari Watson, Tel.: +1 781 235 3060
Christine Labaree, Tel.: +1 650 339 7533
stentys@macbiocom.com

STENTYS is listed on Compartment C of the NYSE Euronext Paris
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