

# Further Data on STENTYS Self-Apposing Stent Reinforces Strength of Clinical Results

New Sub-group Analysis of APPOSITION III Presented at EuroPCR in Paris

PRINCETON, N.J. and PARIS – May 22, 2013 - <u>STENTYS</u> (FR0010949404 – STNT), a medical technology company commercializing in Europe the world's first and only Self-Apposing<sup>®</sup> Stent to treat acute myocardial infarction (AMI), announced today <u>new one-year data from the APPOSITION III clinical trial</u> at the international EuroPCR conference in Paris. APPOSITION III was designed to assess the long-term performance of STENTYS Self-Apposing Stents in routine clinical practice in Europe among 1,000 patients suffering a heart attack (ST-elevation myocardial infarction or STEMI).

The patient population was particularly high-risk since 70% of patients had completely occluded arteries (TIMI 0-1); the mean time from the onset of symptoms to treatment was 5 hours and 48 minutes. At one year, the mortality rate was 2.0%, re-infarction was 1.3% and the overall MACE rate (cardiac death, target vessel re-MI, emergent by-pass, or clinically-driven TVR) was 9.3%. Further analysis of data showed that the STENTYS Self-Apposing Stent performs equally well in many sub-groups: clinical outcome in female patients (23% of the population) was as good as in male (p=0.41), and diabetic patients (15% of the population) had similar clinical results as the rest of the population (p=0.85). Importantly, the first 5 patients treated in a center exhibited no statistically significant difference in MACE compared to patients treated onwards (p=0.65), indicating the absence of a learning curve in using the STENTYS Self-Apposing Stent.

"We continue to be encouraged by the excellent data produced to date for the STENTYS Self-Apposing Stent, including very low rates of death and re-infarction in STEMI patients," said Giovanni Amoroso, M.D., OLVG Hospital of Amsterdam and Principal Investigator of the study. "The drug-eluting version, which was selected by investigators for their higher risk patients, also showed very low rate of cardiac complications."

"The STENTYS Self-Apposing Stent is becoming an invaluable tool for cardiologists in Europe for treating patients with AMI," said Gonzague Issenmann, CEO and co-founder of STENTYS. "The additional clinical data will contribute to further adoption of our stent and to swift enrollment in the recently started APPOSITION V trial in the United States and worldwide."

## About the STENTYS Self-Apposing<sup>®</sup> Stent

The STENTYS Self-Apposing<sup>®</sup> 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.

### 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 the STENTYS Self-Apposing Stent 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. The MACE rate at one year was 9.3% for the full study population, where conventional stents average 11.1%. Mortality rate at one year was 2.0%, where conventional stents average 3.9% (pooled analysis from ACTION Study Group, Prof. G. Montalescot at La Pitié-Salpêtrière Hospital).



## 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 *Autorité des marchés* 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

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

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

US: MacDougall Biomedical Communications Charles Liles, Tel.: 781 235 3060 Christine Labaree, Tel.: 650 339 7533 stentys@macbiocom.com

