STENTYS Stent continues to show low mortality two years after treatment of a heart attack

Final 2 Year Results from APPOSITION III Study Presented Today at TCT Conference in Washington, D.C

PRINCETON, N.J. and PARIS – September 16, 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 announced the results of the 1,000 patient APPOSITION III clinical study at two years after the treatment of a severe heart attack.

APPOSITION III is the largest trial ever conducted to evaluate the use of a self-apposing stent in primary PCI. It is an international, prospective, single arm and multi-center clinical study. At two years, the MACE (defined as the composite of cardiac death, target-vessel myocardial infarction, emergent by-pass and clinically driven target lesion revascularization), was 11.2% compared to 9.3% at one year, and cardiac death at two years was 2.3% compared to 2.0% at one year.

Maik Grundeken, M.D., from Amsterdam Medical Center (Amsterdam, the Netherlands) who will present these results at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in Washington, D.C on Tuesday, Sept. 16 at 5:30 pm EDT, said: “The low rate of cardiac death, myocardial infarction and stent thrombosis that occurred between 30 day and two year follow up clearly confirms the long term safety profile of the stent platform.”

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, stated: “The continued strength of the clinical data for the Self-Apposing platform in the very long run is yet another body of evidence supporting the superiority of our technology in the treatment of AMI.”

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. More than 10,000 STENTYS Self-Apposing stents have been implanted since receiving CE Mark in 2010. The STENTYS Sirolimus-eluting stent should receive the CE Mark during the second half of 2014.

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 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.

Forward Looking 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.

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