



STENTYS Enrolls First Heart Attack Patient in Pivotal U.S. Clinical Trial

PRINCETON, N.J. and PARIS – May 20, 2013 - 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 that the first patient was enrolled in APPOSITION V, the pivotal FDA-approved IDE trial which will enable the Company to apply for marketing approval of the Self-Apposing Stent in the United States.

APPOSITION V is a multi-center, randomized, two-arm clinical trial that will enroll up to 880 heart attack (ST-elevation myocardial infarction or STEMI) patients at 50 sites in the U.S. and worldwide. The trial is designed to compare the clinical outcome of patients treated with the STENTYS Self-Apposing Stent with a balloon-expandable stent already approved for this indication, the Abbott Multi-Link stent, at 12 months after the procedure. Principal investigators of the study are Roxana Mehran, M.D., Professor of Medicine and Director of Interventional Cardiovascular Research and Clinical Trials at Mount Sinai School of Medicine (New York), and Maurice Buchbinder, M.D., Professor of Clinical Medicine at Stanford University (Stanford, Calif.).

"The APPOSITION V trial will be a landmark study as it is the first time a novel device, that has already shown impressive clinical results in Europe, will benefit our STEMI patients here in the U.S.," said Dr. Mehran. *"We would like to congratulate Dr. Karel Koch from Amsterdam Medical Center for enrolling the first patient in this study."*

"This is a historic milestone for STENTYS, as we begin the U.S. trial that will allow us to file our marketing application with the FDA," said Gonzague Issenmann, CEO and co-founder of STENTYS. *"The STENTYS Self-Apposing Stent has the potential to replace the current gold standard of conventional balloon-expandable stents in the AMI setting."*

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.

About the APPOSITION V Study

APPOSITION V is an interventional, multi-center, randomized, two-arm clinical trial to evaluate the safety and effectiveness of the STENTYS Self-Apposing® Stent in the treatment of de novo stenotic lesions in coronary arteries in 880 patients undergoing primary revascularization due to ST-elevation myocardial infarction (STEMI) as compared to the Multi-Link coronary system (Abbott Vascular, Inc.). The trial's primary endpoint is target vessel failure (TVF), which is defined as a composite of cardiac death, target vessel recurrent myocardial infarction or clinically driven target vessel revascularization (TVR), at 12 months post-procedure. The powered secondary endpoint is acute stent malapposition and will be assessed by intravascular ultrasound (IVUS) on the first 225 patients. All patients will undergo clinical follow up at 30 days, six months, nine months and 12 months, with an annual checkup through three years. Fifty sites are expected to participate in the U.S. and worldwide. More information can be found at www.clinicaltrials.gov.

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.

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