STENTYS Receives FDA Approval to Initiate First U.S. Clinical Trial With Self-Apposing® Stent

The Associated Press

PRINCETON, N.J. & PARIS--(BUSINESS WIRE)--Oct 22, 2012--STENTYS (FR0010949404 – STNT), a medical technology company that is commercializing in Europe the world's first and only Self-Apposing ® stent to treat acute myocardial infarction (AMI), announced today that it has received Investigational Device Exemption (IDE) approval from the Food and Drug Administration (FDA) to conduct a pivotal clinical trial in the United States which, if successfully completed, will enable the Company to apply for marketing approval of the STENTYS Self-Apposing stent.

Under this FDA-approved IDE, up to 880 heart attack (ST-elevation myocardial infarction or STEMI) patients at 50 sites in the U.S. and worldwide will be enrolled in the APPOSITION V clinical trial. The randomized trial is designed to compare the clinical outcome of patients treated with the bare metal STENTYS Self-Apposing ® Stent versus the stent already approved for use in this indication, the Abbott Multi-Link Vision™ stent, at 12 months after the procedure. The trial is expected to begin in early 2013.

“With an AMI global market estimated at $2 billion, this IDE approval represents a significant milestone for the company and an opportunity to expand upon the data gathered to date in our European clinical trials,” said Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS. “The IDE allows us now to progress toward a pre-market application to bring the self-apposing technology to cardiologists and their AMI patients in the U.S.” During a heart attack treatment procedure, the presence of a 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 is designed to address that ‘stent sizing dilemma’ by fitting into the contour of a blood vessel. The shape and diameter of the stent adapt as the vessel dilates and the initial clot dissolves during the post-AMI phase.

About APPOSITION V APPOSITION V is a prospective, 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 Vision™ 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. Enrollment is expected to begin in early 2013.

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.

This press release contains forward looking statements about the Company’s business and prospects. Such forward looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future which may not be accurate. Such forward-looking statements involve known and unknown risks, uncertainties and other factors 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 development and commercialization of the Company’s products, 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, including the APPOSITION V clinical trial, market acceptance of the Company’s products, and other factors, including those described in the Section 4 “Risk Factors” of our 2011 Registration Document (document de reference) filed with the Autorité des marches financiers (the “AMF”) in France on June 25, 2012 under number R.12-033 as such section may be updated from time to time.

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

CONTACT: STENTYS Stanislas Piot, +33 (0)1 44 53 99 42 CFO stan.p@stentys.com or Europe: NewCap.

Axelle Vuillermet / Pierre Laurent, +33 (0)1 44 71 94 93 stentys@newcap.fr or US: MacDougall Biomedical Communications Kari Watson, +1 781-235-3060 or Christine Labaree, +1 650-339-7533 stentys@macbiocom.com KEYWORD: UNITED STATES NORTH AMERICA NEW JERSEY INDUSTRY KEYWORD: HEALTH CLINICAL TRIALS HOSPITALS MEDICAL DEVICES FDA GENERAL HEALTH SOURCE: STENTYS Copyright Business Wire 2012 PUB: 10/22/2012 01:02 PM/DISC: 10/22/2012 01:02 PM
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