

STENTYS to Present Final Results From 1,000 Heart Attack Patient Study at ACC.13

Educational Symposium Also to Highlight FDA-Approved U.S. Pivotal Study for Self-Apposing[®] Stent in STEMI Patients

PRINCETON, N.J. and PARIS – February 26, 2013 – <u>STENTYS</u> (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 results for the primary endpoint in the APPOSITION III study (MACE at one year on 1,000 STEMI patients) will be presented during ACC.13, the American College of Cardiology's Scientific Session & Expo, March 9-11, 2013 in San Francisco. Prof. Gilles Montalescot, M.D., Ph.D, Head of the Cardiac Care Unit at Pitié-Salpêtrière Hospital (Paris), will present "One Year Clinical Results on 1,000 STEMI Patients Treated With a Self-Expanding Coronary Stent (APPOSITION III)" during <u>Session #2667</u> of the Featured Clinical Research I: Interventional session on Saturday, March 9, 2013 at 3:00 p.m.

STENTYS is also hosting an educational symposium during ACC.13 that will provide an overview of the Self-Apposing Stent clinical results to date and the U.S. IDE trial in STEMI, APPOSITION V. The <u>event</u>, "STENTYS IDE Trial in STEMI: The Self-Apposing Stent Revolution is Coming to the U.S.," is being held Sunday, March 10, 2013 from 6:45 a.m. to 7:45 a.m. at the InterContinental San Francisco Hotel and features a panel discussion and presentations relating to the Self-Apposing technology by prominent cardiologists:

- Maurice Buchbinder, M.D., of the Foundation for Cardiovascular Medicine (San Diego) will present "Better Stent Sizing Leads to Better Outcomes: The Self-Apposing Stent Technology."
- Karel Koch, M.D., of the Academic Medical Center, University of Amsterdam will present "Real-world Experience: Case Studies and APPOSITION III One-Year Results on 1,000 STEMI Patients."
- Roxana Mehran, M.D., of Mount Sinai Hospital (New York) will present "STENTYS Randomized IDE Trial in STEMI, the APPOSITION V Study in the United States and Worldwide."
- Timothy D. Henry, M.D., of the Minneapolis Heart Institute Foundation will also be participating in panel discussions.

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.

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 at 12 months. The trial's secondary endpoints are MACE at 30 days and 24 months post-procedure. The MACE rate at 30 days was 3.5% for the full study population and 2.5% when post-dilation was performed. Mortality rate at 30 days was 1.2% for the full study population. An interim analysis conducted on the first 600 patients at the one-year time point showed a death rate of 1.7% where conventional stents average 3.9% (pooled analysis from ACTION Study Group, Prof. G. Montalescot at Pitié-Salpêtrière Hospital).

About the APPOSITION V Study

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 H1 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's 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.*

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