

STENTYS Self-Apposing® Stent Demonstrates Lowest Mortality Rate Among Large Heart Attack Trials

The Associated Press

PRINCETON, N.J. & PARIS--(BUSINESS WIRE)--Mar 9, 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 one-year results of the APPOSITION III clinical trial in 1,000 patients post treatment of a severe heart attack at ACC.13, the American College of Cardiology's Scientific Session & Expo.

The APPOSITION III trial is a prospective, single-arm, multi-center study designed to assess the long term performance of STENTYS Self-Apposing Stents in routine clinical practice in Europe among patients suffering from ST-elevation myocardial infarction (STEMI). The primary endpoint, Major Adverse Cardiac Events rate (MACE, defined as cardiac death, target vessel re-MI, emergent by-pass, or clinically-driven TVR) at one year, was 9.3%, where conventional stents average 11.1% in a pooled analysis from ACTION Study Group (Pitié-Salpêtrière Hospital, Paris). At the one-year time point, the cardiac death rate was 2.0%, as compared with rates for conventional stents in other published trials which average 3.9%, the lowest rate being 2.2%.

"The very low rates of mortality (2.0%) and target-vessel re-infarction (1.3%) in the APPOSITION III study clearly highlight the excellent safety profile of Self-Apposing stents," commented Prof. Gilles Montalescot, M.D., Ph.D., Head of the Cardiac Care Unit at Pitié-Salpêtrière Hospital and investigator of the study, who presents the data at the conference.

"The strong results reported today continue to suggest the superiority of the Self-Apposing Stent in the treatment of AMI," said Gonzague Issenmann, CEO and co-founder of STENTYS. "We expect these data will contribute to the ongoing adoption of the technology among cardiologists in Europe and further support the initiation of our FDA-approved U.S. pivotal trial, APPOSITION V, during the first half of 2013." In its latest guidelines on AMI treatment, the European Society of Cardiology (ESC) calls attention to the importance of selecting the appropriate stent size. During a heart attack treatment procedure, the presence of a thrombus (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 solves that "stent-sizing dilemma": 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.

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 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 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 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.

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