

**NEWS RELEASE** 

### FOR IMMEDIATE RELEASE

Contact: Ronald Trahan, APR, President, Ronald Trahan Associates Inc., +1-508-359-4005,x108

# STENTYS Self-Apposing® Stent shows very low mortality at one month in 1,000 high risk heart attack patients

## APPOSITION III study results reveal mortality at 1.2% compared to 3.5% in pooled analysis of conventional stents

PRINCETON, N.J., and PARIS, May 16, 2012 — **STENTYS S.A.** (STNT.PA), a medical technology company commercializing the world's first and only **Self-Apposing® Stent** to treat **Acute Myocardial Infarction** (**AMI**), announced today the definite results on the 1,000 patient APPOSITION III clinical study at one month after treatment of a severe heart attack.

The 30-day rate of MACE (Major Adverse Cardiac Events) and death were compared to a pooled analysis conducted by the ACTION Study Group (Pitié-Salpêtrière Hospital, Prof. G. Montalescot) of all prior recent trials with conventional stents in heart attack patients.

APPOSITION III results showed a MACE rate of 3.5% when conventional stents are at an average of 6%; the death rate was 1.2% with STENTYS when compared to 3.5% with conventional stents.

"When the current guideline on balloon post-dilation was applied, the MACE rate was even lower at 2.5%, which is a drastic improvement for our patients", commented **Dr Giovanni Amoroso**, OLVG Hospital, Amsterdam, The Netherlands and principal investigator of the study.

"These impressive clinical results validate our Self-Apposing® Stent as *the best* solution for treating heart attack patients in routine practice," said **Gonzague Issenmann**, **CEO** and **co-founder of STENTYS**.

The STENTYS Self-Apposing® Stent solves the stent-sizing dilemma that cardiologists are confronted with when treating heart attack patients with conventional stents. It "fits snugly" 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, eliminating malapposition and its major complications seen with all other conventional stents.

### **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 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 at as cardiac death, target vessel re-MI, emergent CABG, 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 study completed enrolment in January 2012. After a preliminary analysis of the first 350 patients, the guideline on balloon post-dilation was modified from a limitation (only when residual stenosis above 30%, cohort A) to a general recommendation (cohort B).

MACE rate at 30 days was 3.5% for the whole study, and 2.5% when post-dilation was applied. Mortality represented 1.2% on the whole study.

STENTYS expects to release the primary endpoint interim results of the APPOSITION III study in 600 patients during Q4 2012 and the full results on 1,000 patients in H1 2013.

#### **About STENTYS**

Based in Princeton, N.J., and Paris, STENTYS has developed a new generation of stents to treat acute myocardial infarction (AMI). Founded by **Jacques Séguin, M.D., Ph.D., (also founder of CoreValve, which was acquired by Medtronic)** and **Gonzague Issenmann**, STENTYS received CE-marking for its flagship products in 2010. Its Self-Apposing® stent adapts to the anatomic changes of arteries in the post-infarction phase and thus prevents the malapposition problem associated with conventional stents. STENTYS has commenced marketing activities in several European countries.

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