STENTYS Revenues for the First Quarter of 2013 Up 47% Over Prior Year

PRINCETON, N.J. and PARIS - 25 April 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), today reports its first quarter revenues to 31 March 2013 and announces the first distributor contracts signed outside of Europe.

- **Change in quarterly revenues***

€ thousands	**Q1 2013**	**Q1 2012**	**Var. (%)**
Revenues	725.0	494.0	+47%

* *Audited*

STENTYS recorded a solid first quarter of 2013 with revenues totaling €725.0 thousand, an increase of 47% compared with the same quarter last year. Revenues during the quarter were driven largely by sales of Self-Apposing stents using the new-generation catheter introduced in the third quarter of 2012.

- **Geographic expansion beyond Europe**

Backed by experience acquired during the pre-marketing phase of the Self-Apposing stent, STENTYS is pursuing commercial expansion beyond Europe by forming partnerships with local distributors in new high-potential countries where the European CE mark is recognized. STENTYS recently signed agreements with leading regional distributors of cardiovascular products in Saudi Arabia, Jordan, Lebanon and Egypt. The Company estimates that the Middle East market for coronary stenting is about €160 million.

- **Clinical update on recent and ongoing trials**

  - APPOSITION III clinical trial
    Definitive 12-month data from the APPOSITION III clinical trial on 1,000 heart attack patients were presented in early March at the prestigious annual American College of Cardiology conference. The impressive results were covered in the US press and were well received by cardiologists, notably in the United States, the world's largest stent market. In the study, STENTYS' stent showed the lowest mortality rate (2.0%) of any major heart attack trial with conventional stents, and the rate of re-infarction was also particularly low (1.3%).

  - APPOSITION IV clinical trial
    This randomized trial enrolled 150 heart-attack patients treated with either the STENTYS Sirolimus-eluting stent or the Medtronic Resolute® stent, with the objective of comparing long-term stent apposition. The 4-month results should be announced during the second half of 2013.

  - APPOSITION V clinical trial
    The IDE for the APPOSITION V pivotal study, the last trial in the APPOSITION program, has been approved by the US Food and Drug Administration (FDA). The trial aims to compare the clinical efficacy of the Self-Apposing stent with that of the stent already approved for the AMI indication in the US, the Abbott MultiLink stent. The trial is expected to be launched during the second quarter of 2013 and will enroll approximately 880 patients who will be evaluated 12 months after treatment.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, concludes: "*The solid growth recorded this quarter confirms STENTYS' steady expansion, in line with the Company's plan. Growth in the new countries outside Europe is expected to be fueled by the excellent results from the APPOSITION III clinical trial: these results represent the most significant developments since the creation of STENTYS and provide further evidence that the Self-Apposing stent is the optimal solution for treating heart attacks.*"

- **Upcoming financial results**

STENTYS expects to publish its revenues for H1 2013 on 25 July 2013.

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 IV Study

APPOSITION IV is a prospective, randomized, two-arm, multi-center study designed to compare the apposition of the STENTYS Sirolimus-eluting stent with Medtronic Resolute® in 150 patients suffering from ST-elevation Myocardial Infarction. Patients will be followed up at either 4 or 9 months (double randomization). The powered primary endpoint is strut apposition at 9 months under OCT. The secondary endpoints are strut apposition at 4 months under OCT, and strut coverage at 4 and 9 months. The first results are expected to be announced in H2 2013.

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 revascularization due to ST-elevation myocardial infarction (STEMI) as compared to the Multi-Link stent (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' 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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