

STENTYS: Journal of the American College of Cardiology Publication Shows Malapposition Influences Death from Early Stent Thrombosis

Study conducted by Dr Virmani further supports the Self-Apposing technology's scientific rationale

PRINCETON, N.J. and PARIS – May 6, 2014 – STENTYS (FR0010949404 – STNT), a medical technology company commercializing the world's first and only Self-Apposing® Stent for treating acute myocardial infarction (AMI), today announced the publication of an article in the Journal of the American College of Cardiology (JACC) entitled, "Causes of Early Stent Thrombosis in Patients Presenting with Acute Coronary Syndrome: An Ex Vivo Human Autopsy Study."

Researchers led by Renu Virmani, MD, (CVPath Institute, Gaithersburg, Md.), examined autopsy cases of 67 stented coronary lesions from 59 patients who presented with acute coronary syndrome (ACS) and died within 30 days of stent implantation. They identified that 34 patients (58%) died from early stent thrombosis (ST). The authors found that the occurrence of malapposition, medial tear and necrotic core prolapse was greater in the early ST group than the non-ST group (34% vs. 18%, $p=0.008$, 27% vs. 15%, $p=0.004$, and 28% vs. 11%, $p<0.001$ respectively) and that they were independent risk factors associated to ST.

According to the authors, "While complete stent apposition may be important to avoid incomplete apposition in rupture-prone lesions, excess medial tear secondary to high inflation pressure was found to be a major determinant of early ST." The authors suggested that "improvement in implantation technique and refinement of stent design may improve clinical outcomes of ACS patients."

When treating heart attack patients, cardiologists often cannot determine artery diameter with certainty because of the clot and vessel contraction. When selecting a conventional stent, they risk under-sizing (which can lead to malapposition) or over-sizing (which can cause vessel wall tear), and either scenario increases the likelihood of heart attack recurrence and death.

STENTYS' Self-Apposing Stent is designed to adapt to the vessel's unknown diameter, particularly in the post-infarction phase, in order to prevent the malapposition or excessive inflation problems associated with conventional stents. Results from STENTYS' APPPOSITION II clinical trial, published by JACC Cardiovascular Interventions in [December 2012](#), showed 28% of malapposition in conventional stents three days after implant versus 0% for STENTYS stents ($p<0.001$).

Gonzague Issenmann, co-founder and Chief Executive Officer of STENTYS said: "Dr. Virmani and her colleagues have confirmed that malapposition leads to serious complications for patients with acute coronary syndrome. The Self-Apposing Stent data not only show greatly reduced rates of malapposition compared with conventional stents but also very low mortality rates."

Reference: Nakano M, Yahagi K, Otsuka F, Sakakura K, Finn AV, Kutys R, Ladich E, Fowler DR, Joner M, Virmani R, Causes of Early Stent Thrombosis in Patients Presenting with Acute Coronary Syndrome: An Ex Vivo Human Autopsy Study, Journal of the American College of Cardiology (2014), doi: 10.1016/j.jacc.2014.02.607.

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 or patients with atypical artery anatomy. Its flexible, self expanding design takes the shape of the patient's unique vessel anatomy and apposes to the irregular contours of a blood vessel, in particular after an AMI as the vessel dilates and the clot dissolves. It reduces 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. The STENTYS Sirolimus-eluting stent should receive the CE Mark during the second half of 2014.

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 French *Autorité des Marchés Financiers* on August 27, 2013 under number R.13-040 as such section may be updated from time to time.

STENTYS

Stanislas Piot
CFO
Tel.: +33 (0)1 44 53 99 42
stan.p@stentys.com

STENTYS is listed on Comp. B of the NYSE Euronext Paris
ISIN: FR0010949404 – Ticker: STNT

NewCap.

Financial Communication / Investor Relations
Dusan Oresansky / Pierre Laurent
Tel.: +33 (0)1 44 71 94 93
stentys@newcap.fr

US: MacDougall Biomedical Communications

Charles Liles, Tel.: 781 235 3060
Christine Labaree or Hunter Marshall, Tel.: 650 339 7533
stentys@macbiocom.com