STENTYS Self-Apposing Stent Approved in Europe for Additional Coronary Indications

New market segments represent 10% of all coronary interventions

PRINCETON, N.J. and PARIS – July 10, 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 that it received approval from its European Notified Body to expand the CE Mark indications of the Self-Apposing stent.

Patients suffering from chronic chest pain due to narrowed coronary arteries are often treated with a stent. Coronary arteries generally have cylindrical shape and uniform diameters, but in some patients, arteries vary greatly in diameter and conventional stents cannot maintain contact to the artery wall: this inadequate implantation called malapposition can lead to adverse clinical events and heart attacks.

The STENTYS Self-Apposing Stent is engineered to solve the dilemma of artery diameter discrepancy. Its flexible, self expanding design takes the shape of the patient’s unique vessel anatomy and perfectly apposes to the irregular contours of a blood vessel.

The CE Mark certificate of the Self-Apposing Stent was updated on the basis of additional clinical evaluation and now includes specific patient subsets such as those with tapered, aneurysmatic, ectatic (dilated) or very large vessels or those with bypass grafts. Contraindications such as chronic total occlusions and left main bifurcations have also been lifted. These changes allow STENTYS to commercialize its Self-Apposing Stent in new market segments that represent approximately 10% of all percutaneous coronary interventions in Europe.

“Our European customers are using the STENTYS Self-Apposing Stent for their patients with atypical vessel anatomies because this is the only available product that solves this unmet need,” said Gonzague Issenmann, CEO and co-founder of STENTYS. “We are excited that the new product label should allow us to develop these new high-value market segments beyond our traditional heart attack market.”

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, even as the vessel dilates and the initial clot dissolves after an AMI. 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.

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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