



STENTYS Receives CE Mark for Self-Apposing Stent in Lower Limb Artery Disease

PRINCETON, N.J. and PARIS – September 28, 2015 – STENTYS (FR0010949404 – STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announced that the Company's Drug-Eluting stent received CE Mark for treatment of below-the-knee (BTK) arteries, making STENTYS' product the first self-expanding and drug-eluting stent with regulatory approval in Europe for this indication.

The CE Mark was obtained following the strong results achieved by STENTYS' stent in the PES BTK-70 study in which the product prevented foot amputation in 99% of the 70 patients treated for critical limb ischemia (CLI).

The most severe cases of CLI, in which tissue of the foot or ankle does not receive a sufficient supply of oxygen and begins to die (necrosis), often require amputation. To prevent this outcome, surgeons open up the artery with balloons and frequently implant stents. Approximately 25% of diabetics globally suffer from CLI and, according to the International Diabetes Foundation (IDF), the world-wide diabetic population is projected to increase from 387 million in 2014 to nearly 600 million individuals by 2035.

*"Entering the peripheral arterial disease market, which, outside of the US and Japan, is estimated at \$1.3 billion, represents a significant long term growth opportunity for STENTYS," said **Gonzague Issenmann, CEO and co-founder of STENTYS.** "Now that the product is CE Marked, becoming the first stent that combines the benefits of self-expansion and drug-elution in this indication in Europe, we intend to formalize new distribution partnerships and expect to begin commercializing the product in 2016."*

About PES BTK-70

The PES BTK-70 trial treated 70 patients suffering from critical limb ischemia of class 4 and 5 in the Rutherford scale with a STENTYS Paclitaxel-eluting stent from January 2012 to May 2013 in five hospitals. The primary endpoint was the 12 month primary patency rate defined as absence of restenosis ($\geq 50\%$) or occlusion within the originally treated lesion based on angiography verified by Core Lab. At 12 months, the primary patency rate was 73%, freedom from target-lesion revascularization was 79% and freedom from amputation was 99%.

About STENTYS

STENTYS is developing and commercializing innovative solutions for the treatment of patients with complex coronary artery disease. STENTYS' Self-Apposing® Stents are designed to adapt to vessels with ambiguous or fluctuating diameters in order to prevent the malapposition problems associated with conventional stents. The APPOSITION clinical trials in the treatment of acute myocardial infarction showed a very low one year mortality rate and a faster arterial healing compared to conventional stents. The company's product portfolio also includes MiStent SES®, a coronary DES whose new drug delivery mechanism is designed to match vessel response, and is marketed through STENTYS' commercial

Safe Harbor Statements

This press release contains forward-looking statements about the Company that 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, 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 2014 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers on July 29, 2015 under number D.15-0807 as such section may be updated from time to time.

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

