

## **STENTYS initiates the Commercialization of the first Self-Expanding Drug-Eluting stent for the Below-The-Knee Indication**

**PRINCETON, N.J. and PARIS – February 8, 2016 - STENTYS (FR0010949404 – STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announces the first distribution agreements for its drug-eluting stent for treating BTK (Below-The Knee) arteries in Germany and Belgium, making it the first self-expanding drug-eluting stent commercialized for this indication in Europe.**

The STENTYS stent obtained CE Marking for the BTK indication at the end of 2015 following the excellent results achieved by the PES BTK-70 study, where it prevented amputation in 99% of the 70 patients treated for Critical Limb Ischemia (CLI). The rapid launch of its commercialization reflects a major medical need, particularly in Germany, Europe's largest market.

**Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, comments:** *"We are delighted by the interest we received for our stent, the first in Europe to combine the benefits of self-expansion and drug-elution in the BTK indication. The peripheral artery disease market, currently estimated to be worth 1.3 billion dollars outside the United States and Japan and driven by the growing global prevalence of diabetes, represents a major growth driver for STENTYS."*

### **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 network in Europe, the Middle East, Asia and Latin America. **More information is available at [www.stentys.com](http://www.stentys.com).**

### **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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