



STENTYS Expands Benefits of First Drug-Eluting, Self-Expanding Stent to Lower Limb Artery Disease

Clinical Trial Found STENTYS Treatment Prevented Amputation in 99% of Cases

PRINCETON, N.J. and PARIS – January 28, 2015 – STENTYS (FR0010949404 – STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announced that its unique Drug-Eluting and Self-Expanding stent was evaluated in 70 patients suffering from critical limb ischemia (CLI) and prevented foot amputation in 99% of them.

Artery blockage, which is caused by fatty lesions that impede appropriate blood flow to the organs, can be found in arteries other than the heart, such as in the lower part of the limbs below the knee. The most severe cases, in which tissue of the foot or ankle does not receive enough oxygen supply and begins to die (necrosis), often require amputation. To prevent this outcome, surgeons open up the artery with balloons and implant stents when necessary.

STENTYS initiated early 2012 a single-arm, prospective, multi-center clinical study called "PES BTK-70" that enrolled 70 patients with severe foot wounds due to lack of oxygen (critical limb ischemia or CLI) caused by a blockage in an artery below the knee (BTK). They were all treated with a STENTYS Paclitaxel-eluting Self-Apposing stent. At 12 months follow up, 99% of patients did not require an amputation, 79% did not require a new procedure for that same lesion (freedom from Target-lesion Revascularization) and 73% had an open artery under X-ray (primary patency under corelab-verified angiography).

*"Balloons alone have a limited efficacy for BTK lesions and we have yet to find the solution to treat these patients," said **Marc Bosiers, M.D.**, of Sint-Blasius hospital (Belgium) and Principal Investigator of the trial, who presented the data at the LINC conference. "This is the first time we are investigating a drug-eluting self-expanding stent in this setting and the results are extremely promising."*

*"The market to treat below the knee disease, a frequent consequence of diabetes, is growing very fast and our unique product, combining the benefits of self-apposition and drug-elution, could become the new standard of care," added **Gonzague Issenmann, CEO and co-founder of STENTYS.** "Once the product is CE Marked, which we expect in the first half of 2015, this indication will represent an opportunity beyond our coronary business for new revenue growth through distribution partners."*

The diabetes global epidemic is projected to translate into a 54% increase in the diabetic population by 2030. Approximately 25% of diabetics suffer from CLI. The global peripheral arterial disease (PAD) market outside of US and Japan is estimated today at \$1.3b.

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. In the APPOSITION III clinical trial, STENTYS stents demonstrated a very low one year mortality rate among 1,000 heart attack patients when compared to recent studies with conventional stents.

More information is available at www.stentys.com.

Safe Harbor Statements

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, 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 2013 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers on October 29, 2014 under number D.14-1026 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

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

LifeSci Advisors LLC

Andrew McDonald
Tel: +1.646.597.6987
andrew@lifesciadvisors.com