

## STENTYS: Enrollment Completion of MiStent Randomized Trial against Xience

- DESSOLVE III clinical trial enrolled 1,400 “all-comers” patients
  - Primary endpoint results to be announced in H1 2017

**PRINCETON, N.J. and PARIS - December 9, 2015 - STENTYS (FR0010949404 - STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, announced today the completion of patient enrollment in DESSOLVE III, a 1,400 patient randomized clinical trial comparing MiStent SES® Sirolimus Eluting Absorbable Polymer Coronary Stent System to Abbott's Xience® stent.**

The MiStent Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SES®) is a balloon-expandable stent designed to improve long term clinical outcome of patients treated with conventional “workhorse” stents. MiStent's unique Crystalline Sirolimus technology, where thousands of microscopic drug crystals slowly dissolve in the surrounding tissue after absorption of the polymer carrier, allows for a gradual, linear and much longer elution of sirolimus than with other competitive stents, hence reducing vessel over-scarring. With 2.0% re-intervention rate (Target Lesion Revascularization) at three year follow up in previous clinical trials, MiStent SES was shown to be superior to Xience in a retrospective propensity analysis presented by Alexandra Lansky, M.D. (New Haven, CT), during the last EuroPCR conference in Paris.

*“We are very pleased by the speed of enrollment of this landmark study comparing MiStent to the market leader, and by the feedback we received regarding MiStent's acute performance,” said **Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS.** “If DESSOLVE III results confirm previous trials' findings in H1 2017, it could truly be game changing since drug-eluting stents all too often require a repeat intervention after several years”.*

MiStent SES has already received CE Marking. STENTYS is MiStent exclusive distributor worldwide, except in the United States, Canada, China, South Korea and Japan, and is currently conducting a controlled launch in select countries in Europe, Middle East and Asia.

### **About DESSOLVE III**

DESSOLVE III is a prospective, balanced, randomized, controlled, single-blind, multi-center study comparing clinical outcomes between MiStent SES® and Xience in a “real world, all-comers” patient population of 1,400 patients in 20 hospitals in Europe. Patients in the trial suffered from symptomatic coronary artery disease, including those with chronic stable angina, silent ischemia, or acute coronary syndrome, and qualified for percutaneous coronary interventions. The primary endpoint is a non-inferiority comparison of target lesion failure (TLF) of the MiStent SES group versus the Xience group at 12 months post-procedure.

### **About MiStent SES®**

MiStent SES is built out of a Cobalt Chromium alloy with very thin 64µm struts. The bioabsorbable coating of MiStent SES disappears within three months of implantation to promote fast vessel healing. However, sirolimus elution is precisely and consistently controlled up to nine months after implantation, thereby inhibiting vessel renarrowing. These unique properties of both fast polymer absorption and sustained drug release are made possible by an innovative proprietary coating technology that allows sirolimus to be encapsulated as tiny crystals; once the polymer is gone, the crystals slowly dissolve into the tissue surrounding the stent providing a continued local anti-proliferative and anti-inflammatory effect for several months.

### **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).

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.

**STENTYS**

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

**NewCap**

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

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