

## STENTYS: Follow-Up of the APPOSITION IV and OPEN II Clinical Trials at Respectively 3 and 4 Years Confirms the Initial Positive Study Outcomes

PARIS – May 24, 2017 - 7.30 am CEST - STENTYS (FR0010949404 - STNT), a medical technology company commercializing the Xposition S Sirolimus-eluting self-apposing coronary stent, today announced that it has reported final follow-up results of two clinical studies featuring STENTYS stents during the annual EuroPCR meeting held in Paris last week.

# Oral presentation entitled: "Self-expandable Sirolimus-eluting stent in STEMI: long-term OCT follow-up results from the APPOSITION IV study", presented by Robert-Jan van Geuns, M.D., Ph.D., Erasmus Medical Center (Rotterdam, the Netherlands).

APPOSITION IV was a prospective, randomized, multi-center study designed to compare the STENTYS Sirolimus-eluting stent (STENTYS SES) with the Medtronic Resolute<sup>®</sup> stent for the treatment of ST-elevation Myocardial Infarction (STEMI). Presented in 2014, the positive results at 9 months demonstrated the STENTYS SES' best-in-class efficacy and faster healing compared to balloon-expandable stents. These results mainly contributed to the stent CE marking approval in late 2014.

The APPOSITION IV trial was extended in order to assess the positive long term effects of the STENTYS SES in STEMI patients. Global results at a 3-year follow-up showed that treated vessels remain well patent with stable mean lumen diameter and minimalistic late lumen loss (mean= 0.24mm), and that excellent stent apposition is maintained over time. Stent expansion remained limited, without the formation of any aneurysm.

Oral presentation entitled: "Self-expanding DES in coronary bifurcation lesions at 48 months follow-up: long-term results from the OPEN II trial", presented by Christoph K. Naber, M.D., Ph.D., Contilia Heart and Vascular Center (Essen, Germany).

OPEN II was the largest non-randomized study assessing the first-generation of a drug-eluting self-apposing stent (Paclitaxel eluting stent - PES) in bifurcation lesions in more than 200 patients suffering from routine coronary bifurcation stenosis (excluding left main coronary artery).

The 4-year follow-up data showed that the MACE (major adverse cardiac events) rate remains low with a rather flat progression. These results confirm that the STENTYS stent is a true alternative to balloon expandable DES when applying the phased approach technique recommended by the current guidelines.

**Christophe Lottin, Chief Executive Officer of STENTYS, comments:** "We are delighted that the final follow-up results of our APPOSITION IV and OPEN II studies have met a keen interest of the scientific community during the EuroPCR conference in Paris. Presented data have confirmed the advantages of the self-apposing technology for the treatment of a number of specific clinical conditions in the long run. It also supports our growth strategy based on the Xposition S stent and its targeted indications. We firmly believe that our Xposition stent will be used in a growing number of indications, and its unrivaled technical characteristics will establish it as a benchmark."

Furthermore, the results of the DESSOLVE III were disclosed directly by MiCell during EuroPCR and are available through this <u>link</u>.

### **Shareholder Meeting**

STENTYS will hold its Shareholder Meeting on the 2<sup>nd</sup> call on **June 22, 2017** from 4 pm CEST, at 21 place de la Madeleine, 75008 Paris. Preparatory documents for this Meeting, including the postal voting form, are available on the Company's website, <u>www.stentys.com</u>, in the <u>Investors / Filings / Shareholder Meetings</u> section.





#### About STENTYS

STENTYS is developing and commercializing innovative solutions for the treatment of patients with complex artery disease. STENTYS' Self-Apposing<sup>®</sup> drug-eluting 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<sup>®</sup>, 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 <u>www.stentys.com</u>

#### **STENTYS**

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#### **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 2015 Registration Document (*document de référence*) filed with the French *Autorité des Marchés Financiers* (AMF) on August 30, 2016 under number D.16-804..

