STENTYS' Sirolimus-Eluting Stent Receives CE Marking

PRINCETON, N.J. and PARIS – October 27, 2014 – STENTYS (FR0010949404 — STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announces it received CE Marking for its Sirolimus-Eluting Stent (SES). The CE Marking will allow the Company to market its SES in Europe immediately and, starting in 2015, in the many other countries where the Company has commercial activity.

The CE marking approval was based on the excellent outcomes of the APPOSITION IV clinical study, in which the STENTYS SES demonstrated best-in-class efficacy and faster healing compared to balloon-expandable stents in patients treated for a severe heart attack.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, stated: *"STENTYS finally has a drug-eluting stent from the 'limus' family of compounds as requested by the interventional cardiology community."*

"In a global coronary stent market that has seen renewed growth and will reach $7 billion by the end of the decade, unmet patient needs are driving the market towards specialty stent solutions. STENTYS Sirolimus-eluting Self-Apposing stent is the only product that can guarantee complete and continuous apposition in patients with varying vessel anatomy, including in the acute setting, for a safer and more efficacious treatment. This clear competitive advantage will fuel the company's growth worldwide," **added Mr. Issenmann.**

About the APPOSITION IV study

APPOSITION IV is a prospective, randomized, four-arm, multi-center study designed to compare the STENTYS Sirolimus eluting stent (90 patients) with Medtronic Resolute® (62 patients) in the treatment of ST-elevation Myocardial Infarction. Patients were followed up at either 4 months (63 patients) or 9 months (89 patients). Stent apposition was statistically better in the STENTYS group than the balloon-expandable group at 4 months, and a greater percentage of STENTYS stents were fully covered by vessel tissue (33% vs 4%, p=0.02), a marker for healing. At 9 months, the STENTYS SES showed no reduction in artery lumen diameter (Late Lumen Loss of 0.04mm ±0.43 under QCA) with a near perfect arterial healing (99% covered struts at 9 months under OCT).

More information is available at www.stentys.com.

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