STENTYS begins large-scale, “real life” study with its self-apposing stent for treatment of Heart Attacks

50 patients already enrolled

PRINCETON, N.J., and PARIS, Dec. 09, 2010 — STENTYS S.A. (STNT.PA), which develops innovative stents to treat Acute Myocardial Infarction (AMI), announced today that it has begun the international APPOSITION III study of its self-apposing stent, with 50 patients already enrolled out of a total of 500. The trial primary endpoint is Major Adverse Cardiac Events at 12 months post-procedure.

“The cardiologists in our cath lab are extremely excited to be part of the APPOSITION III study, because it allows us to use the STENTYS self-apposing stent in a real-life setting for the treatment of AMI patients,” said study investigator Prof. Harald Mudra, M.D., Ph.D., Head of the Department of Cardiology, Pulmonology and Internal Intensive Care Medicine of the Neuperlach Hospital in Munich, Germany.

“Based on the results of APPOSITION I and II, the clinical evidence is indisputable: malapposition, which is a known cause of early stent thrombosis and repeat AMI, can be eliminated with the use of our self-apposing stent. APPOSITION III, designed as a large scale single-arm prospective clinical study, will confirm that the STENTYS stent is the solution for the treatment of heart attack patients,” added Gonzague Issenmann, CEO and co-founder of STENTYS.

The STENTYS stent represents a major breakthrough compared to conventional stents when treating heart attacks: it is self-apposing, i.e. it “fits snugly” into the contour of a blood vessel, and its shape and diameter adapt to the anatomic changes of the coronary arteries during the post-AMI phase. The APPOSITION II randomized trial compared the STENTYS Self-Apposing Stent with a conventional, market-leading stent in patients suffering a heart attack. It showed that, three days after an AMI, 28% of patients treated with conventional stents displayed significant malapposition, meaning that the stent was not completely in contact with the artery wall. Malapposition puts AMI patients at significant risk of potential fatal complications such as a blockage of the stent (in-stent thrombosis). In contrast, none of the patients treated with the STENTYS stent had stent malapposition.

Acute Myocardial Infarction (AMI) affects 100,000 people each year in France and an additional 900,000 people in the United States and represents an annual worldwide market of $2 billion.

“The start of APPOSITION III is a key milestone of our development plan and confirms that we are perfectly in line with the road map that was presented during the IPO,” concluded Gonzague Issenmann

About STENTYS
Based in Princeton, N.J., and Paris, STENTYS has developed a new generation of stents to treat acute myocardial infarction (AMI). Founded by Jacques Séguin, M.D., Ph.D., (also founder of CoreValve, which was acquired by Medtronic) and Gonzague Issenmann, STENTYS received CE-marking for its flagship products in 2010. Its self-apposing stents adapt to the anatomic changes of the arteries in the post-infarction phase and thus prevent the
malapposition problem associated with conventional stents. STENTYS has commenced marketing activities in several European countries.

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