



*NEWS RELEASE*

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## **STENTYS starts clinical trial to broaden portfolio with new drug-eluting stent**

### **APPOSITION IV clinical study to compare STENTYS new Sirolimus-DES over Medtronic DES**

PRINCETON, N.J., and PARIS, June 14, 2012 — **STENTYS S.A.** ([STNT.PA](#)), a medical technology company commercializing the world's first and only **Self-Apposing® Stent** to treat **Acute Myocardial Infarction (AMI)**, announced today that it has enrolled the first patient in its APPOSITION IV clinical study using its new Self-Apposing® Sirolimus-eluting stent. The randomized study will enroll 150 heart attack patients who will be treated with either the STENTYS stent or Medtronic's Resolute® drug-eluting stent, and will compare stent apposition in both groups at 4 and 9 months after treatment.

Conventional drug-eluting stents have shown high rate of persistent malapposition several months after heart attack treatment. This malapposition can trigger stent re-clotting, recurrence of the heart attack and possible subsequent death years afterwards.

"Long-term malapposition of drug-eluting stents has been associated with late stent thrombosis, so this randomized trial with the new STENTYS sirolimus-eluting self-apposing stent will be carefully followed by the community," said **Dr. William Wijns**, co-principal investigator of the study and Chairman of EuroPCR.

"Following the excellent results from the APPOSITION III study, we are going to add the Sirolimus-eluting stent to our portfolio and combine the *best* stent platform with a proven drug from the 'limus' family," said **Gonzague Isenmann, CEO and co-founder of STENTYS**. "Cardiologists will have access to STENTYS stents eluting the two compound families available on the market."

The STENTYS Self-Apposing® Stent solves the stent-sizing dilemma that cardiologists are confronted with when treating heart attack patients with conventional stents. It "fits snugly" into the contour of a blood vessel, and its shape and diameter adapt as the vessel dilates and the initial clot dissolves during the post-AMI phase, eliminating malapposition and its major complications seen with all other conventional stents.

#### **About the APPOSITION IV Study**

APPOSITION IV is a prospective, randomized, two-arm, multi-center study designed to compare the apposition of the STENTYS Sirolimus-eluting stent with Medtronic Resolute in 150 patients suffering from ST-elevation Myocardial Infarction. Patients will be followed up at either 4 or 9 months (double randomization). The powered primary endpoint is strut apposition at 9 months under OCT. The secondary endpoints are strut apposition at 4 months under OCT, and strut coverage at 4 and 9 months. The trial enrollment is expected to be completed before the end of 2012, and the final results to be announced in H2 2013. The Sirolimus-eluting STENTYS stent CE Mark is expected in H2 2014.

#### **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 Isenmann**, STENTYS received CE-marking for its flagship products in 2010. Its Self-Apposing® stent adapts to the anatomic changes of arteries in the post-infarction phase and thus prevents the malapposition problem associated with conventional stents. The APPOSITION III study showed very low mortality at one month in 1,000 high risk heart attack patients. STENTYS has commenced marketing activities in several European countries.

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