



NEWS RELEASE

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## Stentys *self-apposing* stent proves superior to conventional treatment of Acute Myocardial Infarction

### APPOSITION II clinical trial highlights:

- After an infarction, 28% of patients treated with conventional stents displayed significant *malapposition*, a major cause of thrombotic events and severe complications;
- None of the patients treated with STENTYS self-apposing stent in the same conditions experienced ANY *malapposition*

PRINCETON, N.J., and PARIS, Sept.00, 2010—Stentys, which develops innovative stents to treat **Acute Myocardial Infarction (AMI)**, announced today positive results from an international clinical trial, the **APPOSITION II** study

This randomized trial compared the Stentys *self-apposing* stent with a conventional market-leading stent in patients suffering a heart attack. The trial is the first to quantify one of the major risks associated with conventional treatment that leads to the patient experiencing a repeat infarction, i.e. stent malapposition. The APPOSITION II trial recruited a total of 80 patients and was conducted in 6 European countries, between December 2009 and June 2010.

The trial showed that, three days after the AMI, 28% of patients treated with conventional stents displayed significant malapposition, meaning that the stent is not in contact with the artery wall. Malapposition puts AMI patients at significant risk of potential fatal complications such as implant blockage (in-stent thrombosis). In contrast, none of the patients treated with the STENTYS stent had malapposition. The trial results demonstrate that the STENTYS stent eliminates malapposition and that is therefore a safer solution than conventional stents for the treatment of heart attack patients.

The Stentys stent represents a major breakthrough compared to conventional stents when treating heart attack patients: it is *self-apposing*, i.e. it “fits snugly” into the contour of a blood vessel, behaving as a spring once implanted; its shape and diameter adapt to the anatomic changes of the coronary arteries during the post-AMI phase. By being in permanent contact with the vessel wall, the Stentys stent avoids *malapposition* (“loosely” fit stent) observed with conventional stents.

“We are very excited that the primary endpoint of the Apposition II study was reached successfully. The STENTYS stents were all perfectly apposed whereas gross malapposition was observed in more than one in four patients treated with conventional stents. This is very important because malapposition is one of the key contributing factors causing stent thrombosis,” said principal investigator **Stefan Verheye, M.D., Ph.D.**, Department of Cardiology, Middelheim Hospital, Antwerp, Belgium.

“The clinical evidence is now indisputable: malapposition, which is a known cause of early stent thrombosis and repeat AMI, *can* be eliminated with the use of a self-apposing stent. This is the very first time that a clinical trial has investigated this issue, and the findings of the APPOSITION II study will be well-received

by cardiologists worldwide who will see the Stentys stent as the solution to one of their key concerns with AMI patients,” added **Gonzague Issenmann, CEO and co-founder of Stentys.**

**Acute Myocardial infarction affects 100,000 people each year in France and an additional 900,000 people in the United States.**

**About Stentys**

Based in Princeton, N.J., and Paris, Stentys has developed a new generation of stents for the treatment of acute myocardial infarction. Founded by **Jacques Séguin, M.D., Ph.D., (founder of CoreValve, which was acquired last year by Medtronic for \$700 million)** and by **Gonzague Issenmann**, Stentys received CE Mark of its flagship products in 2010 and has started the pre-release phase in selected European countries. Institutional shareholders are Sofinnova Partners, Crédit Agricole Private Equity and Scottish Equity Partners.

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