Stentys completes enrollment in clinical study of its breakthrough stent to treat Acute Myocardial Infarction

International clinical trial could soon prove superiority of the novel stent over conventional techniques in a $5 billion market

PRINCETON, N.J., and PARIS, July 15, 2010—Stentys, which develops innovative stents to treat Acute Myocardial Infarction (AMI), announced today the enrolment of the final patient in the APPOSITION II clinical study—a randomized trial comparing the Stentys self-expanding stent with a conventional balloon-expandable stent in patients with AMI. The study results will be announced in September.

Founded in 2006, Stentys develops radically innovative solutions with the best North American and European cardiologists and high-tech R&D for the treatment of AMI which affects 100,000 people every year in France and an additional 900,000 people in the United States.

The Stentys stent features a major breakthrough compared to conventional stents: it is self-expanding, i.e., it behaves 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 observed with conventional stents, which put the patient at risk of potential fatal complications such as implant blockage (in-stent thrombosis).

“The Stentys stent, once implanted, continues expanding and, in our experience, has provided very good apposition to the wall of the vessel compared to conventional stents. This is important because malapposition is one of the factors causing stent thrombosis,” said study investigator Corrado Tamburino, M.D., Ph.D., Chair of the Cardiology Department, Ferrarotto Hospital, Italy.

“If the APPOSITION II study results are positive in September, we will have the indisputable proof of the superiority of the Stentys stent over conventional stents. This will be a significant advance for cardiology because all AMI patients could benefit from it,” said Prof. Jacques Seguin, Chairman and co-founder of Stentys.

“After receiving European market approval for our two flagship products in the first half of the year, this clinical study will confirm scientifically the efficacy of our solution. Since the technological and regulatory risks are behind us, Stentys will now begin a pre-release phase in Europe, giving cardiologists the possibility to use the Stentys stent immediately,” said Gonzague Issenmann, CEO and co-founder of Stentys. “Each year, more than 3 million stents are implanted worldwide. This annual market is estimated at $5 billion,” added Issenmann.

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 will start pre-release phase in selected European countries. Institutional shareholders are Sofinnova Partners, Crédit Agricole Private Equity and Scottish Equity Partners.

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