Stentys self-expanding stent receives CE Marking to treat acute coronary syndrome (ACS)

PRINCETON, N.J., and PARIS, March 5, 2010—Medical device pioneer Stentys announced today that it has received CE Marking for its self-expanding and disconnectable stent to treat acute coronary syndrome (ACS).

The self-expanding feature of the Stentys platform, unrivaled in the stent industry, is designed to ensure optimal apposition of a stent in the critical initial hours and days after an acute myocardial infarction (AMI) procedure, by being continuously applied to the vessel’s internal surface even during thrombus and vessel spasm relief—thereby avoiding malapposition, a significant concern to cardiologists.

“For European regulatory approval we have demonstrated how the Stentys stent perfectly conforms to a variable vessel anatomy after AMI stenting,” said Gonzague Issenmann, CEO and co-founder of Stentys. “Our strategy is to expand clinical evaluation with our ‘APPOSITION II’ clinical study. This is a randomized trial comparing the Stentys self-expanding stent with a conventional balloon-expandable stent in AMI patients, using extremely high-resolution OCT (optical coherence tomography) imaging to validate endpoints.”

About Stentys
Based in Princeton, N.J., and Paris, Stentys intends to make treatment of complex blocked coronary arteries as simple and effective as a conventional stenting procedure. The Company announced in December 2009 that it has started enrolling patients in the randomized APPOSITION II clinical trial to compare the Stentys self-expanding stent against conventional stents in treating AMI patients, looking specifically at stent apposition and adaptation to vessel growth. Stentys was co-founded by Gonzague Issenmann and Jacques Séguin, M.D., Ph.D., founder of CoreValve, which was acquired last year by Medtronic for $700 million plus earn-outs.

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