



NEWS RELEASE

Axxess™ Self-Expanding Bifurcation Drug-Eluting Stent Shown To Be Safe And Effective Up To Three Years

Paris, France, 19 May 2011 – New long-term data from the DIVERGE study, presented yesterday at EuroPCR 2011, showed that the use of the Axxess™ DES for the treatment of complex coronary bifurcation lesions resulted in low levels of both MACE and VLST over a three-year period. Axxess™ is a self-expanding bifurcation stent which releases Biolimus A9™ from an abluminal biodegradable polymer coating.

DIVERGE, a prospective, single-arm, multi-center study of 302 patients with de novo bifurcation lesions across 16 sites in Europe, Australia and New Zealand, is the largest study conducted to date with a DES specifically designed for treating coronary bifurcation lesions. Following implantation of Axxess, the sidebranch treatments were left at the operators' discretion. Additional conventional sirolimus-eluting stents (SES) were placed in 21.7% of the distal parent and/or side branch vessels. In 64.7% of the cases both branches were treated with an additional SES.

At three years post-procedure, the cumulative rate of MACE (a composite of cardiac death, MI and ischemia-driven TLR) was 16.3%. The occurrences of the individual components were 2.0% for cardiac death, 7.5% for myocardial infarction and 10.2% for ischemia-driven TLR.

There were only three cases (1.0%) of definite VLST (Very Late Stent Thrombosis), all of which involved at least one SES: however, just one of these cases also involved Axxess.

"These long-term results from DIVERGE are important because of the frequent presentation of bifurcation lesions in our daily clinical practice," commented Principal Investigator Dr. Stefan Verheye, Middelheim Hospital, Antwerp, Belgium. "These types of lesions are associated with higher complication and restenosis rates compared to conventional lesions. The three-year results confirm the earlier results already presented, and strengthen the evidence that the Axxess stent is a safe and effective alternative for patients with certain bifurcation lesions."

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The Axxessbifurcation DES consists of a self-expanding, conically-shaped Nitinol (nickel/titanium) stent platform, specifically designed to conform to the shape of the bifurcation anatomy. It supports the carina while preserving the side branch. The Axxess stent is abluminally coated with a biodegradable poly-lactic acid (PLA) polymer that releases Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with drug-eluting stents. BA9 is a vital component of the BioMatrix Flex™ DES system, which has been proven safe and effective in the landmark “all-comers” LEADERS study.

Biosensors received CE Mark approval for the Axxessbifurcation DES in April 2011, supported by the positive nine-month results from the DIVERGE trial, which were published in the Journal of the American College of Cardiology (JACC) in March 2009. These demonstrated low overall rates of MACE (7.6%), restenosis (0.7%) and late stent thrombosis (0.3%) in patients treated with Axxess.

Biosensors expects to make the Axxessbifurcation DES available later this year. The device will be manufactured in diameters of 3.0 mm and 3.5 mm, and lengths of 11 mm and 14 mm.

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About Biosensors International

Biosensors International develops, manufactures and markets innovative medical devices for interventional cardiology and critical care procedures. We aim to improve patients' lives through pioneering medical technology that pushes forward the boundaries of innovation.

With the increasing use of the BioMatrix™ family of drug-eluting stents, we are rapidly emerging as a leader in the global coronary stent market. The forthcoming launch of the Axxess™ self-expanding bifurcation drug-eluting stent and the development of the BioFreedom™ drug-coated stent will further reinforce our market position.

All three stents incorporate Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with drug-eluting stents. Both the BioMatrix stent family and the Axxess stent feature a unique abluminal biodegradable polymer coating, which fully degrades into carbon dioxide and water over a six-to-nine-month period as it releases BA9. The BioMatrix stent family features workhorse stent platforms for a broad range of lesions, and the Axxess stent employs a self-expanding stent platform specifically designed for treating bifurcation lesions. BioFreedom, a completely polymer-free stent abluminally coated with BA9, is currently undergoing clinical evaluation.

For more information, please visit www.biosensors.com.