# NEWS RELEASE

## Axxess™ Self-Expanding Bifurcation DES Shown to be Safe and Effective up to Four Years

**Paris, France, 18 May 2012 –** New long-term data from the DIVERGE study, presented yesterday at EuroPCR 2012 by Dr. John Ormiston, showed that the use of the Axxess™ drug-eluting stent (DES) for the treatment of complex coronary bifurcation lesions resulted in low levels of both MACE and VLST over a four-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 14 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 side branch 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 four years post-procedure, 96.7% of patients originally enrolled in the study (292) were available for follow-up. The cumulative rate of MACE (a composite of death, MI and ischemia-driven TLR) was 18.5%. The occurrences of the individual components were 5.1% for death, 7.9% for myocardial infarction and 10.6% for ischemia-driven TLR.

There were only three cases (1.0%) of ARC-defined definite VLST (Very Late Stent Thrombosis), all of which involved at least one SES: just one of these cases also involved Axxess. No VLST events were observed in Axxess patients between years three and four of the study.

"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, Antwerp Cardiovascular Institute, ZNA Middelheim Hospital, Belgium. "These types of lesions are associated with higher complication and restenosis rates compared to conventional lesions. The four-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."

**More/...**

The Axxess bifurcation DES consists of a conical-shaped self-expanding nitinol (nickel/titanium) stent platform, specifically designed to conform to the shape of the bifurcation anatomy. It has been tailored to reconstruct the bifurcation without creating a false carina (the ridge where the two vessels join), lowering the risk of uncovered struts at the flow divider. The stent is coated with a biodegradable poly-lactic acid (PLA) polymer that releases Biolimus A9™ (BA9™), an anti-restenotic drug designed by Biosensors specifically for use with DES. Both BA9 and the biodegradable polymer are vital components of the BioMatrix™ DES family, which has more published data to support its safety and efficacy than any other biodegradable polymer DES.

Biosensors received CE Mark approval for Axxess 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.

Axxess is now available in most major markets worldwide.

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**About Biosensors International Group, Ltd**

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 recent launch of the Axxess™ self-expanding bifurcation drug-eluting stent and the development of the BioFreedom™ drug-coated stent further establish our technology leadership.

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 after six to nine months 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.