



## **NEWS RELEASE**

### **Axxess™ Self-Expanding Bifurcation Drug-Eluting Stent Shown To Be Safe and Effective Up To Five Years**

**San Francisco, USA, 8 November 2011** – Biosensors International Group, Ltd (“Biosensors”, “Company”, BIG:SP) has announced final results of the AXXESS PLUS trial, which demonstrated the long-term efficacy and safety of the Axxess™ stent in the treatment of patients with coronary bifurcation lesions. Axxess is a self-expanding bifurcation stent which releases Biolimus A9™ from an abluminal biodegradable polymer coating. Results will be presented today by Professor Eberhard Grube, University Hospital Bonn, Germany, at the 23<sup>rd</sup> annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

AXXESS PLUS is a prospective, single-arm multi-center study involving 139 patients at 13 clinical sites in Europe, South America and New Zealand. 117 patients were followed-up through five years. In addition to Axxess implantation in the proximal parent vessel, conventional stents could be implanted in the distal parent vessel and/or the side branch at the discretion of the operator. In over 76% of cases, the additional stent implanted was sirolimus-eluting. 23% were non-sirolimus DES, and less than 1% were BMS.

Axxess implantations in the parent vessel achieved high levels of procedural and angiographic success (94.9% and 100% respectively). At five years post-procedure, the cumulative rate of MACE (a composite of cardiac death, MI, emergent cardiac artery bypass graft (CABG) and clinically-driven target lesion revascularization) was 19.7%. The occurrences of the individual components were 3.4% for cardiac death, 9.4% for MI, and 12.8% for clinically-driven TLR (there were no incidences of emergent CABG). There were no cases of definite and/or probable VLST (Very Late Stent Thrombosis) observed, as defined by ARC.

"These results confirm that this new dedicated bifurcation DES is both safe and effective in the long term for the treatment of bifurcation lesions," commented Professor Grube. "This is particularly impressive considering that these types of lesion are associated with higher complication and restenosis rates than conventional lesions."

"We have already conclusively demonstrated the patient benefits of a stent which releases Biolimus A9 from a biodegradable polymer coating with our increasingly popular BioMatrix stent family", added Jeffrey B. Jump, Co-CEO of Biosensors. "Now with Axxess, physicians have the option of using the same proven technology with a stent platform specifically designed for bifurcation lesions".

**More/...**

The Axxess bifurcation DES consists of a 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, lowering the risk of uncovered struts at the flow divider. 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 efficacious in the landmark “all-comers” LEADERS study.

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 (7.7%), restenosis (0.7%) and late stent thrombosis (0.3%) in patients treated with Axxess. Three-year data from the DIVERGE trial, presented at EuroPCR in May 2011, confirmed that low overall rates of MACE (16%) and VLST (1%) were maintained over the long term.

Axxess is now available in certain markets in Europe and Asia.

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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 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](http://www.biosensors.com).

**About CRF**

The Cardiovascular Research Foundation (CRF) is an independent, academically focused nonprofit organization dedicated to improving the survival and quality of life for people with cardiovascular disease through research and education. Since its inception in 1991, CRF has played a major role in realizing dramatic improvements in the lives of countless numbers of patients by establishing the safe use of new technologies and therapies in the subspecialty of interventional cardiology and endovascular medicine.

For more information, visit [www.crf.org](http://www.crf.org).