

NEWS RELEASE

BioFreedom[™] Demonstrates Comparable Long-Term Safety and Efficacy to Conventional Drug-Eluting Stent

San Francisco, USA, 10 November 2011 – Biosensors International Group, Ltd. ("Biosensors", "Company", BIG:SP) has announced two-year results from BioFreedom FIM, which showed similar clinical outcomes between BioFreedom[™], a polymer-free drug-coated stent ("DCS"), and Boston Scientific's Taxus[™] Liberté[™] drug-eluting stent (DES), with no evidence of stent thrombosis. Results were presented by Professor Eberhard Grube, University Hospital Bonn, Germany, at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

"The results from this study are very significant as they demonstrate that a polymer free drug-coated stent is as safe and efficacious as a conventional drug-eluting stent with a durable polymer coating over a two-year period", commented Professor Grube. "I am excited about the concept of a polymer-free stent, as the rapid drug clearance and absence of a polymer drug carrier could promote more rapid vessel healing and ultimately reduce the need for longer term dual anti-platelet therapy. A larger study is now required to confirm these encouraging findings."

BioFreedom represents the latest development in Biosensors' stent technology, featuring a microstructured abluminal surface which permits the controlled release of Biolimus $A9^{TM}$ ($BA9^{TM}$) without the use of a polymer. BA9 is a highly lipophilic antirestenotic drug developed by Biosensors specifically for use with stents. Two versions of the stent were studied in this trial: one with a drug dosage of 15.6 µg/ per mm of stent length (standard dose) - the same as that used in BioMatrix FlexTM; and the other with a drug dosage of 7.8 µg/ per mm of stent length (low dose).

In this First in Man ('FIM') study, 182 patients were equally randomized into three treatment groups: BioFreedom standard dose (SD); BioFreedom low dose (LD); and Taxus Liberté. 99% of enrolled patients were followed up at two years.

The rate of MACE (a composite of all death, MI, emergent cardiac artery bypass graft (CABG) and target lesion revascularization (TLR)) observed in patients treated with BioFreedom SD was numerically lower than that observed in patients treated with Taxus Liberté (6.8% vs. 10.0%: p=0.54). TLR was performed half as often on patients treated with BioFreedom SD as on those treated with Taxus Liberté (3.4% vs. 6.7% p=0.42).

Both BioFreedom SD and BioFreedom LD demonstrated sustained safety up to two years, including absence of stent thrombosis.

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"These latest results confirm that Biosensors continues to lead the industry in stent innovation, trailblazing first with biodegradable polymer technology and now with polymer-free technology", said Jeffrey B. Jump, Co-CEO of Biosensors. "Based on these positive results, we have committed to a major follow-on study assessing the potential for BioFreedom to reduce the need for dual anti-platelet therapy, working closely with the Center of European Cardiovascular Research (CERC)".

BioFreedom FIM is a prospective, multi-centre study involving 182 patients with symptomatic ischemic heart disease. It involves a first cohort of 75 patients, evaluated for in-stent late lumen loss at four months, and a second cohort of 107 patients, evaluated at 12 months. The primary endpoint of BioFreedom FIM was in-stent late lumen loss at 12 months in the second cohort. Results from the first cohort, showing four-month non-inferiority of late lumen loss between BioFreedom and Taxus Liberté, were presented at TCT in 2009. Twelve-month data from the second cohort was presented at TCT in 2010, in which BioFreedom SD demonstrated similar efficacy, measured by late lumen loss, compared with Taxus Liberté (p non-inferiority = 0.001), with a trend towards superiority (p sup = 0.11).

The clinical status of the patients in the trial is being followed up out to five years and reported annually.

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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 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 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.

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 <u>www.crf.org</u>.