NEWS RELEASE

Biosensors Announces First Patient Enrolled in LEADERS FREE

13 December 2012 – Biosensors International has announced enrollment of the first patient in LEADERS FREE, a ground-breaking study involving BioFreedom™, the polymer-free drug-coated stent (DCS) from Biosensors.

LEADERS FREE is the world's first prospective, randomised double-blind trial exclusively involving patients at high risk of bleeding. The study has been designed to confirm that BioFreedom is as safe as a bare-metal stent (BMS) in this patient group, and can deliver the anti-restenotic benefit of a drug-eluting stent (DES), with only a one-month course of DAPT.

BioFreedom represents the latest development in Biosensors' stent technology, featuring a micro-structured abluminal surface which permits the controlled release of Biolimus A9™ (BA9™) without the use of a polymer. BA9 is a highly lipophilic anti-restenotic drug developed by Biosensors specifically for use with stents.

The first patient has been enrolled by the study's Principal Investigator Dr Philip Urban at the Hôpital de la Tour, Geneva.

"The results of this study will be particularly important as we hope that they will show, for the first time, that a drug-coated stent can be more effective than a bare metal stent in a subgroup of patients not previously studied, yet just as safe", Dr Urban commented. "This study could therefore potentially change clinical practice by permitting the use of a drug-coated stent in conjunction with one month's DAPT duration".

LEADERS FREE is in the process of enrolling approximately 2,500 patients identified as having a high risk of bleeding from 60 sites across Europe, Asia and South America, with follow-up for two years. Patients in both arms of the study are being prescribed only one month of DAPT.

The co-primary endpoints of the study are: 1) non-inferiority of BioFreedom compared with BMS as measured by specific safety factors (cardiac death, myocardial infarction, and definite/probable stent thrombosis) after one year and; 2) superiority over BMS in terms of clinically-driven TLR at 12 months.

Investigators anticipate completing the enrollment process by early 2014. Primary endpoint data is likely to be presented during 2015.

“We anticipate that the results from LEADERS FREE will bring real benefits to patients at high risk of bleeding, who cannot currently be given a drug-eluting stent due to the need for a prolonged course of DAPT”, concluded Jeffrey B. Jump, President of Biosensors’ Cardiovascular Business Unit. “With BioFreedom, they will be now be able to benefit from a stent with an anti-restenotic drug, yet still only take a month-long course of DAPT”.

Three-year results from the BioFreedom FIM study were presented at TCT on 23 October 2012. They showed similar rates of MACE (a composite of all death, MI, emergent cardiac artery bypass graft (CABG) and target lesion revascularization (TLR)) between BioFreedom™ and Boston Scientific’s Taxus™ Liberté™ DES (11.9% vs. 10.0%), with no evidence of stent thrombosis in either group.

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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 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.