NEWS RELEASE

Biosensors Announces First Large-Scale Study with BioFreedom™

Paris, France, 16 May 2012 – Plans for a ground-breaking new study involving BioFreedom™, the polymer-free drug-coated stent (DCS) from Biosensors, were announced yesterday at EuroPCR by Principal Investigator Dr Philip Urban, Hôpital de la Tour, Geneva.

LEADERS FREE is the world's first prospective, randomised double-blind trial between a DCS and bare-metal stent (BMS), assessing the potential to deliver the anti-restenotic benefit of a drug-eluting stent with a shorter course of dual anti-platelet therapy (DAPT) in patients at high risk of bleeding.

"The results of this study will be particularly important as we hope that they will show, for the first time, that a new type of stent can be more effective than a bare metal stent in a subgroup of patients not previously studied, yet just as safe", commented Dr Urban. "Furthermore, this study could potentially change clinical practice by facilitating short DAPT duration in patients who may not be suitable for longer courses of treatment".

LEADERS FREE will enrol approximately 2,500 patients from 60 sites across Europe, Asia and South America, with follow-up for two years. The trial will include patients identified as having a high risk of bleeding. Patients in both arms of the study will be prescribed only one month of DAPT, although they will take a single anti-platelet drug indefinitely.

The co-primary endpoints of the study will be: 1) non-inferiority of BioFreedom compared with BMS in terms of 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 enrolling the first patient within the next few months, and completing the process by early 2014. Primary endpoint data is likely to be presented during 2015.

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.

More/...

Biosensors has applied for CE Mark approval for BioFreedom. As with its other products, the company is committed to building a significant body of clinical evidence before making BioFreedom commercially available. LEADERS FREE will represent a major contribution to the evidence surrounding the use of BioFreedom in patients at high risk of bleeding.

-Ends-

For further information, please contact:
Richard Kenyon
Biosensors International
+44 7831 569940
r.kenyon@biosensors.com

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.