



BIOSENSORS
INTERNATIONAL™

NEWS RELEASE

Biosensors Receives CE Mark Approval for BioFreedom™

28 January 2013 – Biosensors International has announced CE Mark approval for its polymer-free drug-coated stent (DCS), BioFreedom™.

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.

CE Mark approval for BioFreedom was supported by strong data from the BioFreedom First in Man study. In this study BioFreedom was compared to Boston Scientific's Taxus™ Liberté™ drug-eluting stent (DES). At 12 months, BioFreedom demonstrated equivalent efficacy, measured by in-stent late lumen loss, compared with Taxus Liberté, with a trend towards superiority. Median in-stent late lumen loss in patients receiving BioFreedom was reduced to 0.17 mm as compared with a median in-stent late lumen loss of 0.35 mm in the Taxus Liberté group. Three-year clinical results, presented at TCT in October 2012, showed similar rates of MACE (Major Adverse Cardiac Events) between BioFreedom and Taxus Liberté, with no evidence of stent thrombosis in either group.

To further evaluate BioFreedom in a larger patient population, Biosensors recently announced initiation of enrolment in LEADERS FREE, the world's first prospective, randomised double-blind trial between a DCS and bare-metal stent (BMS), exclusively involving patients at high risk of bleeding. The study has been designed to confirm that BioFreedom is as safe as a BMS in this patient group, and can deliver the anti-restenotic benefit of a DES, with only a one-month course of dual anti-platelet therapy administered to all patients.

This trial will provide additional data to support the launch of BioFreedom in select markets during 2013. The full commercial launch is currently anticipated during 2014.

###

For further information, please contact:

Corporate Communications
Richard Kenyon
Biosensors International Group
+44 7831 569940
r.kenyon@biosensors.com

Investor Relations
Wong Teck Yenn
Biosensors International Group
+65 6213 5708
ty.wong@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 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, has recently received CE Mark approval.

For more information, please visit www.biosensors.com.