NEWS RELEASE

Initial Patient Enrolled in BioFreedom USA: First Major American Trial for Biosensors

4 September 2014 – Biosensors has announced enrollment of the initial patient in BioFreedom USA, an Investigational Device Exemption (IDE) Feasibility Trial designed to collect additional U.S.-based safety and effectiveness data for BioFreedom™, the company's novel polymer and carrier-free drug-coated stent (DCS). The company believes this is the first clinical trial within the United States to evaluate a polymer-free DCS. Results from this study will support a future pivotal IDE study in the U.S.

The trial design is multicenter and prospective, enrolling up to 100 patients at up to ten centers. Due to the unique features of the BioFreedom DCS, the U.S. Food and Drug Administration (FDA) has approved a post-implant strategy requiring only three months of dual anti-platelet therapy (DAPT) for this trial. The initial patient has been enrolled in the trial by Principal Investigator Dr. Ron Waksman at the MedStar Washington Hospital Center, Washington DC.

Biosensors received conditional IDE approval from the FDA to conduct a U.S.-based clinical trial of BioFreedom in May 2014. Enrollment in this study is anticipated to last around four months from initial patient enrollment.

"I am very excited to be involved in this first U.S. study of a drug-coated stent", commented Dr. Waksman. "This will hopefully prove to be the first step towards FDA approval of BioFreedom, offering U.S. patients all the benefits of a drug-eluting stent but with a shorter DAPT requirement".

The BioFreedom US IDE Feasibility Trial is enrolling patients with symptomatic ischemic heart disease due to *de novo* native coronary artery lesions. The primary safety endpoint of the study is the occurrence of MACE (a composite of cardiac death, myocardial infarction, target lesion revascularization and definite stent thrombosis) within nine months following stent implantation. The primary efficacy endpoint is in-stent late lumen loss at nine months compared with a historical control.

Another important BioFreedom trial, LEADERS FREE, is currently applying a one-month DAPT strategy in patients at high risk of bleeding to further develop the product's safety and efficacy profile. The goal is to demonstrate that treatment with BioFreedom delivers the safety profile of a bare-metal stent with the anti-restenotic benefit of a drug-eluting stent.

BioFreedom represents the latest development in Biosensors' stent technology, featuring a micro-structured abluminal surface that permits the controlled release of Biolimus A9™ (BA9™) without the use of a polymer or other carrier. BA9 is a highly lipophilic anti-restenotic drug developed by Biosensors specifically for use with stents. In its First in Man ("FIM") study, treatment with BioFreedom demonstrated excellent 12-month late lumen loss and sustained safety up to four years, including absence of definite and/or probable stent thrombosis.

BioFreedom received CE Mark approval in January 2013 and is currently available in select markets.

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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.

With the BioMatrix™ family of drug-eluting stents and the Axxess™ self-expanding bifurcation stent, we are a leader in the global coronary stent market. These stents incorporate Biolimus A9™ (BA9™), an anti-restenotic drug developed specifically for use with stents and patented by Biosensors, together with 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 family features workhorse stent platforms for a broad range of lesions, and Axxess employs a self-expanding stent platform specifically designed for treating bifurcation lesions.

The BioFreedom™ drug-coated stent, which has received both CE Mark and conditional IDE approval, underscores our technology leadership in the field of coronary stents. BioFreedom is the world's first polymer-free stent with BA9. Chroma™, a cobalt chromium bare-metal stent featuring an innovative platform design, offers exceptional deliverability without any compromise on radial strength or recoil.

Our drug-eluting balloon range complements the stent portfolio and offers interventional cardiologists a broader range of treatment options.

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