



NEWS RELEASE

LEADERS Free Japan Trial Enrolls First Patient

17 June 2014 – Biosensors International has announced enrollment of the first patient in LEADERS Free Japan, a ground-breaking trial involving BioFreedom™, the company's novel polymer and carrier-free drug-coated stent (DCS).

LEADERS Free is the world's first prospective, randomised double-blind clinical trial employing only a one-month course of dual anti-platelet therapy (DAPT) after implantation of an active stent. The trial is focused on patients at high risk of bleeding, and has been designed to confirm that BioFreedom is as safe as a bare-metal stent (BMS) in this patient group, while delivering the anti-restenotic benefit of a drug-eluting stent (DES). LEADERS Free Japan will apply the same principles as LEADERS Free (patient selection criteria and duration of DAPT), but with just the BioFreedom treatment arm.

The objective of LEADERS Free Japan is to confirm that the safety and efficacy of BioFreedom in Japanese patients is equivalent to that observed in patients of other ethnicities, as assessed in the active (BioFreedom) arm of LEADERS Free. Safety is to be measured by the composite of cardiac death, myocardial infarction and definite/probable stent thrombosis at one year, and efficacy by the incidence of clinically driven target lesion revascularization at one year.

LEADERS Free Japan aims to enroll 139 patients identified as having a high risk of bleeding from 12 centres across the country. All patients are being prescribed only one month of DAPT. The first patient has been enrolled in LEADERS Free Japan by the trial's Principal Investigator, Dr. Shigeru Saito, Shonan Kamakura General Hospital, Kanagawa, Japan.

"I am very excited about starting a trial in Japan using BioFreedom", commented Dr. Saito. "It is a unique clinical trial, not only for the stent itself but for the challenging trial design and the patient population. We expect to gain both valuable scientific and clinical findings from the trial and the technology may offer unique clinical benefits for patients in the future."

"We hope that the results from LEADERS Free Japan will show, for the first time, that a drug-coated stent can be used safely and effectively in Japanese patients at high risk of bleeding with only one month of DAPT", added Dr Philip Urban, Principal Investigator for LEADERS Free.

LEADERS Free has now completed enrollment, with 2466 patients identified as having a high risk of bleeding from 68 sites across Europe, Asia, Australia and Canada. The trial plans to conduct two years of follow-up. Patients in both arms of the trial are being prescribed only one month of DAPT. Primary endpoint data is expected in late 2015.

BioFreedom represents the latest development in Biosensors' stent technology, featuring an abluminal coating 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. LEADERS Free Japan will be the first clinical trial ever conducted by Biosensors of a BA9-coated stent in Japan. 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. Last month Biosensors announced that they had received conditional IDE approval to conduct a US-based clinical trial of BioFreedom, designed to collect additional safety and effectiveness data to support a future pivotal IDE study.

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Media Contacts:

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

Biosensors 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.

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 CE Mark 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