



## NEWS RELEASE

### LEADERS Free Japan Trial Completes Enrollment

**9 February 2015** – Biosensors International has announced completion of patient enrollment 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, a prospective, multi-centre open-label trial, is applying the same patient selection criteria and duration of DAPT as LEADERS Free, 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 being 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 has enrolled 140 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.

"I am delighted to have completed patient enrollment in this groundbreaking study", commented Principal Investigator Dr. Shigeru Saito, Shonan Kamakura General Hospital, Kanagawa, Japan. "It is a unique clinical trial, not only for the stent itself but for the unprecedented trial design and the challenging patient population. We expect to gain valuable scientific and clinical findings from the trial, potentially showing the technology offers unique clinical benefits for our patients."

"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 with only one month of DAPT in Japanese patients at high risk of bleeding", added Dr Philip Urban, Principal Investigator for LEADERS Free.

LEADERS Free has enrolled 2466 patients identified as having a high risk of bleeding from 68 sites across Europe, Asia, Australia and Canada. Patients in both arms of the trial are being prescribed only one month of DAPT. Primary endpoint data is expected later this year, and follow up is planned out to two years.

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 has received CE Mark approval and is currently available in select markets. Biosensors has also received conditional IDE approval to conduct a US-based clinical trial of BioFreedom, designed to collect additional safety and effectiveness data.

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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 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](http://www.biosensors.com)