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## **NEWS RELEASE**

### **LEADERS FREE Patient Population Data Presented at EuroPCR: Enrollment Now Complete**

**Paris, France, 21 May 2014** – With enrollment now complete, the baseline patient population data from Biosensors' LEADERS FREE study was presented for the first time today at EuroPCR 2014 by Principal Investigator Dr. Philip Urban.

LEADERS FREE is the world's first prospective, randomised double-blind trial employing only a one-month course of dual anti-platelet therapy (DAPT) after implantation of an active stent. The study is focused on patients at high risk of bleeding, and has been designed to confirm that BioFreedom, Biosensors' novel polymer and carrier-free drug-coated stent (DCS), 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).

The baseline data confirmed that patients considered by enrolling doctors to be at high bleed risk are significantly older and have more co-morbidities than the 'all comers' patient population routinely seen in clinical studies of cardiac stents. LEADERS Free reported a mean average patient age of 76, more than a decade older than the norm. Analysis also revealed more patients than normal with additional conditions to coronary heart disease, predominantly cancer, peripheral vascular disease, prior stroke and renal failure.

"The results of this study will be particularly important as we hope that they will show, for the first time, that a drug-coated stent can be more effective than a bare metal stent, yet just as safe, in a subgroup of patients not previously studied", Dr Urban commented. "This study could potentially change clinical practice by permitting the use of a DCS in conjunction with only one month of DAPT".

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.

LEADERS FREE has enrolled 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 study are being prescribed only one month of DAPT.

The co-primary endpoints of the study are: 1) non-inferiority of BioFreedom compared with a bare-metal stent (BMS) after one year as measured by specific safety factors (cardiac death, myocardial infarction, and definite/probable stent thrombosis) and; 2) superiority over BMS in terms of clinically-driven TLR after one year.

Primary endpoint data is expected in late 2015.

BioFreedom received CE Mark approval in January 2013 and is currently available in select markets. Earlier this 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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**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).