



NEWS RELEASE

## **BioFreedom™ Drug-Coated Stent Demonstrates Superior Safety and Efficacy with One-Month of DAPT in Patients at High Bleeding Risk**

**San Francisco, USA, 14 October 2015** – Biosensors International Group, Ltd. (“**Biosensors**” or the “**Company**”, Bloomberg: BIG SP; Reuters: BIOS.SI; SGX: B20), a developer, manufacturer and marketer of innovative medical devices, announced today that the LEADERS FREE clinical trial demonstrated superior safety and efficacy for BioFreedom™ compared with a bare-metal stent (BMS). The results were presented by Dr. Philip Urban, Principal Investigator for LEADERS FREE, at the 27<sup>th</sup> Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, and simultaneously published in the *New England Journal of Medicine*.

LEADERS FREE is a double-blinded randomized study comparing BioFreedom™—a polymer-free stent coated with Biolimus A9™ (BA9™)—with an uncoated BMS (Gazelle™) in patients at high risk of bleeding undergoing percutaneous coronary intervention (PCI) with only one month of dual anti-platelet therapy (DAPT). The trial assessed the shortest course of DAPT ever used with an active stent.

“Per U.S. and European guidelines, DAPT is typically continued for 6 to 12 months following PCI with drug-coated stents,” said Dr. Philip Urban, Director of Interventional Cardiology at La Tour Hospital in Geneva, Switzerland and Principal Investigator for LEADERS FREE. “A one-month course of DAPT is currently only recommended for bare-metal stents, which pose an increased risk for recurrence of stenosis. These results suggest physicians and patients now have an option for an active stent that no longer requires months of DAPT, which may be beneficial for patients at high bleeding risk, who are frequently seen in the cath lab but for whom we still lack optimal management strategies.”

Patients enrolled in LEADERS FREE were specifically selected for high bleeding risk and were significantly older (mean 75.7 ± 7.3 years) and had more co-morbidities, such as kidney failure, cancer, need for major surgery or anticoagulation, than patients included in a typical stent trial.

The new results of LEADERS FREE showed a 50 percent reduction in the need for repeat revascularization, the primary efficacy endpoint: 5.1 percent of patients receiving BioFreedom™ experienced clinically driven target lesion revascularization (TLR) at 390 days versus 9.8 percent of patients receiving a BMS [hazard ratio 0.50 (95% CI 0.37 to 0.69), P<0.001].

Patients in the BioFreedom™ arm also had a 29 percent reduction in risk of cardiac death, myocardial infarction or stent thrombosis: 9.4 percent of BioFreedom™ patients versus 12.9 percent of BMS patients at 390 days [hazard ratio 0.71 (95% CI 0.56 to 0.91) P<0.001 for noninferiority and P=0.005 for superiority]. The difference between groups was statistically highly significant for both the safety and efficacy endpoints.

“Interventional cardiologists around the world have been asking for a better solution to treat patients at high bleeding risk,” said Jose Calle, Biosensors International Group CEO. “The evidence provided by LEADERS FREE suggests that BioFreedom™ is a breakthrough technology that offers an optimal option these patients deserve. LEADERS FREE is a first of its kind study combining an active stent with only one month of DAPT. This continues to highlight Biosensors’ tradition of introducing evidence-based, pioneering and innovative medical technologies to the global healthcare community.”

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

### **About LEADERS FREE**

LEADERS FREE is the world's first prospective, double-blind, randomized trial exclusively focusing on patients at high bleeding risk. The trial randomized a total of 2,466 patients at 68 sites across Europe, Asia, Australia and Canada, with a follow-up phase for two years. In both arms of the study, patients were prescribed only one month of DAPT, while taking a single anti-platelet drug indefinitely. The trial was double-blinded using identical generic stent packaging making the stents undistinguishable for the implanting physicians and all participants in the trial.

### **About BioFreedom™**

BioFreedom™ represents the latest development in Biosensors' stent technology, featuring a unique micro-structured abluminal surface which permits the controlled release of BA9™ using neither a polymer nor a carrier. BA9™ is a highly lipophilic antirestenotic drug developed by Biosensors specifically for use with stents and is the only widely available polymer-free stent technology in the world today.

### **Conference Call Information**

*Biosensors' management will also host an analyst conference call on 14 Oct 2015 at 6pm (San Francisco time) or 15 Oct 2015 at 9am (Singapore time). This briefing will allow the investment community to have a better understanding of the results. A live audio webcast of this analyst conference call will be available through Biosensors' corporate website at [www.biosensors.com](http://www.biosensors.com) on the day of the event.*

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### **About Biosensors International Group, Ltd**

Biosensors International Group, Ltd. develops, manufactures and markets innovative medical devices, aiming to improve patients' lives through pioneering medical technology that pushes forward the boundaries of innovation. Founded in 1990, we were listed on the Mainboard of the Singapore Stock Exchange in 2005.

The Group currently operates through four business units ("BU"): the Cardiovascular BU, composed primarily of the BioMatrix™ & EXCEL™ families of drug-eluting stents, BioFreedom™ drug-coated stents, and stent technologies such as BA9™; the Cardiac Diagnostic BU, including Spectrum Dynamics products that offer advanced medical imaging and clinical solutions to help interventional cardiologists determine the most appropriate treatment for patients; the Peripheral Intervention BU, offering solutions for the treatment of patients with peripheral arterial disease; and the Critical Care Products BU.

The Group has operations worldwide and is headquartered in Singapore.

For more information, please visit [www.biosensors.com](http://www.biosensors.com).

### **Forward-Looking Statements**

*Certain statements herein include forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements generally can be identified by the use of forward-looking terminology, such as “may,” “will,” “expect,” “intend,” “estimate,” “anticipate,” “believe,” “project” or “continue” or the negative thereof or other similar words. All forward looking statements involve risks and uncertainties, including, but not limited to, customer acceptance and market share gains, competition from companies that have greater financial resources; introduction of new products into the marketplace by competitors; successful product development; dependence on significant customers; the ability to recruit and retain quality employees as Biosensors grows; and economic and political conditions globally. Actual results may differ materially from those discussed in, or implied by, the forward-looking statements. The forward-looking statements speak only as of the date of this release and Biosensors assumes no duty to update them to reflect new, changing or unanticipated events or circumstances.*