NEWS RELEASE

Early Healing Profile Established for BioFreedom

Paris, France, 20 May 2015 – The first study to demonstrate rapid early healing for BioFreedom™, a novel polymer and carrier-free drug-coated stent (DCS), was presented at EuroPCR 2015 by Professor Stephen Lee, Division of Cardiology, Queen Mary Hospital, University of Hong Kong. Results in the first twelve months demonstrate rapid strut coverage, suggesting an early healing profile for patients using BioFreedom.

Lee's Optical Coherence Tomography (OCT) analysis demonstrated that 86% of struts were covered at one month, and 97% at five months. The BioFreedom stent also showed effective neointimal suppression at nine months and favourable clinical outcomes at twelve months.

The EGO BioFreedom study used OCT to assess the degree of strut coverage in 100 patients treated with BioFreedom stents. All patients received a baseline OCT assessment during PCI, and were then randomly divided into five groups of 20 for a second OCT assessment at one, two, three, four or five months. Every patient received a third OCT assessment at nine months, to determine total tissue coverage and neointimal growth. Clinical follow-up and MACE to 12 months were also documented.

An average 85.77% of struts were covered at one month, 97.14% at five months, and 99.55% at nine months. Neointimal thickness remained low over the study follow-up, reaching 0.10mm at nine months, thereby confirming the antiproliferative effect of the drug. At twelve months, there was a TLR rate of 4%. No other incidents of MACE were recorded, and no definite or probable late stent thrombosis was observed.

"This study provides proof of concept for a polymer-free biolimus-coated stent", commented Prof. Lee. "BioFreedom demonstrated an early healing profile, in the form of rapid early strut coverage, while retaining its efficacy in terms of neointimal suppression at nine months and clinical outcomes at twelve months. If supported by long-term clinical results, this concept could have a major impact on the future development of new stent platforms."

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. In its First-in-Man ("FIM") study, treatment with BioFreedom demonstrated excellent twelve-month late lumen loss and sustained safety up to five years, including absence of definite and/or probable stent thrombosis.

Another important clinical trial where BioFreedom is being studied is LEADERS FREE, 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 has enrolled 2466 patients identified as having a high risk of bleeding from 68 sites across Europe, Asia, Australia and Canada. Primary endpoint data is expected later this year, and follow up is planned out to two years.

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 compromising 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