



## NEWS RELEASE

### **BioFreedom™ Continues to Demonstrate Comparable Long-Term Safety and Efficacy to Conventional DES**

**San Francisco, USA, 30 October 2013** – Biosensors International has announced four-year results from the BioFreedom First in Man study (FIM), which demonstrated similar clinical outcomes between BioFreedom™, a polymer-free drug-coated stent (DCS), and Boston Scientific's Taxus™ Liberté™ drug-eluting stent (DES), with no evidence of definite and/or probable stent thrombosis. Results were presented by Dr. Ricardo Costa, Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil, at the 25<sup>th</sup> annual Transcatheter Cardiovascular Therapeutics (TCT) meeting, sponsored by the Cardiovascular Research Foundation.

“These encouraging results demonstrate that a polymer-free drug-coated stent is as safe and efficacious as a conventional drug-eluting stent with a durable polymer coating over a four-year period”, commented Dr. Costa. “We now look forward to seeing if the results of the ongoing LEADERS FREE study confirm the initial promise shown by this innovative stent.”

BioFreedom represents the latest development in Biosensors' stent technology, featuring a micro-structured abluminal surface which permits the controlled release of Biolimus A9™ (BA9™) without the use of a polymer. BA9 is a highly lipophilic antirestenotic drug developed by Biosensors specifically for use with stents.

In this First in Man ('FIM') study, 182 patients were randomized into three equally sized treatment groups: BioFreedom; a low-dose formulation of BioFreedom that is not being commercialized; and Taxus Liberté. 93.5% of enrolled patients were followed up at four years.

At four years, the rate of MACE (a composite of all death, MI, emergent cardiac artery bypass graft (CABG) and target lesion revascularization (TLR)) observed in patients treated with BioFreedom was not significantly different from that observed in patients treated with Taxus Liberté (13.6% vs. 13.3%: p= non-significant (>0.05)). TLR was performed nearly half as often on patients treated with BioFreedom as on those treated with Taxus Liberté (5.2% vs. 10.2% p= non-significant (>0.05)).

BioFreedom demonstrated sustained safety up to four years, including absence of definite and/or probable stent thrombosis.

LEADERS FREE has been designed to assess the potential for a DCS to deliver the anti-restenotic benefits of a DES while giving a shorter one-month course of DAPT, currently only recommended for a bare-metal stent (BMS). It is the world's first prospective, randomised double-blind trial between a DCS and BMS, exclusively involving patients at high risk of bleeding. Patients in both arms of the study are being prescribed only one month of DAPT, although they are taking a single anti-platelet drug indefinitely.

Approximately 2,500 patients are being enrolled in the study at 65 sites across Europe, Asia and South America, with follow-up scheduled for two years. 1,000 patients have been enrolled to date. Investigators anticipate completing the enrollment process by early 2014. Primary endpoint data is likely to be presented during 2015.

BioFreedom received CE Mark approval in January 2013, supported by strong primary endpoint data from the FIM study. At 12 months, BioFreedom was non-inferior ( $p_{\text{non-inferiority}}=0.001$ ) to Taxus Liberté in terms of Late Lumen Loss, with a trend towards superiority ( $p=0.11$ ). Median in-stent late lumen loss in patients receiving BioFreedom was reduced to 0.17 mm as compared with a median in-stent late lumen loss of 0.35 mm in the Taxus Liberté group.

BioFreedom is in the process of being launched in selected markets, with a full commercial launch anticipated during 2014.

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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. We aim to improve patients' lives through pioneering medical technology that pushes forward the boundaries of innovation.

With the BioMatrix™ family of drug-eluting stents and the Axxess™ self-expanding bifurcation stent, we are one of the leaders in the global coronary stent market. These stents incorporate Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with stents, 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 now received CE Mark approval, re-establishes 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.

The recent launch of our drug-eluting balloon range complements our stent portfolio and offers interventional cardiologists a broader range of treatment options.

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

## **About The Cardiovascular Research Foundation**

The Cardiovascular Research Foundation (CRF) is an independent, academically focused nonprofit organization dedicated to improving the survival and quality of life for people with cardiovascular disease through research and education. Since its inception in 1991, CRF has played a major role in realizing dramatic improvements in the lives of countless numbers of patients by establishing the safe use of new technologies and therapies in interventional cardiovascular medicine. CRF is the sponsor of the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Celebrating its 25th anniversary this year, TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

For more information, visit [www.crf.org](http://www.crf.org) and [www.tctconference.com](http://www.tctconference.com).