



## **NEWS RELEASE**

**EMBARGOED UNTIL 12:40 PM EST**

### **Novel Polymer-Free Drug-Coated Stent Demonstrates Comparable Safety and Efficacy to Conventional Drug-Eluting Stent with Durable Polymer at 12 Months**

**Washington DC, USA, 25 September 2010** – Biosensors International Group, Ltd (“Biosensors”, “Company”, BIG:SP) today announced 12-month results from the First-In-Man (“FIM”) trial of BioFreedom™, a novel polymer-free drug-coated stent (“DCS”) which showed a similar reduction in in-stent late lumen loss to Boston Scientific’s Taxus® Liberté® drug-eluting stent (DES), with no evidence of stent thrombosis. These results were presented by the Principal Investigator, Professor Eberhard Grube, International Heart Center Essen, Germany, as part of the First Report Investigations III session at the 22<sup>nd</sup> annual Transcatheter Cardiovascular Therapeutics (“TCT”) scientific symposium, sponsored by the Cardiovascular Research Foundation.

BioFreedom represents the latest development in Biosensors stent technology, featuring a micro-structured abluminal surface which permits the controlled release of BiolimusA9™ without the use of a polymer. Two versions of the stent were studied in this trial – one with a drug dosage of 15.6 µg/per mm of stent length (standard dose) and the other with a drug dosage of 7.8µg/per mm of stent length (low dose).

In this second cohort of the FIM trial, 107 patients were equally randomized to each of three treatment groups: BioFreedom standard dose (SD); BioFreedom low dose (LD); or Taxus Liberté. Median in-stent late lumen loss in patients receiving BioFreedom SD was 0.17 mm and in those receiving BioFreedom LD 0.22 mm, compared with a median in-stent late lumen loss of 0.35 mm in the Taxus Liberté group. BioFreedom SD demonstrated equivalent efficacy, measured by late lumen loss, compared with Taxus Liberté (P = 0.001), with a trend towards superiority (P=0.11).

Both BioFreedom SD and BioFreedom LD demonstrated sustained safety up to 12 months, including absence of stent thrombosis.

“The results from this study are very significant as they demonstrate for the first time that a polymer free drug-coated stent is as safe and effective as a conventional drug-eluting stent with a durable polymer coating over a twelve-month period”, commented Professor Grube. “I am excited about the concept of a polymer-free stent, as the rapid drug clearance and absence of a polymer drug carrier could promote more rapid vessel healing and ultimately reduce the need for longer term dual anti-platelet therapy. However, additional clinical data is required to confirm these initial encouraging results.”

**More/...**



“These latest results confirm that we continue to lead the industry in stent innovation, first in terms of biodegradable polymer technology and now polymer-free technology”, added Jeffrey B. Jump, President & CEO of Biosensors. “We are now in the process of planning larger studies with longer-term follow-up to further investigate this exciting development”.

BioFreedom FIM is a prospective, multi-centre study involving 182 patients with symptomatic ischemic heart disease. It consists of a first cohort of 75 patients, with a secondary endpoint of in-stent late lumen loss at 4 months, and a second cohort of 107 patients, with a primary endpoint of in-stent late lumen loss at 12 months. In each cohort patients were randomized into three groups: those treated with BioFreedom SD; those treated with BioFreedom LD; and those treated with Taxus Liberté. Results from the first cohort, showing equivalence between BioFreedom and Taxus Liberté, were presented at TCT in 2009. The clinical status of the patients in the trial is being reported annually for five years from the date of stent implant.

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#### **Note to Editors**

In-stent late lumen loss is defined as the maximum narrowing of the stent lumen due to tissue that builds up inside it at between 9 and 12 months after implantation, and has long been considered a primary measure of device effectiveness.

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

Biosensors develops, manufactures and markets innovative medical devices used in interventional cardiology and critical care procedures. Biosensors is well-positioned to emerge as a leader in drug-eluting stents and has developed a pipeline of next-generation products that are set to gain market share from traditional therapies such as conventional drug-eluting stents, bare-metal stents and open-heart surgery. It has three separate drug-eluting stent programs: BioMatrix™, a drug-eluting stent with abluminal biodegradable polymer; BioFreedom™, a completely polymer-free drug coated stent; and Sparrow®, a novel ultra-low profile “stent on a wire” system.



### **About CRF and TCT**

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.

Transcatheter Cardiovascular Therapeutics (TCT) is the annual scientific symposium of the Cardiovascular Research Foundation. TCT gathers leading medical researchers and clinicians from around the world to present and discuss the latest developments in the field.

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

### **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.*