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## **NEWS RELEASE**

### **BioMatrix Flex™ Chosen for Largest Ever Clinical Trial Involving a Drug-Eluting Stent**

**Paris, France, 16 May 2012** – BioMatrix Flex™, Biosensors' Biolimus A9™-eluting stent system with abluminal biodegradable polymer, has been chosen as the stent system for use in GLOBAL LEADERS, the largest ever randomized clinical trial involving a drug-eluting stent (DES). The latest plans for the trial were announced yesterday at EuroPCR by Study Chairman Professor Patrick W. Serruys.

GLOBAL LEADERS, an investigator-driven trial supported by both Biosensors and AstraZeneca, aims to enroll around 16,000 patients from an “all-comers” population to assess the potential benefits of new antiplatelet regimens. These drugs are prescribed to patients who have received a stent, to prevent long-term complications.

All patients will receive BioMatrix Flex™, then be randomized to either standard treatment with a 12-month course of dual antiplatelet therapy (DAPT), followed by 12 months of aspirin monotherapy; or an innovative antiplatelet strategy utilizing an abbreviated one month of DAPT followed by an extended 23 months of ticagrelor monotherapy. Ticagrelor is a new anti-platelet drug.

Recruitment is due to commence by the end of this year. Patients will be followed-up for two years.

“BioMatrix Flex is a logical choice as the stent platform for GLOBAL LEADERS”, commented Prof. Serruys. “Its abluminal biodegradable coating gives it the long-term safety profile of a bare-metal stent. In addition, the four-year results from the LEADERS trial have provided solid evidence of improved clinical outcomes versus the gold-standard first-generation sirolimus-eluting stent”.

GLOBAL LEADERS is being independently designed, implemented and analyzed by the study investigators, led by Professor Serruys (Erasmus Medical Center, Rotterdam, Netherlands), Professor Stephan Windecker (University Hospital, Bern, Switzerland) and Dr. Marco Valgimigli (University of Ferrara, Italy). This latest plan for the trial represents a significant evolution in the concept, protocol, management and support of GLOBAL LEADERS, as announced at EuroPCR last year, which this study supersedes and replaces.

“We are delighted that such a prestigious international group of physicians has independently chosen our DES for this landmark study”, added Dr. Jack Wang, CEO of Biosensors.

The BioMatrix Flex stent system offers the unique combination of Biolimus A9™ (BA9™), an anti-restenotic drug developed by Biosensors specifically for use with stents, combined with a biodegradable poly-lactic acid (PLA) polymer abluminally coated onto an advanced, highly flexible stent platform designed for enhanced deliverability. The PLA polymer fully degrades into carbon dioxide and water after six to nine months as it releases BA9.

**More/...**

Use of BioMatrix Flex continues to expand throughout the world as clinicians become more familiar with the benefits it offers their patients, and recognize the growing body of supporting clinical evidence. BioMatrix Flex has more published data to support its safety and efficacy than any other biodegradable polymer DES.

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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 increasing use of the BioMatrix™ family of drug-eluting stents, we are rapidly emerging as a leader in the global coronary stent market. The recent launch of the Axxess™ self-expanding bifurcation drug-eluting stent and the development of the BioFreedom™ drug-coated stent further establish our technology leadership.

All three stents incorporate Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with drug-eluting stents. Both the BioMatrix stent family and the Axxess stent feature 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 stent family features workhorse stent platforms for a broad range of lesions, and the Axxess stent employs a self-expanding stent platform specifically designed for treating bifurcation lesions. BioFreedom, a completely polymer-free stent abluminally coated with BA9, is currently undergoing clinical evaluation.

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