



**BIOSENSORS**  
INTERNATIONAL™

## **NEWS RELEASE**

### **Plans For Largest Ever Drug-Eluting Stent Randomized Clinical Trial Announced at EuroPCR**

**Paris, France, 18 May 2011** – Plans for Global LEADERS (“LEADERS II”), the largest ever randomized clinical trial involving a head-to-head comparison between two drug-eluting stents (DES), were announced yesterday during the opening session of EuroPCR by Co-Principal Investigator Professor Patrick W. Serruys.

The trial will enroll more than 10,000 patients from an “all-comers” population eligible for PCI, allocated to receive either BioMatrix Flex™ (Biosensors’ Biolimus A9™-eluting stent system with abluminal biodegradable polymer), or the market-leading DES system with a durable polymer. Recruitment into the study, involving over 100 sites around the globe, is due to start in early 2012, with data being collected for up to two years following stent implantation.

The protocol of the study is currently under development, and is likely to involve a “2x2 factorial” design, with the second randomization being to either a short or long duration of anti-platelet therapy. The primary endpoint will be a true clinical evaluation, assessing patient safety. Global LEADERS will be independently designed, implemented and analyzed by the study investigators, who in addition to Prof. Serruys (Erasmus Medical Center, Rotterdam, Netherlands) will include Co-Principal Investigator Professor Stephan Windecker (University Hospital, Bern, Switzerland). The study will also have regional Principal Investigators in Europe, South America and Asia. Dr. Marco Valgimigli (University of Ferrara, Italy) will act as Principal Investigator for the anti-platelet therapy portion of the study.

Global LEADERS aims to build on the concept of the landmark LEADERS study, which was the first head-to-head randomized trial between two limus DES in an “all-comers” patient population using clinical outcomes as its endpoint. LEADERS results suggested that a DES with biodegradable polymer could be safer in the long term than a DES with durable polymer – especially in high-risk patient populations – under conditions which resemble those of routine clinical practice.

“I am delighted to be involved with this logical development of the original LEADERS study”, commented Prof. Serruys. “By continuing the concept of a head-to-head study against a widely-used drug-eluting stent with durable polymer using a true clinical endpoint, and involving nearly six times as many patients, we anticipate that the study will be sufficiently powered to produce meaningful results on the benefits of a drug-eluting stent with biodegradable polymer in a broad range of pre-defined patient subgroups.”

“Global LEADERS should provide us with further valuable information, in that it will evaluate the risks and benefits associated with a short versus a long duration course of anti-platelet therapy following DES implantation in a large number of patients”, added Prof. Windecker.

**More/...**

“We are delighted to once again have the opportunity to be involved in a truly ground-breaking study, which represents another first for Biosensors in the field of drug-eluting stent research” concluded Biosensors Co-CEO Jeffrey B. Jump. “LEADERS changed the mind-set of how DES trials were perceived, and established a new benchmark for their design. Now Global LEADERS will raise the bar again for DES trial design in a wider population”.

The BioMatrix Flex stent system offers the unique combination of Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with drug-eluting stents, combined with a biodegradable poly-lactic acid (PLA) polymer abluminally coated onto an advanced, highly flexible stent platform designed for enhanced deliverability. BA9 has the highest lipophilic profile of the common limus drugs, enabling rapid absorption by the tissue and minimizing systemic exposure. The PLA polymer fully degrades into carbon dioxide and water over a six to nine month period as it releases BA9.

**-Ends-**

**For further information, please contact:**

Corporate Communications

Richard Kenyon

Biosensors International

+44 7831569940

[r.kenyon@biosensors.com](mailto:r.kenyon@biosensors.com)

Investor Relations

Wong TeckYenn

Biosensors International Group

+65 6213 5708

[ty.wong@biosensors.com](mailto:ty.wong@biosensors.com)

**About Biosensors International**

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 forthcoming launch of the Axxess™ self-expanding bifurcation drug-eluting stent and the development of the BioFreedom™ drug-coated stent will further reinforce our market position.

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 over a six-to-nine-month period 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).