# NEWS RELEASE

## BioMatrix Flex™ Improves Long-Term Clinical Outcomes Compared to Cypher® Select™
## Four-Year Results Simultaneously Published by *The Lancet*

**San Francisco, USA, 9 November 2011 –** Biosensors International Group, Ltd. ("Biosensors", "Company", BIG:SP) has announced four-year results of the LEADERS trial, showing improved long-term clinical outcomes for BioMatrix Flex™, Biosensors' Biolimus A9™-eluting stent system with abluminal biodegradable polymer, compared to Cypher® Select™, Johnson & Johnson's sirolimus-eluting stent system with a durable polymer. This improvement was mainly achieved by reducing the risk of cardiac events associated with very late stent thrombosis (VLST) occurring beyond the first year of follow-up. Results were presented yesterday by Professor Thomas A. Ischinger, Kardiologie im Zentrum, Munich, Germany, at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation. The results were simultaneously published online by *The Lancet*.[1]

"These findings are the basis for the proof of concept of biodegradable polymer drug-eluting stents", commented Principle Investigator Professor Stephan Windecker, University Hospital, Bern, Switzerland. "They provide evidence of a difference in stent thrombosis translating into a difference in clinical outcomes."

There was an excellent follow-up rate of over 96% at four years, at which time the risk of MACE (Major Adverse Cardiac Events) was lower in patients treated with BioMatrix Flex than in those treated with Cypher Select (18.7% vs. 22.6%: p = 0.050). The benefit of BioMatrix Flex appeared more pronounced between years one and four. During this one to four year period, BioMatrix Flex was also associated with an 80% relative risk reduction in terms of definite VLST compared with Cypher Select.

An analysis of the correlation between MACE and definite stent thrombosis events showed that the benefit in favor of BioMatrix Flex in terms of MACE was largely driven by a lower risk of MACE associated with definite VLST beyond the first year of follow-up.

"We are very encouraged by these results, which further support the long-term patient benefit of BioMatrix Flex", added Jeffrey B. Jump, Co-CEO of Biosensors. "LEADERS has been given further credibility by the fact that results have now been simultaneously published in *The Lancet* twice, which must be a first for a drug-eluting stent study".

The initial results from LEADERS, presented at the European Society of Cardiology ("ESC") congress in 2008 and simultaneously published in The Lancet, demonstrated BioMatrix Flex to be non-inferior to Cypher Select in respect of the primary endpoint, incidence of MACE at nine months. This non-inferiority was confirmed in the one, two and three year results, during which time a diverging trend towards a safety benefit for BioMatrix Flex was observed.

**More/…**

Sponsored by Biosensors, LEADERS was independently designed, implemented and analyzed by the study investigators. Data management and analysis were performed by an independent academic institution.

***Reference***

1 Stefanini GG, Kalesan B, Serruys PW *et al*. Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4 year follow-up of a randomised non-inferiority trial. *The Lancet*, Early Online Publication, 9 November 2011. doi:10.1016/SO140-6736(11)61672-3

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**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 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.

**About CRF**
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 the subspecialty of interventional cardiology and endovascular medicine.

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