



NEWS RELEASE

LEADERS Three-Year Results Suggest Improved Safety and Efficacy of BioMatrix Flex™ over Cypher® Select™

Washington DC, USA, 21 September 2010 – Biosensors International Group, Ltd (“Biosensors”, “Company”, BIG:SP) today announced three-year results of the LEADERS trial, which showed a continuing positive trend towards a safety and efficacy benefit 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. Results were presented by Professor Patrick W. Serruys, Erasmus Medical Center, Netherlands, at the 22nd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

In the overall study population, there were similar outcomes for BioMatrix Flex and Cypher Select in respect of MACE (major adverse cardiac events) at three years. There was a diverging trend towards a lower rate of MACE (15.7% vs. 19.0%; P value for superiority = 0.09) in patients treated with BioMatrix Flex versus those treated with Cypher Select when compared to both one and two year results.

In the high risk sub-group of STEMI patients (ST Elevation Myocardial Infarction), a statistically significant reduction in MACE rate was demonstrated with BioMatrix Flex compared to Cypher Select (9.6% vs. 20.7%; P value for superiority = 0.01). In another high-risk group of patients, those with SYNTAX High scores (>16), there was a significant 57% reduction in risk of cardiac death for BioMatrix Flex compared to Cypher Select (4.6% vs. 10.4%; P value for superiority = 0.02).

Although this was an all-comers study, occurrence of very late stent thrombosis (VLST) events was very low: a cumulative 0.2% for BioMatrix Flex out to three years, compared with 0.9% for Cypher Select observed within the same period. No VLST events were observed in BioMatrix Flex patients between years two and three of the study. VLST events in the BioMatrix Flex group were limited to patients with Saphenous Vein Grafts (SVG), who are traditionally excluded from drug-eluting stent trials. It was also notable there were no VLST events in patients treated with the BioMatrix Flex stent after discontinuation of dual anti-platelet therapy (DAPT).

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“These further follow-up results from LEADERS confirm that the BioMatrix Flex stent continues to be safe and effective three years after implantation in an all-comers population, reflecting patients treated in routine clinical practice”, commented Professor Serruys.



“We are very encouraged by these results, which demonstrate that BioMatrix Flex continues to offer superior patient benefits compared to the industry standard over the longer term”, added Jeffrey B. Jump, President & CEO of Biosensors. “Our innovative drug-eluting stent, with its unique combination of anti-restenotic drug and abluminal biodegradable polymer, is providing an increasingly attractive alternative to conventional drug-eluting stents with durable polymers.”

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

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.

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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.

About the BioMatrix™ Stent Family

The BioMatrix™ stent system offers the unique combination of an innovative anti-restenotic drug, BA9™, combined with a biodegradable poly-lactic acid polymer (PLA), abluminally coated onto an advanced, highly flexible stent designed for enhanced deliverability.

Biolimus A9 was designed specifically for use in drug-eluting stent systems. In addition to effective immunosuppressive and anti-inflammatory properties, the drug has a higher lipophilic and hydrophobic profile than other limus analogs, enabling rapid absorption of the drug into the targeted tissue and reduced systemic exposure. Precision automated coating ensures the PLA and drug combination is applied only to the abluminal (outer) surface of the stent. The PLA fully degrades into water and carbon dioxide over a six to nine month period as the drug elutes, ultimately leaving in place a biocompatible stent surface.

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.