



## **NEWS RELEASE**

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### **LEADERS Two-Year Results Indicate Improved Safety and Efficacy of Biodegradable Polymer Technology over Conventional Durable Polymers**

**San Francisco, USA, 23 September 2009** – Biosensors International Group, Ltd (“Biosensors”, “Company”, BIG:SP) today announced the two-year results of the LEADERS trial, which showed an increasing trend towards a safety benefit for the Biosensors Biolimus A9™-eluting stent with abluminal biodegradable polymer (“BES”) compared to Johnson & Johnson’s sirolimus-eluting stent with a durable polymer (“SES”). Results were presented by Professor Volker Klauss as part of the Late Breaking Trial session at the 21st annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

“These additional follow-up results from LEADERS confirm that the Biosensors Biolimus A9-eluting stent is safe and effective two years after implantation in an all-comers population reflecting patients we treat in our routine clinical practice”, commented LEADERS Principal Investigator Professor Stephan Windecker, University Hospital, Bern, Switzerland.

In the overall study population there were similar outcomes for BES and SES, with an increasing advantage observed for BES in both Major Adverse Cardiac Events (“MACE”) (BES: 13% vs. SES: 15.4%  $p=0.18$ ) and Cardiac Death/Myocardial Infarction (BES: 8.3% vs. SES: 9.1%  $p=0.59$ ) compared with both nine and 12-month results. The differences were not statistically significant. In the high risk sub-group of STEMI patients (ST Elevation Myocardial Infarction), a statistically significant improved MACE rate was demonstrated with BES compared to SES (8.1% vs. 19.3%  $p<0.01$ ).

Although this was an all-comers study, occurrence of very late stent thrombosis events was rare (BES 0.2% vs. SES 0.5%  $p=0.73$ ). In the BES group, the two events observed were limited to patients with Saphenous Vein Grafts (SVG), who are traditionally excluded from drug-eluting stent trials. Notably, there were no very late stent thrombosis events in BES patients after discontinuation of dual anti-platelet therapy (DAPT).

“We are extremely pleased with these long-term results”, concluded Michael Kleine, President & CEO of Biosensors. “They confirm that our drug-eluting stent technology, with its unique combination of anti-restenotic drug and abluminal biodegradable polymer, has created a new industry standard.”

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LEADERS (Limus Eluted from **A** Durable versus **E**Rodable **S**tent coating), is a multi-centre randomized study in which 1,707 patients eligible for PCI for symptomatic coronary disease received either a Biosensors Biolimus A9™-eluting stent with an abluminal biodegradable polymer coating (BES), or a sirolimus-eluting stent with a durable polymer (SES). Inclusion criteria were broad, reflecting routine clinical practice, without limitations regarding type of coronary vessel, lesion length or number of treated lesions. The nine-month results, presented at the European Society of Cardiology (“ESC”) congress in 2008 and simultaneously published in *The Lancet*, demonstrated BES to be non-inferior to SES in respect of the primary endpoint, incidence of MACE at nine months. This non-inferiority was confirmed in the 12-month results, at which time a non-significant difference in the rates of stent thrombosis in favor of BES was also observed.

Although funded by Biosensors, LEADERS was independently designed, implemented and analyzed by the study investigators. Moreover, 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 being positioned to gain market share from traditional therapies such as conventional drug-eluting stents, bare-metal stenting and open-heart surgery. It has three separate stent programs, Gazelle, a bare-metal stent, *BioMatrix™*, a drug eluting stent with a biodegradable polymer, and BioFreedom™, a completely polymer-free drug-eluting stent in development. For more information, please visit [www.biosensors.com](http://www.biosensors.com).

### **About Cardiovascular Research Foundation**

The Cardiovascular Research Foundation 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 1990, 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. For more information, please visit [www.crf.org](http://www.crf.org).