



NEWS RELEASE

New Data Reinforces Safety and Efficacy of Biosensors DES in Complex Patient Populations

Barcelona, Spain, 20 May 2009 – Biosensors International Group, Ltd (“Biosensors”, “Company”, BIG:SP) today announced new data on its Biolimus A9™-eluting stent with abluminal biodegradable polymer, demonstrating equal safety and efficacy to Johnson & Johnson’s sirolimus-eluting stent with a durable polymer, CYPHER SELECT™ (“Cypher”), in patients with acute coronary syndrome (“ACS”) and bifurcation lesions. The results of these two subgroup analyses of the landmark LEADERS trial were presented today at EuroPCR 2009.

In the first pre-specified subgroup, 470 ACS patients were treated with the Biosensors stent and 473 with Cypher. After 12 months, the incidence of MACE – defined as the composite of cardiac death, myocardial infarction, and clinically-indicated Target Vessel Revascularization (“TVR”) – was 9.4 percent for the Biosensors stent and 11.2 percent for the Cypher stent ($p=0.34$). These results, observed in particularly complex patients, confirm those already published for the overall LEADERS population.

Interestingly, if only patients with STEMI were considered, there was a significant 50 percent reduction in the incidence of MACE at 12 months, with 6.7 percent for the Biolimus A9™-eluting stent versus 15.7 percent for the sirolimus-eluting stent ($p=0.02$). This significant difference was not only driven by clinically-indicated TVR but also by the composite of cardiac death and MI that shows a significant reduction for the Biosensors stent (3.7 percent versus 10.0 percent respectively; $p=0.04$). In this subgroup, 135 patients received a Biolimus A9™-eluting stent and 140 patients received a sirolimus-eluting stent.

In the second subgroup, 258 bifurcation patients were treated with the Biosensors stent and 239 with Cypher. After 12 months, patients given the Biosensors stent experienced similar levels of MACE to patients given the Cypher stent (12.8 percent versus 16.3 percent; $p=0.31$). However, the need for revascularization as measured by TVR was significantly lower with the Biolimus A9™-eluting stent at 12 months ($p=0.004$).

“These additional results from LEADERS are reassuring as they confirm that a Biolimus A9-eluting stent with an abluminal biodegradable polymer is as safe and effective one year after implantation as the well-established sirolimus-eluting stent with a durable polymer in the types of complex patient populations encountered in routine clinical practice”, commented LEADERS Principal Investigator Professor Stephan Windecker, University Hospital, Bern, Switzerland.

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R Michael Kleine, President & CEO of Biosensors added, "We are tremendously encouraged by these further results from our LEADERS trial which confirm our drug-eluting stent technology, with its unique combination of anti-restenotic drug and abluminal biodegradable polymer as the new industry standard."

LEADERS (Limus Eluted from **A Durable** versus **ERodable Stent** coating), nine-month results were presented at the European Society of Cardiology ("ESC") congress in 2008 and simultaneously published in *The Lancet*. LEADERS 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, or a sirolimus-eluting stent with a durable polymer. Inclusion criteria were broad, reflecting routine clinical practice, without limitations regarding type of coronary vessel, lesion length or number of treated lesions. In this trial, the Biolimus A9™-eluting stent was demonstrated to be non-inferior to the sirolimus-eluting stent in the primary endpoint, incidence of MACE at 9 months.

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.

Biosensors develops, manufactures and markets innovative medical devices used in interventional cardiology and critical care procedures. Biosensors has developed a pipeline of next-generation products that are set to gain market share from traditional therapies such as conventional DES, bare-metal stents and open-heart surgery. It has two separate drug-eluting stent programs, *BioMatrix™* and *BioFreedom™*, a completely polymer-free drug-eluting stent.

For further information about Biosensors, please visit: www.biosensors.com

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For further information or to arrange interviews, please contact:

On site at EuroPCR: Susanne Meis: s.meis@biosensors.com +49 171 8918919

Office-based support: Richard Kenyon: richard@rkpr.co.uk +44 7831 569940