



## NEWS RELEASE

### **Biosensors DES Demonstrates Equivalent Safety and Efficacy to Industry Leading DES in First 'Real World, All Comers' Clinical Study**

**2 October 2008** – According to data published in this week's *Lancet*, a Biosensors-developed drug-eluting stent (DES) with biodegradable polymer has demonstrated equal safety and efficacy to Johnson & Johnson's industry leading DES, CYPHER SELECT™ ("Cypher"), based upon nine-month clinical and angiographic follow-up data. This study was presented last month at the European Society of Cardiology meeting in Munich.

LEADERS (Limus Eluted from A Durable versus ERodable Stent coating) is the first head-to-head randomized study between the two drug-eluting stent systems (DES) in a 'real world, all comers' population using clinical results as its primary endpoint.

This multi-centre European study randomized 1,707 patients eligible for percutaneous coronary intervention (PCI) for symptomatic coronary disease to receive either a Biosensors Biolimus-eluting DES with an abluminal biodegradable polymer coating, or a Cypher Sirolimus-eluting DES with a durable polymer. In total, 2,472 coronary lesions were treated. Inclusion criteria were broad, reflecting routine clinical practice, without limitations regarding type of coronary vessel, lesion length or number of treated lesions. Patient conditions known as "off-label indications", including acute coronary syndromes, saphenous vein grafts and previously treated lesions were also included in the trial.

The primary endpoint of the study was non-inferiority of the composite of cardiac death, myocardial infarction, and clinically-driven target vessel revascularization ("TVR") at nine months follow-up. In addition, 25 percent of all patients were randomly assigned to undergo angiographic follow-up at nine months. The principal endpoint of the pre-specified angiographic sub-group was in-stent percent diameter stenosis at nine months.

During the first nine months, 9.2 percent of patients receiving the Biosensors DES, and 10.5 percent of patients given the Cypher DES experienced a clinical adverse event that could be included in the primary composite endpoint, thus demonstrating that the Biosensors stent was non-inferior to the Cypher stent. A favorable trend towards the Biosensors stent was non-significant at the nine months follow-up endpoint. As anticipated, clinical event rates were higher in LEADERS compared with previous DES trials performed in patients with only on-label indications, because the LEADERS trial design permitted inclusion of any patient eligible for PCI. As a result, rates of death, myocardial infarction and stent thrombosis were similar for both stent types, but were



2.6% higher when compared to the earlier, less inclusive trials.

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In the angiographic sub-group, there were no significant differences at 9 months between the in-stent percent diameter stenosis observed in the two patient groups, but there was a non-significant trend favoring the Biosensors stent.

“The results from LEADERS are very significant as they demonstrate for the first time that a drug-eluting stent with an abluminal biodegradable polymer is as safe and effective at nine months as a conventional drug-eluting stent with a durable polymer, considered to be the most effective, under conditions which resemble those of routine clinical practice”, commented LEADERS Principal Investigator Professor Stephan Windecker, University Hospital, Bern, Switzerland. “Longer-term follow-up of the patients in LEADERS or studies of a similar nature are now needed to confirm the theoretical advantage of the abluminal biodegradable polymer in terms of reduced risk of late thrombosis.”

Mike Kleine, President & CEO of Biosensors added, “We are tremendously encouraged by the results of LEADERS, believing this to be just the first in a series of studies which will ultimately confirm our drug-eluting stent technology, with its unique combination of anti-restenotic drug and abluminal biodegradable polymer, as the new industry standard.”

Although funded by Biosensors, LEADERS was independently developed, 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 three separate drug-eluting stent programs, *BioMatrix™*, *Axxion™*, and *BioFreedom™*, a completely polymer-free drug-eluting stent.

For further information about Biosensors, please visit: [www.biosensors.com](http://www.biosensors.com)

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**Reference:**

Windecker S, Serruys P, Wandel S *et al.* Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomised non-inferiority trial. *The Lancet* 2008; **372**:1163-1173

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