NEWS RELEASE

Long-Term Clinical Benefits of BioMatrix Flex™ Confirmed in *The Lancet*: Proof of Concept for Biodegradable Polymer

5 December 2011 – Four-year results from the LEADERS trial, published in the latest issue of *The Lancet*[1], show that BioMatrix Flex™, Biosensors' Biolimus A9™-eluting stent system with a biodegradable polymer coating, significantly reduces the risk of very late stent thrombosis (VLST) compared to that of a drug-eluting stent (DES) system with a durable polymer coating. This reduced risk of VLST is positively associated with a reduced risk of cardiac events, therefore demonstrating for the first time 'proof of concept' that a DES with biodegradable polymer improves long-term clinical outcomes compared to a DES with durable polymer.

"This study shows that the problem of very late stent thrombosis, which was prevalent with first-generation durable-polymer drug-eluting stents, is markedly reduced by a stent using a biodegradable polymer", commented Principal Investigator Professor Stephan Windecker, University Hospital, Bern, Switzerland. "This translates into a late benefit in terms of cardiac death or myocardial infarction."

The LEADERS study is a head-to-head randomized trial between two limus-eluting stents, BioMatrix Flex and Cypher® Select™, Johnson & Johnson's sirolimus-eluting stent system with a durable polymer. The study involves an "all-comers" patient population and measures clinical outcomes. The primary endpoint from LEADERS, published in *The Lancet* in 2008[2], demonstrated BioMatrix Flex to be non-inferior to Cypher Select with respect to the primary endpoint, incidence of MACE (a composite of cardiac death, myocardial infarction, or clinically-indicated target vessel revascularization) at nine months. This non-inferiority has been confirmed in the one, two, three and four-year results, during which time a diverging trend towards a safety benefit for BioMatrix Flex was observed.

At four years, the risk of MACE was lower in patients treated with BioMatrix Flex than in those treated with Cypher Select (18.7% vs. 22.6%: p = 0.050, 96% of patients followed up). The benefit of BioMatrix Flex appeared more pronounced between years one and four. During this one to four year period, BioMatrix Flex was associated with a significant 80% relative risk reduction in definite VLST compared with Cypher Select (p=0.004).

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 [1].

"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 shows that improvement in drug-eluting stent technology directly translates into improved patient safety".

More/…

Sponsored by Biosensors, LEADERS was independently designed, implemented and analyzed by the study investigators.

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References

1 Stefanini GG *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* 2011; 378: 1940-1948.

2 Windecker 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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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.