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NEWS RELEASE

BioMatrix Flex™ Improves Clinical Outcomes Compared to Cypher® Select™ For Up To Five Years

Miami, USA, 24 October 2012 – Biosensors International has announced five-year results from the LEADERS trial, showing improved long-term clinical outcomes for BioMatrix Flex™, Biosensors' Biolimus A9™-eluting stent system with a biodegradable polymer coating, compared to Cypher® Select™, Johnson & Johnson's sirolimus-eluting stent system with a durable polymer. BioMatrix Flex significantly reduced the risk of clinical events compared with Cypher Select, which was associated with a reduced risk of very late stent thrombosis (VLST).

The final report from LEADERS was presented yesterday by Professor Patrick W. Serruys, Erasmus Medical Center, Rotterdam, The Netherlands, at the 24th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

“As a result of LEADERS, most drug-eluting stents currently being developed use biodegradable polymer technology”, commented Principal Investigator Professor Stephan Windecker, University Hospital, Bern, Switzerland. “BioMatrix was one of the pioneering stent platforms to use a biodegradable polymer applied to the abluminal surface only.”

Results at five years demonstrated that the relative risk of MACE (Major Adverse Cardiac Events) was 17% lower in patients treated with BioMatrix Flex than in those treated with Cypher Select (22.3% vs. 26.1%; $P_{\text{sup}} = 0.071$). During the one to five year period, BioMatrix Flex was also associated with a significant 74% reduction in definite VLST compared with Cypher Select (0.66% vs. 2.5%; $P_{\text{sup}} = 0.003$). The study had an excellent follow-up rate of 96.5%.

“Results from LEADERS have helped patients to benefit from our superior technology, as this was the first study to actually show that a drug-eluting stent with a biodegradable polymer was better than one with a durable polymer”, added Jeffrey B. Jump, President of Biosensors' Cardiovascular Business Unit.

The initial results from LEADERS, presented at the European Society of Cardiology (“ESC”) congress in 2008 and simultaneously published in *The Lancet*¹, demonstrated BioMatrix Flex to be non-inferior to Cypher Select in respect of the primary endpoint, incidence of MACE at nine months. The four-year results, published in *The Lancet* in 2011², reinforced the long-term benefits of BioMatrix Flex. Compared with Cypher Select, it significantly reduced the risk of cardiac events, which was associated with a reduced risk of VLST.

LEADERS has achieved a series of notable firsts: it was the first head-to-head randomized clinical study (RCT) between two limus-eluting stents; the first RCT between two stents to involve an “all-comers” patient population; and the first RCT between two stents to be independently monitored and assessed by its investigators.

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References

1. 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** No. 9644:1163-1173.
2. Stefanini GG, Kalesan B, Serruys PW *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.

For further information, please contact:

Corporate Communications

Richard Kenyon
Biosensors International Group
+44 7831 569940
r.kenyon@biosensors.com

Investor Relations

Wong Teck Yenn
Biosensors International Group
+65 6213 5708
ty.wong@biosensors.com

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 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.

About CRF

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, drugs 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.

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