NEWS RELEASE

Study Published in JAMA Confirms BioMatrix™ Reduces Cardiac Events in Acute MI Patients More Effectively Than a Bare-Metal Stent

28 August 2012 – Biosensors International Group has welcomed publication of a study in the prestigious medical journal JAMA which demonstrates that BioMatrix™, its stent system which elutes Biolimus A9™ from a biodegradable polymer, is more effective in reducing events and potentially safer than a bare-metal stent in the treatment of patients with acute myocardial infarction.

COMFORTABLE AMI, a physician-initiated multicentre international randomized clinical trial, showed that the use of BioMatrix reduced the rate of major cardiovascular events by more than 50% compared to the use of a bare-metal stent in patients with ST-segment elevation myocardial infarction (STEMI) at one year following implantation.

“Results from COMFORTABLE AMI are important, as they show for the first time that a biodegradable polymer drug-eluting stent is superior to a bare-metal stent in the treatment of STEMI patients”, commented Senior Author Professor Stephan Windecker, University Hospital, Bern, Switzerland. “This could gradually lead to a change in the type of stent that these patients are routinely given: a drug-eluting stent instead of a bare-metal stent”.

In the study, 1,161 patients presenting with STEMI were randomized to receive either BioMatrix or a bare-metal stent of otherwise identical design. The primary endpoint was the rate of major adverse cardiac events (MACE), a composite of cardiac death, target vessel-related reinfarction, and ischemia-driven target lesion revascularization (TLR) at one year. The researchers found that the primary endpoint occurred in 4.3% of patients receiving a BioMatrix stent and in 8.7% of patients receiving a bare-metal stent, which is a significant 51% relative reduction (P=0.004) in the risk of MACE: meaning that 42 adverse cardiac events per 1,000 patients can be prevented when treated with BioMatrix stents compared with bare-metal stents over a one year period.

“We are delighted by this prestigious publication of these results, which further add to the already impressive body of clinical evidence to support the use of our BioMatrix family of drug-eluting stents”, added Jeffrey B. Jump, President of Biosensors’ Cardiovascular Business Unit.

“The growing confidence of cardiologists in the use of the BioMatrix family of drug-eluting stents has been reflected in the steady increase of sales worldwide”, concluded Biosensors CEO Dr. Jack Wang.

These one-year results from COMFORTABLE AMI were first presented at EuroPCR in May 2012.

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Reference:

Räber L *et al*. Effect of biolimus-eluting stents with biodegradable polymer vs bare-metal stents on cardiovascular events among patients with acute myocardial infarction. The COMFORTABLE AMI randomized trial. *JAMA* 2012; **308:**777-787.

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About Biosensors International Group, Ltd
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 and the recent launch of our Axxess™ self-expanding bifurcation drug-eluting stent, we are rapidly emerging as a leader in the global coronary stent market. The development of the BioFreedom™ drug-coated stent will further reinforce our market position.

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