



NEWS RELEASE

EMBARGOED UNTIL 15:00 CET

BioMatrix Flex™ Significantly Reduces Cardiac Mortality compared to Cypher® Select™ in Patients with Complex Coronary Artery Disease

Paris, 25 May 2010 – A new independent analysis of the pivotal LEADERS study demonstrated that BioMatrix Flex™, the recently-launched Biolimus A9™-eluting stent system with abluminal biodegradable polymer, reduced cardiac mortality to a significantly greater degree than did Cypher® Select™, Johnson & Johnson's sirolimus-eluting stent system with a durable polymer, in patients with high SYNTAX scores. The SYNTAX score is a widely-accepted grading tool to determine the lesion complexity of patients with Coronary Artery Disease. The results were presented today by Dr. Joanna Wykrzykowska as part of the Late Breaking Registry and Trial Update session at the annual EuroPCR congress in Paris.

LEADERS (Limus Eluted from A Durable versus ERodable Stent coating), is a multi-centre randomized study in which 1,707 patients eligible for percutaneous coronary intervention (PCI) to treat symptomatic coronary artery disease received either the BioMatrix Flex or Cypher Select stent. Inclusion criteria were broad, reflecting routine clinical practice, without limitations regarding type of coronary vessel, lesion length or number of treated lesions. LEADERS was the first trial in which the SYNTAX score was applied to a PCI population. The SYNTAX score was prospectively collected in 1,397 of these patients. Post-hoc analysis was performed by stratifying clinical outcomes at one- and two-year follow-up, according to one of three SYNTAX score tertiles: SX_{low}: ≤8 (n=464); SX_{mid}: 8 to 16 (n=472); and SX_{high}: >16 (n=461). Usage of the two study stents was distributed equally across each tertile.

The two stents performed equivalently across all three tertiles. At two years follow-up there was a non-significant trend towards a lower rate of major adverse cardiac events (MACE) in patients treated with the BioMatrix Flex stent compared with those treated with the Cypher Select stent in the SX_{high} tertile (15.3% vs. 21.8%: p=0.08). The cardiac death rate was significantly lower in the SX_{high} patients treated with the BioMatrix Flex stent compared with those treated with the Cypher Select stent (4.7% vs. 9.6%: p=0.045). Target lesion revascularization occurred less frequently in SX_{high} patients treated with the BioMatrix Flex stent compared with those treated with the Cypher Select stent (8.3% vs. 13.1%: p=0.07).

More/...



“This new analysis of LEADERS using the SYNTAX score is particularly interesting as it shows that the BioMatrix Flex stent appears to offer an advantage over the Cypher Select stent in treating patients with complex disease”, commented Professor Patrick Serruys, Erasmus Medical Centre, Netherlands, LEADERS Investigator and developer of the SYNTAX score. “These findings need to be further verified in a larger study, and the mechanism behind these results also needs to be determined”.

Managing Director of Biosensors International Europe, Jeffrey B. Jump, added, “These latest results from LEADERS reinforce our confidence in the benefits of the BioMatrix Flex stent – the latest addition to the BioMatrix DES family – over conventional drug-eluting stents with durable polymers in treating patients suffering from complex cardiovascular disease”.

The nine-month results from LEADERS, presented at the European Society of Cardiology (“ESC”) congress in 2008 and simultaneously published in *The Lancet*, demonstrated the BioMatrix Flex stent to be non-inferior to the Cypher Select stent in respect of the primary endpoint: incidence of MACE at nine months. This non-inferiority was confirmed in the two year results, at which time an increasing trend towards a safety benefit for the BioMatrix Flex stent was observed.

Funded by Biosensors, LEADERS was independently designed, implemented and analyzed by the study investigators. Data management and analysis were performed by an independent academic institution.

-Ends-

For further information or to arrange interviews, please contact:

Susanne Meis: s.meis@biosensors.com +49 171 8918919

Richard Kenyon: richard@rkpr.co.uk +44 7831 569940

About BioMatrix Flex™ Drug-Eluting Stent

The BioMatrix Flex drug-eluting stent received CE Mark approval in January 2010 and is currently available in major European, Middle East and African markets, as well as in selected Asian markets. It has been approved for use in treating a comprehensive range of indications, including STEMI, Acute Coronary Syndromes and diabetes mellitus.

The BioMatrix Flex stent combines the proven combination of Biosensors’s unique biodegradable polymer technology with an improved mechanical platform for enhanced deliverability. The new stent platform combines a curved strut connector with the established Quadrature Link™ design of the existing BioMatrix platform, improving



flexibility and trackability, while ensuring stent security and vessel scaffolding. A larger initial cell opening than the original also improves side branch accessibility.

About Biosensors International Group, Ltd

Biosensors International Group, Ltd. (“Biosensors” or the “Company”; Bloomberg BIG SP) develops, manufactures and markets innovative medical devices used in interventional cardiology and critical care procedures. Biosensors is well-positioned to emerge as a leader in drug-eluting stents and has developed a pipeline of next-generation products that are being positioned to gain market share from traditional therapies such as conventional drug-eluting stents, bare-metal stenting and open-heart surgery. It has three separate stent programs, Gazelle, a bare-metal stent, *BioMatrix*™, a drug eluting stent with a biodegradable polymer, and BioFreedom™, a completely polymer-free drug-eluting stent in development. For more information, please visit www.biosensors.com.