# NEWS RELEASE

## Biosensors Launches BioMatrix Flex™ DES

**21 May 2010 –** Biosensors International today announced the launch of its BioMatrix Flex™ drug-eluting stent (DES) system in major European markets and selected regions in the Middle East, Africa and Asia. An extension of the company's breakthrough BioMatrix™ DES system, the BioMatrix Flex stent has received CE Mark approval for a comprehensive range of indications, including STEMI, Acute Coronary Syndromes and Diabetes Mellitus.

The BioMatrix Flex stent incorporates an improved mechanical platform for enhanced deliverability. The unique combination of a Biosensors-developed abluminal biodegradable polymer and proprietary limus drug, Biolimus A9™ (BA9™), which made the BioMatrix stent so successful, remains unchanged.

The new stent platform combines a curved strut connector with the established Quadrature Link™ design of the existing platform, improving flexibility and trackability, while ensuring stent security and vessel scaffolding. A larger initial cell opening also improves side branch accessibility. There has also been a simplification to the manufacturing process, reducing manufacturing time. This has removed the need for a primer coating to adhere the polymer and drug to the stent, with a Biosensors' proprietary process now applying the polymer and drug directly onto the stent struts.

"Since launching BioMatrix in 2008, Biosensors has helped physicians around the world offer improved treatment options to patients suffering from complex cardiovascular disease," said Jeffrey B. Jump, Managing Director of Biosensors Europe. "With BioMatrix Flex, we now offer the same proven clinical and safety benefits with improved deliverability to help doctors treat even the most complex and hard-to-reach lesions. And we continue our commitment to developing innovative medical products that help improve patients' lives."

The BioMatrix Flex stent has been studied extensively in both pre-clinical and clinical settings, including the groundbreaking 1,707-patient LEADERS study, the results of which were published in *The Lancet* in October 2008. In that trial, the first head-to-head randomized trial between two DES in a 'real world, all comers' population using a clinical primary endpoint, the BioMatrix Flex stent demonstrated equivalent safety and efficacy to the Cypher® Select™ stent, based on nine-month clinical and angiographic follow-up data. In the two-year LEADERS results, presented at the Transcatheter Cardiovascular Therapeutics conference (TCT) in September 2009, the BioMatrix Flex stent continued to demonstrate equivalent safety and efficacy as compared to the Cypher Select stent, with an increasing trend towards a long-term safety benefit in favor of the BioMatrix Flex stent.

**More/…**

Significant new data from the LEADERS trial will be presented at EuroPCR 2010, as part of the Hot Line I Late Breaking Registries and Trial Update session on 25 May.

**-Ends-**

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## About Biosensors International Group, Ltd

Biosensors 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 set to gain market share from traditional therapies such as conventional drug-eluting stents, bare-metal stents and open-heart surgery. It has two separate drug-eluting stent programs, BioMatrix™ and BioFreedom™, a completely polymer-free drug coated stent.

## About the BioMatrix™ Stent Family

The BioMatrix™ stent system offers the unique combination of an innovative anti□restenotic drug, BA9™, combined with a biodegradable poly□lactic acid polymer (PLA), abluminally coated onto an advanced, highly flexible stent designed for enhanced deliverability.

Biolimus A9 was designed specifically for use in drug-eluting stent systems. In addition to effective immunosuppressive and anti-inflammatory properties, the drug has a higher lipophilic and hydrophobic profile than other limus analogs, enabling rapid absorption of the drug into the targeted tissue and reduced systemic exposure. Precision automated coating ensures the PLA and drug combination is applied only to the abluminal (outer) surface of the stent. The PLA fully degrades into water and carbon dioxide over a six to nine month period as the drug elutes, ultimately leaving in place a biocompatible stent surface.