



## NEWS RELEASE

### Novel Drug-Eluting Stent System for Treatment of Small Vessels Demonstrated Safe and Effective at Eight Months

**Washington DC, USA, 22 September 2010** – Biosensors International Group, Ltd (“Biosensors”, “Company”, BIG:SP) today announced 8-month results from the CARE II Study, which showed that its novel Sparrow® drug-eluting stent system, developed by recently-acquired CardioMind, Inc., is both safe and effective in the treatment of small vessel lesions. These results were presented by the Principal Investigator, Dr. Alexandre Abizaid, Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil, at the 22<sup>nd</sup> annual Transcatheter Cardiovascular Therapeutics (“TCT”) scientific symposium, sponsored by the Cardiovascular Research Foundation.

The Sparrow drug-eluting stent system combines a limus drug in a fully biodegradable polymer matrix with a self-expanding ultra-thin nitinol stent, mounted within a 0.014-inch guidewire delivery system. Due to its unique “stent-on-the-wire” construction, Sparrow has been developed as the smallest profile drug-eluting stent system in the world, 60% smaller than the nearest available coronary stent system. Stent deployment is achieved through a novel release mechanism which utilizes electrochemical dissolution.

The CARE II trial included 138 patients with single *de novo* native coronary artery lesions with a diameter between 2.00 mm and 2.75 mm and lengths up to 20 mm, randomized to receive either the Sparrow limus-eluting stent (DES), Sparrow bare-metal stent equivalent (BMS), or the established MicroDriver® BMS designed for small vessel use. The trial’s primary endpoint was in-stent late loss at eight months. In-stent late loss is defined as the amount of tissue that builds up inside the stent after stent implantation and has long been considered a primary measure of device effectiveness.

Average in-stent late loss in patients treated with the Sparrow DES was 0.29 mm, compared with 0.86 mm in patients treated with the Sparrow BMS, and 0.99 mm in patients treated with the MicroDriver. The difference was statistically significant in both cases (Sparrow DES vs. Sparrow BMS:  $p=0.0001$ ; Sparrow DES vs. MicroDriver:  $p<0.0001$ ). Cumulative MACE results through 12 months showed favorable safety profiles for both the Sparrow DES (6.25%) and the Sparrow BMS (14.3%), while the MicroDriver exhibited a MACE of 26.7% (Sparrow DES vs. MicroDriver:  $p=0.040$ ). A low or reduced MACE (Major Adverse Cardiac Event) rate (a composite of death, myocardial infarction and clinically-indicated target-vessel revascularization) is considered a primary measure of device safety.

**More/...**



In a CARE II sub-study presented separately at TCT by Dr. Teruyoshi Kume, Stanford University Medical Center, intravascular ultrasound (IVUS) was performed on 74 patients (31 receiving the Sparrow DES; 22 receiving the Sparrow BMS and 21 receiving the MicroDriver). IVUS is an advanced catheter-based technology that provides images of the structures in the walls of coronary arteries. The IVUS technique allows physicians to determine and measure the volume and pattern of new tissue growing inside the stent; the higher the increase in stent volume index (SVI) at follow-up, the more effective the stent is in preserving lumen.

Average stent volume index increased 15% in the Sparrow DES-treated patient group and 9% in the Sparrow BMS-treated patient group, compared with a 1% decrease in the MicroDriver-treated group. The difference between the Sparrow DES and Micro-Driver was statistically significant ( $p < 0.01$ ).

“The CARE II eight-month results demonstrate the efficacy and safety of the Sparrow drug-eluting stent system in small coronary arteries, and suggest that its guidewire-like delivery mechanism and less traumatic stent expansion characteristic may improve outcomes in small vessels”, commented Dr. Abizaid.

“These latest results support our strategic decision to acquire CardioMind”, added Jeffrey B. Jump, President & CEO of Biosensors. “We are delighted with the results for both the Sparrow DES and BMS, and intend to pursue development of both options for various clinical applications in small vessels throughout the body”.

**-Ends-**

For further information or to arrange interviews, please contact:

Richard Kenyon: [richard@rkpr.co.uk](mailto:richard@rkpr.co.uk) +44 7831 569940

#### **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 three separate drug-eluting stent programs: BioMatrix™, a drug-eluting stent with abluminal biodegradable polymer; BioFreedom™, a completely polymer-free drug coated stent; and Sparrow®, a novel ultra-low profile “stent on a wire” system.



### **About CRF and TCT**

The Cardiovascular Research Foundation (CRF) is an independent, academically focused non-profit 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 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.

For more information, visit [www.crf.org](http://www.crf.org).

### **About the Sparrow Stent System**

The Sparrow® stent system consists of a 0.014" guidewire-based stent delivery platform: a diameter 60% smaller than any other currently-approved stent. The bare-metal (BMS) version is the first CE Mark approved stent system specifically designed to treat blood vessels smaller than 2.75 mm in diameter, which currently constitute nearly 40 per cent of all stent implants.

### **Forward-Looking Statements**

*Certain statements herein include forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements generally can be identified by the use of forward-looking terminology, such as "may," "will," "expect," "intend," "estimate," "anticipate," "believe," "project" or "continue" or the negative thereof or other similar words. All forward looking statements involve risks and uncertainties, including, but not limited to, customer acceptance and market share gains, competition from companies that have greater financial resources; introduction of new products into the marketplace by competitors; successful product development; dependence on significant customers; the ability to recruit and retain quality employees as Biosensors grows; and economic and political conditions globally. Actual results may differ materially from those discussed in, or implied by, the forward-looking statements. The forward-looking statements speak only as of the date of this release and Biosensors assumes no duty to update them to reflect new, changing or unanticipated events or circumstances.*