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NEWS RELEASE

New Registry Data Confirms Safety of BioMatrix™ DES Family in Over 5000 Patients

Paris, France, 21 May 2013 – New registry data presented today at EuroPCR 2013 has confirmed that the BioMatrix™ drug-eluting stent (DES) family is safe over a 12-month period in a “real-world” population of 5559 patients.

Initiated in March 2008, e-BioMatrix is a prospective, multi-center, observational registry. e-BioMatrix was designed to assess the reproducibility of the long term results from LEADERS, Biosensors’ landmark randomized clinical trial, but in a broader range of centres representing “real world” patients. Data was pooled from two different registries: e-BioMatrix PMS, involving 1106 patients, and e-BioMatrix PMR, involving 4453 patients. The primary endpoint for the registry was MACE (a composite of cardiac death, MI and clinically-indicated TVR) at 12 months.

Of the 5559 patients studied, 5327 patients (96%) were followed up at 12-months. Only 239 (4.3%) were reported as experiencing a primary endpoint event. A very low rate of definite/probable stent thrombosis was observed (0.6%), with most incidences occurring in the first month, while low rates of major bleeding continued out to 12 months, with an incidence of 1.6%.

A broad range of inclusion criteria have ensured that e-BioMatrix is a “real-world” registry: patients just had to be a minimum of 18 years old and have been treated with one of the BioMatrix family of DES (any size, any vessel). Multiple stents were allowed. There were no limitations on the number of treated lesions, vessels, or lesion length.

“The findings of this real-world registry are very important in helping us to learn more about the safety aspects of drug-eluting stents. The very low 12-month rate of definite and probable stent thrombosis confirm that stent thrombosis, while still associated with significant mortality, is no longer a frequent problem”, commented Principle Investigator Dr. Philip Urban, Hôpital de la Tour, Geneva, Switzerland. “Shorter DAPT courses could be expected to be associated with a decreased incidence of major bleeding”.

The registry involved patients treated with either BioMatrix or BioMatrix Flex™. Both DES incorporate Biolimus A9 (BA9™), a highly lipophilic anti-restenotic drug developed by Biosensors specifically for use with stents, together with a Biosensors-designed abluminal biodegradable polymer coating, which fully degrades into carbon dioxide and water after six to nine months as it releases BA9.

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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, received CE Mark Approval in January 2013.

For more information, please visit www.biosensors.com