



NEWS RELEASE

New Data Confirms Safety of BioMatrix™ at One Year

Paris, France, 19 May 2011 – e-BioMatrix post-marketing surveillance (PMS) registry information presented for the first time yesterday at EuroPCR 2011 has confirmed that BioMatrix™, Biosensors' Biolimus A9™-eluting stent system with abluminal biodegradable polymer, is safe over a 12-month period in a “real-world” patient population.

The e-BioMatrix PMS Registry, initiated in March 2008, is a prospective, multi-center, observational registry to assess the outcomes of over 1,000 “real-world” patients across nine European study sites over a five-year period. Enrolment was completed in September 2009. All patients are being comprehensively monitored, including for baseline information, index hospitalization and the patient file until last reported cardiac-related event. The primary endpoint of the registry was MACE (a composite of cardiac death, MI and clinically-driven TVR) at 12 months. Of the 1102 patients studied over this period, 74 (6.7%) experienced a clinical adverse event that could be included in the primary endpoint according to the independent Critical Events Committee. The registry will also examine a range of secondary endpoints, including primary and stent thrombosis over several periods; MACE at intervals up to five years; and death and MI rates for up to five years.

A broad range of inclusion criteria have ensured that e-BioMatrix is a “real-world” registry: patients have had to be at least 18 years old; need treatment with a DES; and have one or more coronary artery stenoses in a native coronary artery or a saphenous bypass graft from 2.25 to 4.0 mm in diameter that can be covered with one or multiple stents. There have been no limitations on the number of treated lesions, vessels, or lesion length.

“These registry findings provide further reassurance on the safety of a biolimus-eluting stent with biodegradable polymer in a wide range of patient types requiring PCI that we routinely see in our daily practice”, commented Principle Investigator Dr. Philip Urban, La Tour Hospital, Geneva, Switzerland. “The results are especially reputable due to the high levels of follow-up that have been achieved, with 97.6 percent at one year.”

A similar registry to e-BioMatrix PMS, the e-BioMatrix Post-Marketing Registry (PMR), was initiated at the same time, involving up to 4,800 patients. The protocols of the two studies are identical, with e-BioMatrix PMR monitoring for reported cardiac-related events only. Enrollment for this second registry is due to be completed by October 2011.

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The PMS registry solely involved patients given the original BioMatrix, whereas the PMR involved patients given both BioMatrix and BioMatrix Flex™. Introduced in May 2010, BioMatrix Flex

incorporates an improved mechanical platform for enhanced deliverability, whilst retaining the Biosensors-developed abluminally-coated biodegradable polymer and Biolimus A9, an anti-restenotic drug developed by Biosensors exclusively for use with drug-eluting stents, as used in the original BioMatrix stent system.

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About Biosensors International

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, we are rapidly emerging as a leader in the global coronary stent market. The forthcoming launch of the Axxess™ self-expanding bifurcation drug-eluting stent and 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 drug-eluting 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 over a six-to-nine-month period 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.