



BIOSENSORS
INTERNATIONAL™

NEWS RELEASE

Large International Registry Confirms the Long-Term Safety and Efficacy of the BioMatrix™ DES Family Observed in LEADERS

Paris, France, 21 May 2015 – The final long-term results of the e-BioMatrix registry, presented at EuroPCR 2015 by Dr. David Hildick-Smith, have confirmed that the BioMatrix™ drug-eluting stent (DES) family is safe and efficacious over a three-year period in a “real-world” population of 5,470 patients.

Initiated in March 2008, e-BioMatrix is a large, prospective, multi-center, single-arm observational registry designed to assess the reproducibility of the excellent safety and efficacy profile of the BioMatrix DES family, as seen in LEADERS, an all-comers randomized clinical trial in “real world” patients, across a broader range of centres over the long term. 5470 patients were enrolled at 57 different centres. 4903 patients (89.6%) were followed-up out to three years. The primary endpoint for the registry was MACE¹ at 12 months. Key secondary endpoints included MACE and stent thrombosis at three years. The rationale of the registry was to determine outcomes of the Biolimus A9™-eluting stent in routine clinical use across a broad selection of centres, with a focus on stent thrombosis and bleeding.

The MACE rate at three years was only 9% (cardiac death 2.1%; MI 3.2%; clinically-indicated TVR 5.6%). The incidence of definite or probable stent thrombosis was 0.9%, and of major bleeding was 2.5%. DAPT² was given to all patients for a minimum of six months, with a recommendation for up to 12 months. ASA³ was given indefinitely.

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

“The very low rate of definite and probable stent thrombosis confirm that this sequela, while still associated with very significant morbidity and mortality, is no longer a frequent problem”, commented Principal 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”.

¹ Major Adverse Cardiac Events (“MACE”) is a composite of cardiac death, nonfatal myocardial infarction (“MI”), or clinically-indicated target vessel revascularization (“TVR”)

² Dual antiplatelet therapy (“DAPT”) is the combination of aspirin and another platelet inhibitor

³ Acetylsalicylic acid (“ASA”) is commonly termed aspirin

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.

###

Media Contact:

Richard Kenyon
+44 7831 569940
r.kenyon@biosensors.com

About Biosensors International Group, Ltd

Biosensors International develops, manufactures and markets innovative medical devices for interventional cardiology and critical care procedures.

With the BioMatrix™ family of drug-eluting stents and the Axxess™ self-expanding bifurcation stent, we are a leader in the global coronary stent market. These stents incorporate Biolimus A9™ (BA9™), an anti-restenotic drug developed specifically for use with stents and patented by Biosensors, together with 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 family features workhorse stent platforms for a broad range of lesions, and Axxess employs a self-expanding stent platform specifically designed for treating bifurcation lesions.

The BioFreedom™ drug-coated stent, which has received CE Mark approval, underscores our technology leadership in the field of coronary stents. BioFreedom is the world's first polymer-free stent with BA9. Chroma™, a cobalt chromium bare-metal stent featuring an innovative platform design, offers exceptional deliverability without compromising radial strength or recoil.

Our drug-eluting balloon range complements the stent portfolio and offers interventional cardiologists a broader range of treatment options.

For more information, please visit www.biosensors.com