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## **NEWS RELEASE**

### **Drug-Eluting Stents Using Biodegradable Polymer Significantly Improve Overall Clinical Outcomes and Reduce Stent Thrombosis**

**26 May 2011** – Drug-eluting stents (DES) using a biodegradable polymer significantly improve overall clinical outcomes and reduce stent thrombosis by 50% compared with DES using a durable polymer over a three-year period. These were the findings from a new independent patient-level meta-analysis involving over 4,000 patients, presented at EuroPCR last week.

The incidence of the composite primary endpoint (cardiac death, MI or clinically-indicated target vessel revascularization) at three years was significantly lower in the biodegradable polymer DES-treated group than in the durable polymer DES-treated group (18.2 % vs. 20.1%:  $p=0.04$ ). Rates of definite stent thrombosis at three years were also significantly lower in the biodegradable polymer DES-treated group than in the durable polymer DES-treated group (1.2% vs. 2.1%:  $p=0.013$ ).

The meta-analysis involved pooling three-year outcome data from the three largest published randomized clinical trials comparing biodegradable polymer DES with durable polymer sirolimus-eluting DES: LEADERS, ISAR-TEST 3 and ISAR-TEST 4. LEADERS used a biolimus-eluting stent with abluminal biodegradable polymer (BioMatrix Flex™); the two ISAR-TEST trials used a sirolimus-eluting stent with biodegradable polymer. In total, 4,062 patients were included: 2,358 treated with a biodegradable polymer DES and 1,704 with a durable polymer sirolimus-eluting DES.

“This new analysis involving the LEADERS data is particularly gratifying”, commented Biosensors CEO Jeffrey B. Jump. “As the company who pioneered the development of biodegradable polymers for drug-eluting stents, we are delighted that our belief in their long-term patient benefits is being borne out.”

The LEADERS study was the first head-to-head randomized trial between two limus-eluting stents, Biosensors’ Biolimus A9™-eluting stent system with abluminal biodegradable polymer and Cordis’ sirolimus-eluting stent system with durable polymer, in an “all-comers” patient population using clinical outcomes. BioMatrix Flex was shown to be non-inferior to Cypher Select in terms of its primary endpoint, MACE (a composite of cardiac death, myocardial infarction, or clinically-indicated target vessel revascularization) at nine months. Three-year results for LEADERS suggested a strong trend towards a significantly lower MACE rate for BioMatrix Flex compared to results at both one and two years.

The BioMatrix Flex stent system offers the unique combination of Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with drug-eluting stents, combined with a biodegradable poly-lactic acid (PLA) polymer abluminally coated onto an advanced, highly flexible stent platform designed for enhanced deliverability. BA9 has the highest lipophilic profile of the common limus drugs, enabling rapid absorption by the tissue and minimizing systemic exposure. The PLA polymer fully degrades into carbon dioxide and water over six to nine months as it releases BA9.

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## Reference

Byrne R. Biodegradable polymer versus durable polymer drug-eluting stents for patients with coronary artery disease: 3 years pooled data from the ISAR-TEST 4, LEADERS and ISAR-TEST 3 randomized trials. Presented as EuroPCR as part of the *Late Breaking Registries and Trial Updates* session, 20 May 2011.

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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.

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