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## NEWS RELEASE

### **Biosensors Launches Larger 4.0 x 9mm Axxess™ Size, utilized in Live Left Main case from Sao Paulo**

**31 October 2013** – Biosensors has launched a new size of Axxess™, its self-expanding dedicated bifurcation drug-eluting stent (DES), at the 25<sup>th</sup> annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation. Axxess 4.0x9 received CE Mark approval in September 2013.

Axxess 4.0x9 has been specifically designed for the safe and effective treatment of bifurcation lesions involving large main branch vessels (from 3.75 to 4.25 millimeters in diameter) and wide bifurcation angulations (up to 120 degrees) which are not suitable to be treated with the current range of Axxess sizes.

“With the addition of Axxess 4.0x9 to our current Axxess portfolio, a broader range of bifurcation lesions will benefit from our specialized technology. The Axxess line offers the unique benefits of a dedicated self-expanding bifurcation stent, and feature the abluminal biodegradable polymer and BA9 drug coating which has made our BioMatrix DES family so successful”, commented Jeffrey B. Jump, President of Biosensors’ Cardiovascular Division.

Axxess 4.0x9 features a self-expanding nitinol (nickel/titanium) stent platform, to accommodate the anatomical diameter mismatch between the proximal large main branch vessel and bifurcation. Its distal flared end has been specifically designed to protect a higher vessel angulation.

The Axxess 4.0x9 stent was used successfully in a live case at TCT for the first time ever on Tuesday. From the Dante Pazzanese Center in Sao Paulo, Brazil, Alexander Abizaid deployed an Axxess 4.0x9 to protect a bifurcation lesion located in the Left Main Artery. The case was presented in the Coronary Theater of TCT.

As with the existing Axxess range, Axxess 4.0x9 is abluminally coated with a biodegradable poly-lactic acid (PLA) polymer that releases Biolimus A9™ (BA9™), an anti-restenotic drug designed by Biosensors specifically for use with DES. Both BA9 and the biodegradable polymer are vital components of the BioMatrix™ DES family, which has more published data to support its safety and efficacy than any other biodegradable polymer DES.

Biosensors received CE Mark approval for the original Axxess range in April 2011, supported by the positive nine-month results from the DIVERGE trial, which were published in the Journal of the American College of Cardiology (JACC) in March 2009. These demonstrated a very low in-stent restenosis rate of 6.4% in the overall bifurcation, and MACE rate of 7.7%, in patients treated with Axxess. Final data from DIVERGE, recently presented at EuroPCR 2013, showed that low levels of both MACE and definite very late stent thrombosis (VLST) were maintained out to five years (21.3% and 1.7% respectively). Axxess is now the only dedicated bifurcation stent with a substantial body of supporting data out to five years.

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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 BioMatrix™ family of drug-eluting stents and the Axxess™ self-expanding bifurcation stent, we are one of the leaders in the global coronary stent market. These stents incorporate Biolimus A9™ (BA9™), an anti-restenotic drug developed and patented by Biosensors specifically for use with stents, 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 now received CE Mark approval, re-establishes our technology leadership in the field of coronary stents. BioFreedom is the world's first polymer-free stent with BA9.

The recent launch of our drug-eluting balloon range complements our stent portfolio and offers interventional cardiologists a broader range of treatment options.

For more information, please visit [www.biosensors.com](http://www.biosensors.com).

## **About The Cardiovascular Research Foundation**

The Cardiovascular Research Foundation (CRF) is an independent, academically focused nonprofit 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. CRF is the sponsor of the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Celebrating its 25th anniversary this year, TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

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