



NEWS RELEASE

Biosensors Announces Enrollment of First Patient in New US Pivotal BioFreedom Trial – “LEADERS FREE II”

Morges, Switzerland, 15 February 2017 – Biosensors International Group, Ltd. (“Biosensors” or the “Company”), a developer, manufacturer and marketer of innovative medical devices, announced today the enrollment of the first patient in LEADERS FREE II, its new BioFreedom Pivotal Study, conducted under an Investigational Device Exemption (IDE), which will include sites in the United States, Canada, Denmark, France Germany, Italy, and the United Kingdom.

The BioFreedom drug-coated stent (DCS) has been implanted to date in over 150,000 patients in more than 40 countries outside the United States. The initiation of LEADERS FREE II marks a key milestone on the path towards obtaining FDA approval for the BioFreedom DCS. Similar to LEADERS FREE, the therapeutic focus of this new US pivotal IDE trial is on patients at high bleeding risk (HBR) who receive an ultra-short dual anti-platelet drug regimen of only 1 month.

Professor Keith Oldroyd performed the first LEADERS FREE II implant earlier this week at the Golden Jubilee National Hospital in Glasgow, Scotland and stated: “We are excited to participate in the European arm of the BioFreedom DCS US Pivotal IDE study and further contribute to building the HBR patient experience for potential expansion of the availability of BioFreedom to American patients.”

The study is conducted under the leadership of Dr. Mitchell W. Krucoff from Duke University, NC, USA, as Principal Investigator and Dr. Philip Urban from La Tour hospital in Geneva, Switzerland, who is the co-Principal Investigator in Europe. The chairman of the Executive Physician Committee is Dr. Marty Leon, Columbia University, New York. Dr. Urban commented: “The results of the LEADERS FREE trial underscore the need to improve treatment of patients at high bleeding risk throughout the world. With the development of the BioFreedom stent, Biosensors has successfully addressed an unmet need for a patient population that had been very largely overlooked.”

About BioFreedom™

BioFreedom™ represents the latest development in Biosensors’ stent technology, featuring a unique micro-structured abluminal surface which permits the controlled release of BA9™ using neither a polymer nor a carrier. BA9™ is a highly lipophilic anti-restenotic drug developed by Biosensors specifically for use with stents and is the world’s first polymer-free active stent releasing BA9.

For more information, please visit www.biosensors.com.

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