NEWS RELEASE

Biosensors Announces Enrollment of the First American Patient in the new US Pivotal BioFreedom Trial – "LEADERS FREE II"

Singapore, 22 March 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 American 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 start of LEADERS FREE II in the United States 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.

Dr. Michael Butler with HH Heart Center performed the first American LEADERS FREE II implant earlier this week at Huntsville Hospital in Huntsville, AL, and said: "We are excited to participate in the BioFreedom DCS US Pivotal IDE study and begin building the HBR patient database in America, which is a significant and relatively unstudied US population."

Dr. Mitchell W. Krucoff from Duke University, NC, USA, the Principle Investigator of the trial stated "We are very excited to finally explore the unmet needs of these high bleeding risk patients, who historically have routinely been excluded from clinical trials of drug eluting stents". Dr. Philip Urban from La Tour hospital in Geneva, Switzerland, is the co-Principal Investigator in Europe. The chairman of the Executive Physician Committee is Dr. Marty Leon, Columbia University, New York, who commented: "Patients at high bleeding risk have not been sufficiently investigated in clinical trials and still present to the cath lab with limited options for safe and effective treatment. The polymer-free BioFreedom stent may help to address this unmet need for our most complex patients."

Enrollment in the LEADERS FREE II study is ongoing, and patients are being recruited at up to 85 clinical sites across Europe and North America.

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