Press Release

Biosensors International Announces Japanese PMDA Approval for BioFreedom™ Ultra and US FDA Approval for BioFreedom™ Biolimus A9™ Coated Polymer Free Coronary Stent Systems

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April 21st, 2022 - Switzerland, Singapore.

Biosensors International Group, Ltd. ("Biosensors" or the "Company"), a developer, manufacturer and supplier of innovative medical devices, is pleased to announce both Japanese PMDA Approval for BioFreedom™ Ultra on 31st March 2022 and also US FDA approval for BioFreedom™ on 14th April 2022.

BioFreedom™ is Biosensors', novel polymer and carrier-free DCS with their proprietary limus drug Biolimus A9™(BA9™). BA9™ is Biosensors' proprietary highly lipophilic anti-restenotic drug, developed specifically for use in coronary vascular applications.

BioFreedom™ gives physicians the opportunity to reduce DAPT to one month in patients post-PCI who are at High Bleeding Risk (HBR).

Biosensors Chief Executive Officer Yu Suhua said, *"We are excited to launch these coronary stent systems and broaden their availability in both Japan and the USA. The proven benefits of this Biolimus A9™ Coated Stent System will help interventional cardiologists to further improve the clinical outcomes for many patients requiring a stent, particularly the High Bleeding Risk patients".*

"Biosensors has been at the forefront of clinical research for the treatment of High Bleeding Risk Patients undergoing PCI since the LEADERS FREE study was presented at TCT and published in the NEJM in 2015. It is great to finally be able to bring these technologies to Japan & the United States, " commented Biosensors Chief Medical Officer, Prof Keith Oldroyd.

The BioFreedom™ stent systems optimize the PCI procedure for High Bleeding Risk (HBR) patients by simplifying stent choice pre-procedure. In the LEADERS FREE trial program, >2,500 HBR[1] patients have been successfully studied and treated with BioFreedom™ and only one month DAPT post procedure followed by single antiplatelet therapy.

The LEADERS FREE II[2] trial enrolled 1203 HBR patients at 66 sites across the USA and Europe, using the same inclusion criteria as the LEADERS FREE[3] randomized trial. LEADERS FREE II[2] is a single arm trial with all patients being treated using the BioFreedom™ DCS, with the BMS arm of LEADERS FREE used as the control arm. The primary safety endpoint of the trial was a composite of cardiac death and myocardial infarction, the primary efficacy endpoint was clinically driven target lesion revascularization. BioFreedom™ was both significantly safer (9.3% versus 12.4%; HR, 0.72 [95% CI, 0.55–0.94]; P=0.0150 for superiority) and significantly more efficacious (7.2% versus 9.2%; HR, 0.72 [95% CI, 0.52–0.98]; P=0.0338 for superiority) than the BMS at 1 year, in this previously understudied North American high bleeding risk patient population.

BioFreedom is our first stent product to be approved in all the key markets globally, as well as many other country specific registrations across the world.

About Biosensors International Group

Biosensors International has over 30 years in designing, manufacturing and marketing innovative medical devices that improve patients' lives, including cardiovascular devices for Percutaneous Coronary Intervention and structural heart devices for Transcatheter Aortic Valve Replacement (TAVR). The company has worldwide operations through a combination of direct sales teams and distribution networks. Biosensors has manufacturing facilities in Germany, Singapore and China. Its products are sold in over 90 countries and regions. It is one of the world's top four companies engaged in the research and development, manufacturing and sales of stents and is a subsidiary of Blue Sail Medical.

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

Forward-Looking Statements

Certain statements herein include forward-looking statements which generally can be identified by the use of forward-looking terminology, such as "may," "will," "expect," "intend," "estimate," "anticipate," "believe," "project" or "continue" or the negative thereof or other similar words. All forward looking statements involve risks and uncertainties, including, but not limited to, customer acceptance and market share gains, competition from companies that have greater financial resources; introduction of new products into the marketplace by competitors; successful product development; dependence on significant customers; the ability to recruit and retain quality employees as Bluesail Medical and Biosensors grow; and economic and political conditions globally. Actual results may differ materially from those discussed in, or implied by, the forward-looking statements. The forward-looking statements speak only as of the date of this release and Bluesail Medical or Biosensors assumes no duty to update them to reflect new, changing or unanticipated events or circumstances.

1. Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk. Urban p. et al. N Engl J Med. 2015;373(21):2038-47. S.Saito. LEADERS FREE Japan study (single BioFreedom DCS arm with 1-month DAPT, compared to BMS arm of LEADERS FREE). ePoster EuroPCR 2017. Global Approach to High Bleeding Risk Patients With Polymer-Free Drug-Coated Coronary Stents: The LF II Study. M.W. Krucoff. Circ Cardiovasc Interv. 2020 Apr;13

2. Global Approach to High Bleeding Risk Patients With Polymer-Free Drug-Coated Coronary Stents: The LF II Study. M.W. Krucoff. Circ Cardiovasc Interv. 2020 Apr;13

3. Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk. Urban p. et al. N Engl J Med. 2015;373(21):2038-47

4. 2-Year Outcomes of High Bleeding Risk Patients After Polymer-Free Drug-Coated Stents. Garot P et al. JACC VOL.6 9, NO.2 , 2017

5. Naber C. Biolimus-A9 polymer-free coated stent in high bleeding risk patients with acute coronary syndrome: a Leaders Free ACS sub-study et al. Eur Heart J 2016;38:961-969