



Press Release

Biosensors International Group Ltd announces CE Mark Approval for Biolimus A9™ Coated Cobalt Chromium Coronary Stent System BioFreedom™ Ultra

16th October 2020 – Biosensors International Group Ltd (Biosensors) has announced the award of a CE Mark for BioFreedom™ Ultra, their new drug-coated coronary stent system. BioFreedom™ Ultra is Biosensors' new, novel thin strut (84µm^β) CoCr polymer and carrier-free Drug Coated Stent with Biosensors' proprietary Biolimus A9™ drug. BA9™ is Biosensors' proprietary highly lipophilic anti-restenotic drug, developed specifically for use in coronary vascular applications.

The BioFreedom™ Ultra stent will optimize the PCI procedure for High Bleeding Risk (HBR) patients by simplifying stent choice pre-procedure based on the LEADERS FREE legacy, enhancing procedure success[™] thanks to the stent design and maximizing outcomes¹ for HBR patients treated with one month DAPT.

The LEADERS FREE III¹ trial enrolled 400 HBR patients at 18 sites, using the same inclusion criteria as the LEADERS FREE² randomized trial. LEADERS FREE III¹ is a single arm trial with all patients being treated using the BioFreedom™ Ultra device. The data was compared to the BioFreedom™ stainless steel drug-coated stent (DCS-StS) and bare metal stent (BMS) groups from LEADERS FREE. The primary safety endpoint of the trial was a composite of cardiac death, myocardial infarction or definite/probable stent thrombosis and the primary efficacy endpoint was clinically driven target lesion revascularization. BioFreedom™ Ultra was non-inferior to the DCS-StS for safety and superior to the BMS for efficacy. Definite or probable stent thrombosis at 1 year in this high bleeding risk population was only 1.0%.

LEADERS FREE III¹ adds to the wealth of safety and efficacy evidence for the use of the BioFreedom™ stent with a one-month duration of DAPT. The trial program LEADERS FREE², LEADERS FREE JAPAN³, LEADERS FREE II⁴ and LEADERS FREE III¹ now includes more than 4,000. LEADERS FREE² showed that the safety and efficacy benefits are maintained at 2 years and the LEADERS FREE ACS⁵ subgroup had a significant reduction in cardiac death.

Biosensors Chief Medical Officer Prof Keith G Oldroyd said, "Biosensors are looking forward to further increasing their interventional cardiovascular portfolio by making another Biolimus A9™ eluting device available for the treatment of patients with coronary artery disease. In addition, and as a testament to our commitment to making new treatment options available to our clinicians and their patients, Biosensors parent company have expanded into the rapidly growing field of structural heart disease intervention through the acquisition of New Valve Technology, the developers of the Allegra™ TAVI device."

About Bluesail Medical

Bluesail Medical Co., Ltd. is a subsidiary of the Bluesail Group and represents its medical industrial arm. Founded in 2002 as a China Mainland-Hong Kong joint venture enterprise (former Shandong Blue Sail Plastic & Rubber Co., Ltd); and successfully listed on the Shenzhen Stock Exchange on April 2, 2010 (stock code 002382). Bluesail Medical has two primary business divisions: protective and sanitary products and cardiovascular and neurovascular devices. Protective and sanitary products are manufactured in Asia and Greater China region. Its sales network covers over 100 different countries and regions in North and South America, Europe, Oceania, and other regions. The products are taking up 22% of the industry's global market share. Since 2012, Bluesail Medical has become the leading enterprise in this industry. The cardiovascular and neurovascular devices business is undertaken by its subsidiary Biosensors which was formed in 1990. Biosensors has production centers in Singapore and China. Its products are sold in over 90 countries and regions. It is the world's top four companies engaged in the research and development, manufacturing and sales of stents business.

For more information about Bluesail Medical, please visit <http://www.bluesail.cn/en/index.php>

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.

BioFreedom, BioFreedom Ultra, Biolimus and BA9 are trademarks or registered trademarks of Biosensors International Group, Ltd.

CAUTION: The law restricts these devices to sale by or on the order of a physician and these products are intended for the use by or under the direction of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Not available in the United States and any other country where applicable health authority product registration has not been obtained.

β Struts for specific stent diameter (small vessel).

Π Main results of the BioFreedom QCA trial. Sabate M. PCR e-course 2020. BioLimus-A9™ coated thin strut stents in High Bleeding Risk patients Oral abstract presentation Eberli R PCR e-course 2020.

1. BioLimus-A9™ coated thin strut stents in High Bleeding Risk patients Oral abstract presentation Eberli R PCR e-course 2020

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

3. S.Saito. LEADERS FREE Japan study (single BioFreedom DCS arm with 1-month DAPT, compared to BMS arm of LEADERS FREE). ePoster EuroPCR 2017.

4. M.W. Krucoff. Pivotal Study of the Biolimus A9™ BioFreedom™ Drug-Coated Stent in High Bleeding Risk Patients: Primary Report. Oral abstract presentation, TCT 2018.

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