NEWS RELEASE

BIOSENSORS ANNOUNCES PRIMARY ENDPOINT DATA RELEASE OF THE NEW US PIVOTAL BIOFREEDOM TRIAL – "LEADERS FREE II"

San Diego 22 September 2018 - Biosensors International Group, Ltd. and BlueSail Medical (Biosensors or the "Company", stock exchange code 002382.SZ), a developer, manufacturer and marketer of innovative medical devices, announced today that primary endpoint results of the LEADERS FREE II trial were presented at the TCT 2018 conference in San Diego, CA, USA. In brief, the outcomes of the new trial confirm that the favorable results gained earlier for the BioFreedom™ stent in the European LEADERS FREE trial are reproducible and generalizable to clinical practice for high-bleeding risk patients in North America.

The trial findings were presented by Dr. Mitchell W. Krucoff, Principal Investigator for LEADERS FREE II, at the 30th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

LEADERS FREE II is the company's new BioFreedom™ Pivotal Trial, conducted under an FDA Investigational Device Exemption (IDE). It is a prospective single-arm study of the BioFreedom™ Biolimus A9™ Drug Coated Stent (DCS) with the therapeutic focus on patients at high risk for bleeding (HBR), who receive an ultra-short dual anti-platelet drug regimen of only 1 month.

This study aims to confirm superior efficacy and non-inferiority safety outcomes of the BioFreedom™ Drug Coated Stent (DCS) in comparison with the historic Gazelle™ Bare Metal Stent arm of the LEADERS FREE study in high bleeding risk patients, who receive only one month of dual anti-platelet therapy. The primary safety endpoint is defined as the composite of cardiac death and myocardial infarction at twelve months; and the primary efficacy endpoint is defined as the incidence of clinically driven target lesion revascularization at 12 months. A total of 1,203 coronary artery disease patients at high bleeding risk received BioFreedom™ stents together with an ultra-short 1-month DAPT regimen. Patient selection, endpoint definitions, core laboratories, and clinical event adjudication rules were kept identical to LEADERS FREE.

At one-year follow-up, the incidence of the primary safety endpoint, a composite of cardiac death and myocardial infarction, was 8.6% for patients receiving BioFreedom™, compared to 12.6% in the bare-metal stent cohort of LEADERS FREE, HR: 0.67 (95% CI = 0.51 – 0.88), *P*=0.0025 for superiority. The primary efficacy endpoint, clinically indicated target lesion revascularization, was reached

by 6.1% of patients receiving BioFreedom™, versus 9.3% of patients in the bare-metal stent control arm from LEADERS FREE, HR 0.63 (95% CI = 0.45 – 0.87), *P*=0.0111 for superiority. The rate of BARC 3-5 major bleeding was 7.0% for BioFreedom™ patients, vs 7.2% in the historic LEADERS FREE bare-metal stent control arm (*P*=0.7970). There was also a close similarity of the event rates for BioFreedom™ patients in the new trial, with BioFreedom™ patients in LEADERS FREE.

Dr. Mitchell W. Krucoff from Duke University, NC, USA, the Principle Investigator of the trial, stated "*LEADERS FREE II reassures the medical community that the favorable findings for the BioFreedom™ Biolimus-A9 drug-coated stent in high bleeding risk patients gained from the European LEADERS FREE trial are not only reproducible but also generalizable to the clinical practice for such patients in North America. -*". Dr Philip Urban from La Tour hospital in Geneva, Switzerland, was the Principal Investigator of the LEADER FREE trial, and is the European co-Principal Investigator for LEADERS FREE II.

Dr. Marty Leon, from Columbia University, New York, the chairman of the Executive Physician Committee, commented: "*The LEADERS FREE II data set constitutes the first robust evidence for safety and efficacy of an active stent with a DAPT regimen of only 1 month for patients at High Bleeding Risk in the United States. It addresses a truly unmet clinical need for these patients.*"

The BioFreedom™ DCS has been implanted to date in over 150,000 patients in more than 40 countries outside the United States. It is not available in the United States or any other country where applicable health authority product registration has not been obtained.

Simon Li, the CEO and Group Chairman of Biosensors International stated: "*The positive data from LEADERS FREE II are a key milestone in our effort to provide the BioFreedom™ Drug-Coated Stent to the American market. We look forward to continuing our FDA submission towards approval for the United States."*

About LEADERS FREE II

The LEADERS FREE II Pivotal Study enrolled 1,203 patients at 66 sites in the United States, Canada, Denmark, France Germany, Italy, and the United Kingdom; with a follow-up phase of 3 years. All patients were prescribed only one month of DAPT, while taking a single anti-platelet drug indefinitely.

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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 lines of products: **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.