



PRESS RELEASE

November 6th 2021. In a Late Breaking Clinical Trials session at TCT, Biosensors has announced the results of the BIO-RISE CHINA study, a Randomized Trial of a Biolimus-Coated Balloon Versus Plain Balloon Angioplasty in Patients with Small Vessel Coronary Artery Disease

MORGES, Switzerland,

Biosensors International Group, Ltd. ("Biosensors" or the "Company"), a developer and manufacturer of innovative medical devices, announced today the results of the **BIO-RISE CHINA study**, sponsored by their sister company JW Medical Systems Ltd. (Shangdong China).

BIO-RISE CHINA is a multi-center, randomized controlled, superiority trial performed in 10 centres across China under the leadership of Prof. Han Yaling, Principal Investigator, and Co-principal Investigators Dr. Guosheng Fu and Dr Yujie Zhou. This first-in-human study assessed the safety and efficacy of a Biolimus A9™ (BA9™) coated balloon (DCB) in patients with small vessel coronary artery disease undergoing PCI.

212 patients were randomized between treatment with the BA9™ coated balloon and plain balloon angioplasty (POBA). The study met its primary end-point by demonstrating a highly statistically significant reduction of late lumen loss with the BA9™ coated balloon compared to POBA at 9 months (**$0.16 \pm 0.29\text{mm}$ vs $0.30 \pm 0.35\text{mm}$ Δ 0.14mm ; 95% CI -0.23 to -0.05 ; $p = 0.001$).**

In addition, late lumen enlargement was 3 times more common with the Biolimus A9™ coated balloon which was also associated with a trend towards improved clinical outcomes at 1 year.

Prof. Han said, "The excellent results of the BioRise™ BA9™ coated balloon (DCB) in this clinical study mean there is now a new therapeutic option for the treatment of small vessel disease in patients undergoing PCI".

This data is the 1st trial in a series of studies Biosensors and JWMS will conduct worldwide, including the REFORM trial (Prospective, Randomized, non-inferiority trial to determine the safety and Efficacy of the Biolimus A9™ Drug Coated Balloon for the treatment of in-stent Restenosis: First-in-Man Trial), a head to head to study comparing the BioRise DCB with the paclitaxel coated Sequent Please DCB across various centers in Europe.

The BioRise™ DCB is coated with the proprietary drug Biolimus A9™ which has demonstrated excellent clinical outcomes when used as a stent coating on both the BioMatrix™ and BioFreedom™ families of coronary stents. BA9™ is a highly lipophilic anti-restenotic drug and was specifically developed by Biosensors International for local drug delivery into vascular tissue. The BioRise™ DCB features a new crystalline form of BA9™ which allows rapid transfer of the drug into the vessel wall.

With this new device, Biosensors continues to invest in their cardiovascular products portfolio and show their commitment to bring innovation to the cardiovascular field. With more than 20 years of experience working with stents, the company started to develop their own balloon portfolio and have already launched their Non-Compliant Balloon (NCB) RISE™NC. The coming launch of the BioRise™ drug coated balloon will bring additional tools designed to improve patients' outcomes.

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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 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.

BioRise is a trademark of Biosensors International Group, Ltd.

The BioRise™ DCB is an investigational device and is not available for sale in any country.

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