



## Press Release

# Biosensors Announces Enrollment of First Patient in New Pivotal Drug Coated Balloon Trial - "REFORM"

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MORGES, Switzerland, 11<sup>th</sup> August 2020

Biosensors International Group, Ltd. ("Biosensors" or the "Company"), a developer, manufacturer and marketer of innovative medical devices, announced today the enrollment of the first patient in **REFORM** a Prospective, **R**andomized, non-inferiority trial to determine the safety and **E**fficacy of the Biolimus A9™ Drug Coated Balloon for the treatment of in-stent **R**estenosis: First-in-**M**an Trial. This trial is targeting CE-mark approval for their new Biolimus A9™ drug coated balloon (DCB) and will include 34 sites in Germany, Italy, Ireland, Spain, the United Kingdom and South Korea.

The trial® is being conducted under the leadership of Prof Robert Byrne, Director of Cardiology, Mater Private Hospital, and Chair of Cardiovascular Research at RCSI University, both in Dublin, Ireland who said, "The REFORM trial is testing the first ever Biolimus A9™ coated balloon and builds on the success of the LEADERS and LEADERS FREE trials which demonstrated the excellent safety and efficacy of Biolimus A9™ eluting coronary stents. If successful, this new drug coated balloon will expand the treatment options for patients with in-stent restenosis undergoing repeat PCI"

PD Dr Tölg enrolled the first REFORM patient at the Segeberger Kliniken GmbH: Heart Center in a 53yr male who had developed ISR >10 years after his initial PCI "After lesion preparation delivery of the BA9™DCB was smooth, with good angiographic result. We are all very excited to see the clinical and angiographic long-term results of this FIM-trial with a novel limus-DCB"

In China, as part of the global registration process, Biosensors have completed the recruitment of a randomized clinical trial of the BA9™DCB in patients with small vessel disease, with first results expected in 2021.

### **About BA9™DCB**

The BA9™DCB represents the latest development in Biosensors balloon technology featuring a BA9™ formulation coated onto the balloon's abluminal surface. BA9™ is Biosensors proprietary highly lipophilic anti-restenotic drug, developed specifically for use in coronary vascular applications.

Until recently, Paclitaxel was used exclusively as the active agent for Drug Coated Balloon (DCB) technology, but this cytotoxic agent has a narrow therapeutic window and is no longer used as a coating on coronary stents.

The REFORM trial, utilising a Biolimus A9™ coated balloon, is particularly timely given the ongoing well-publicised controversy surrounding paclitaxel-coated balloons. Sirolimus eluting balloons are available for coronary applications and sirolimus has a wider therapeutic range than paclitaxel. However, it is absorbed more slowly into the vessel wall and has a short ~ 62-hour half-life\*. Biolimus A9™ has increased lipophilicity and greater tissue retention than sirolimus with a long 20-day in tissue half-life<sup>+</sup>. These properties should make BA9™ particularly well suited to short-term local delivery from an expanded vascular (coronary) balloon into adjacent tissue.

Biosensors new Chief Medical Officer Prof Keith G Oldroyd said, “the interventional cardiology community has been waiting for the introduction of a BiolimusA9™ coated balloon and we are delighted that the REFORM trial has started recruitment, particularly given the challenges of conducting clinical research during the Covid pandemic. Coupled with the ongoing study in China, we hope these trials will confirm the safety and efficacy of this new device and expand the treatment options available to doctors treating patients with coronary heart disease.

### **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](http://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.

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

The BA9™DCB is an investigational device and is not available for sale in any country

Not approved for commercial use and not available for sale, the BA9™DCB is limited to investigational use in Germany, Italy, Spain, UK and South Korea.

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\* Selvamani\_S\_Short-term clinical outcomes after treatment of de novo lesions, ISR and totally occluded stenotic lesions using SCB EuroPCR 2019

^ R. Tzafiri, Poster Presentation EuroPCR 2017

+ Data on file at Biosensors International Group Ltd