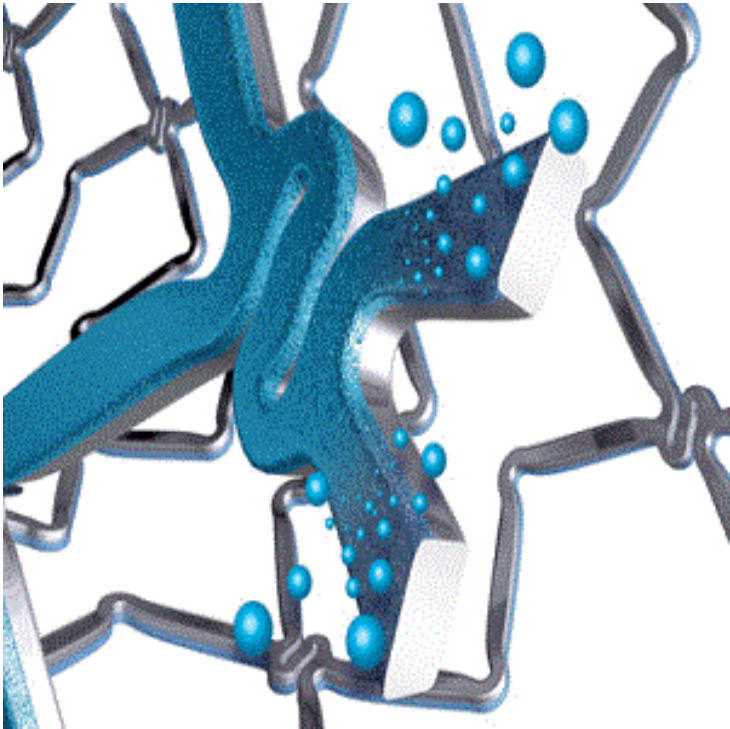


## LEADERS Free Japan Trial Completes Enrollment

11 February 2015 | News | By BioSpectrum Bureau

### LEADERS Free Japan Trial Completes Enrollment



**Singapore:** Biosensors International has announced completion of patient enrollment in LEADERS Free Japan, a trial involving BioFreedom, the company's novel polymer and carrier-free drug-coated stent (DCS).

The trial is focused on patients at high risk of bleeding, and has been designed to confirm that BioFreedom is as safe as a bare-metal stent (BMS) in this patient group, while delivering the anti-restenotic benefit of a drug-eluting stent (DES).

LEADERS Free Japan, a prospective, multi-centre open-label trial, is applying the same patient selection criteria and duration of DAPT as LEADERS Free, but with a BioFreedom treatment arm. The objective of LEADERS Free Japan is to confirm that the safety and efficacy of BioFreedom in Japanese patients is equivalent to that observed in patients of other ethnicities, as assessed in the active (BioFreedom) arm of LEADERS Free. Safety is being measured by the composite of cardiac death, myocardial infarction and definite/probable stent thrombosis at one year, and efficacy by the incidence of clinically driven target lesion revascularization at one year. LEADERS Free Japan has enrolled 140 patients identified as having a high risk of bleeding, from 12 centers across the country. All patients are being prescribed only one month of DAPT.

LEADERS Free has enrolled 2,466 patients from 68 sites across Europe, Asia, Australia, and Canada. Primary endpoint data is expected later this year, and follow up is planned for two years.

BioFreedom represents the latest development in Biosensors' stent technology, featuring an albumin-coating of Biolimus A9 (BA9) without the use of a polymer or other carrier. BA9 is a highly lipophilic anti-restenotic drug specifically for use with

stents. LEADERS Free Japan will be the first clinical trial ever conducted by Biosensors of a BA9-coated stent in Japan. In its First in Man ("FIM") study, treatment with BioFreedom demonstrated excellent 12-month late lumen loss and sustained safety of up to five years, including absence of definite and/or probable stent thrombosis. BioFreedom has received CE Mark approval and is currently available in select markets. Biosensors has also received conditional IDE approval to conduct a US-based clinical trial of BioFreedom, designed to collect additional safety and effectiveness data.