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LEADERS FREE clinical trial demonstrates superior safety, efficacy for BioFreedom compared with bare-metal stent

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Biosensors International Group, Ltd. ("**Biosensors**" or the "**Company**", Bloomberg: BIG SP; Reuters: BIOS.SI; SGX: B20), a developer, manufacturer and marketer of innovative medical devices, announced today that the LEADERS FREE clinical trial demonstrated superior safety and efficacy for BioFreedom™ compared with a bare-metal stent (BMS). The results were presented by Dr. Philip Urban, Principal Investigator for LEADERS FREE, at the 27th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, and simultaneously published in the *New England Journal of Medicine*.

LEADERS FREE is a double-blinded randomized study comparing BioFreedom™—a polymer-free stent coated with Biolimus A9™ (BA9™)—with an uncoated BMS (Gazelle™) in patients at high risk of bleeding undergoing percutaneous coronary intervention (PCI) with only one month of dual anti-platelet therapy (DAPT). The trial assessed the shortest course of DAPT ever used with an active stent.

"Per U.S. and European guidelines, DAPT is typically continued for 6 to 12 months following PCI with drug-coated stents," said Dr. Philip Urban, Director of Interventional Cardiology at La Tour Hospital in Geneva, Switzerland and Principal Investigator for LEADERS FREE. "A one-month course of DAPT is currently only recommended for bare-metal stents, which pose an increased risk for recurrence of stenosis. These results suggest physicians and patients now have an option for an active stent that no longer requires months of DAPT, which may be beneficial for patients at high bleeding risk, who are frequently seen in the cath lab but for whom we still lack optimal management strategies."

Patients enrolled in LEADERS FREE were specifically selected for high bleeding risk and were significantly older (mean 75.7 +/- 7.3 years) and had more co-morbidities, such as kidney failure, cancer, need for major surgery or anticoagulation, than patients included in a typical stent trial.

The new results of LEADERS FREE showed a 50 percent reduction in the need for repeat revascularization, the primary efficacy endpoint: 5.1 percent of patients receiving BioFreedom™ experienced clinically driven target lesion revascularization (TLR) at 390 days versus 9.8 percent of patients receiving a BMS [hazard ratio 0.50 (95% CI 0.37 to 0.69), P<0.001].

Patients in the BioFreedom™ arm also had a 29 percent reduction in risk of cardiac death, myocardial infarction or stent thrombosis: 9.4 percent of BioFreedom™ patients versus 12.9 percent of BMS patients at 390 days [hazard ratio 0.71 (95% CI 0.56 to 0.91) P<0.001 for noninferiority and P=0.005 for superiority]. The difference between groups was statistically highly significant for both the safety and efficacy endpoints.

"Interventional cardiologists around the world have been asking for a better solution to treat patients at high bleeding risk," said Jose Calle, Biosensors International Group CEO. "The evidence provided by LEADERS FREE suggests that BioFreedom™ is a breakthrough technology that offers an optimal option these patients deserve. LEADERS FREE is a first of its kind study combining an active stent with only one month of DAPT. This continues to highlight Biosensors' tradition of introducing evidence-based, pioneering and innovative medical technologies to the global healthcare community."

BioFreedom™ has received CE Mark approval and is currently available in select markets. Biosensors has also received conditional IDE approval to conduct a U.S.-based clinical trial of BioFreedom™, designed to collect additional safety and effectiveness data.

Source:
Biosensors International Group, Ltd.
