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ASIA EDITION

World's First FDA IDE Coronary Patient Treated With a DEB

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The SELUTION SLR (Sustained Limus Release) is a novel sirolimus-eluting balloon that provides a controlled sustained release of drugs, similar to a drug-eluting stent (DES).



MedAlliance has announced enrollment of the first patient in its study of SELUTION SLR™ 014 DEB for the treatment of In-Stent Restenosis (ISR). This is the first DEB accepted by the FDA for its 'Breakthrough Program'. The SELUTION SLR (Sustained Limus Release) is a novel sirolimus eluting balloon that provides a controlled sustained release of drug, similar to a drug-eluting stent (DES).

The objectives of this prospective, randomized, single-blind multicenter study are to demonstrate the safety and efficacy of SELUTION SLR in treatment of ISR with either drug-eluting or bare metal stents (BMS). The study will support the submission for FDA approval.

"This first patient was treated with the investigational device after suffering a DES ISR. We are delighted to be able to offer our patients this promising new technology," commented Professor Pascal Vranckx, Hartcentrum Hasselt, Belgium. "We are excited to participate in a study that validates this novel technology for ISR treatment. SELUTION SLR may provide an additional treatment option for these patients. We very much look forward to the results of this study."

"No coronary drug-eluting balloon has yet been approved in the US, where ISR currently represents 11% of all stent implantations" explained Chairman and CEO Jeffrey B. Jump

SELUTION SLR's technology involves unique MicroReservoirs made from biodegradable polymer intermixed with the anti-restenotic drug sirolimus. These MicroReservoirs provide controlled and *Sustained Limus Release* (SLR) of the drug. Extended release of sirolimus from stents has been demonstrated highly efficacious in both coronary and peripheral vasculatures. MedAlliance's proprietary CAT™ (Cell Adherent Technology) enables the MicroReservoirs to be coated onto balloons and adhered to the vessel lumen when delivered via an angioplasty balloon.

SELUTION SLR was awarded CE Mark Approval for the treatment of peripheral artery disease in February 2020 and for the treatment of coronary arterial disease in May 2020. It is now is available in Europe and all other countries where the CE Mark is recognized. The global market for DEB is estimated to be $2 Billion.