Swiss Enrollment Begins for FLEX Vessel Preparation System: The BELONG Study

- **Actively enrolling up to 150 patients to evaluate lumen patency at one year obtained by arterial vessel preparation with the FLEX Vessel Preparation System prior to conventional endovascular recanalization of the superficial femoral artery (SFA) and popliteal artery (PA).**
- **Dr. Daniel Periard, Angiology, HFR- Hôpital Cantonal Fribourg, is the primary investigator.**
- **More than 12 million people in the U.S. and more than 30 million people worldwide are affected by Peripheral Arterial Disease (PAD)[1].**

Toledo, Ohio, January 16, 2018 - VentureMed Group, Inc., a medical device company that develops and markets innovative interventional vascular solutions, announced enrollment of the first patients in the **BELONG Study – *BEnefit of arterial vessel preparation by LONGitudinal micro-incisions before drug eluting balloon angioplasty of the superficial femoral and popliteal arteries.***

The primary objective of this clinical study is to evaluate lumen patency at twelve months obtained by preparation of vessels with the FLEX Vessel Preparation System prior to conventional endovascular recanalization of the SFA and PA. The FLEX System creates long parallel linear micro-incisions in all plaque morphologies to prepare an ideal vessel environment to facilitate drug-coated balloon angioplasty. The dynamic micro-incision technique of the FLEX system safely facilitates the treatment of difficult, diseased vessels, improving vessel compliance and acute lumen gain.

This prospective, single arm, non-randomized study will enroll up to 150 patients in Switzerland. Patients will exit from the study at the completion of their twelve-month follow-up. The primary investigator and co-investigator are Dr. Daniel Périard, Angiology, and PD Dr. Rolf P Engelberger, Angiology, HFR- Hôpital Cantonal Fribourg, respectively.

“We believe preparing arterial vessels by delivering parallel longitudinal micro-incisions with the FLEX System prior to drug-coated balloon angioplasty has the potential to demonstrate long-term clinical benefits for patients. Our early results have shown that arterial vessel preparation with the FLEX System resulted in improved lumen expansion and vessel compliance after drug-coated balloon angioplasty, with a corresponding reduction in the rate of dissection,” said Dr. Periard. “We look forward to completing the BELONG Study and providing additional clinical evidence to demonstrate and better understand the benefits of vessel preparation with the FLEX System.”

"VentureMed Group is honored that such an accomplished group of interventionalists at an outstanding medical center in Switzerland will be evaluating the FLEX System in a rigorous clinical trial to evaluate long term outcomes." said John Pigott, MD, Founder and Chief Science Officer of VentureMed Group, Jobst Vascular Institute, Promedica Healthcare Systems.

Prof Daniel Hayoz, Head of the Medical Clinic at HFR- Hôpital Cantonal Fribourg, introduced the BELONG Study at the VEITH 45th Annual Symposium in a presentation entitled *Arterial Preparation Improves Outcomes of Drug Coated Balloon Angioplasty*. A poster titled *BEnefit of arterial preparation by LONGitudinal scoring before paclitaxel eluting balloon angioplasty of the superficial femoral and popliteal artery: concept and inclusion status of the swiss multicentric BELONG Study* won Best Poster at the 2018 Union of Vascular Societies of Switzerland UVSS Meeting in Lugano.

Dr. Periard will be presenting "BEnefit of arterial preparation by LONGitudinal scoring before paclitaxel eluting balloon angioplasty of the superficial femoral and popliteal artery (The BELONG Study): recruitment status and early results" at the Leipzig Interventional Course (LINC) on January 22, 2019 in Leipzig, Germany.

VentureMed Group will be exhibiting at the Leipzig Interventional Course (LINC) and the International Symposium on Endovascular Therapy (ISET) in January 2019.

About Peripheral Arterial Disease

Peripheral Arterial Disease (PAD) is a narrowing of the peripheral arteries caused by a hardening of the arteries. More than 12 million people in the US and 30 million people worldwide are affected by PAD which most commonly affects the arteries of the pelvis and legs, including the femoral and popliteal arteries. Left untreated, patients with PAD are five times more at risk for limb amputation.[1]

References:

[1] Stay in Circulation: Campaign Materials: Facts about Peripheral Arterial Disease (P.A.D.). Nhlbi.nih.gov. https://www.nhlbi.nih.gov/health/educational/pad/materials/pad_extfctsht_general.html. Published 2018. Accessed November 5, 2018.

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About VentureMed Group, Inc.

VentureMed Group, Inc. develops and markets innovative interventional vascular medical devices. The FLEX System received 510(k) clearance in the US and a CE Mark for sales in the EU. For more information, visit ***www.FlexVesselPrep.com****.*

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