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Sirtex Medical and BlackSwan Vascular, Inc. announce first patient enrolled in pivotal LAVA Study
LAVA clinical trial underway for potential first FDA-approved liquid embolic system for a peripheral vascular indication

WOBURN, Mass. (April 19, 2021) — Sirtex Medical (Sirtex), a leading manufacturer of targeted liver cancer therapies, and BlackSwan Vascular, Inc. (BlackSwan), a Bay Area-based private company developing groundbreaking therapies in endovascular embolization, announced that the first patient has been enrolled in the LAVA Study to evaluate the safety and effectiveness of the BlackSwan Lava™ liquid embolic system (LES) for the embolic treatment of arterial hemorrhage in the peripheral vasculature.

The LAVA Study, which stands for Liquid Embolization of Arterial Hemorrhages in Peripheral Vasculature, is a prospective, multicenter single-arm study of 113 subjects at 20 investigational sites in the U.S. The first subject has been enrolled at the University of North Carolina School of Medicine in Chapel Hill, North Carolina, where a clinical team successfully treated a patient with a bleeding hypervascular tumor in the liver using the Lava™ LES.

"I was able to experience first-hand the impact of embolization with the Lava™ LES for patient treatment, and I'm very pleased with the result," said Dr. Clayton Commander, Assistant Professor of Radiology at University of North Carolina School of Medicine, who treated the first patient in the LAVA Study. "The system has been well studied in pre-clinical testing, and we are thankful to BlackSwan for leading this clinical program with support from Sirtex that has the potential to bring meaningful advancement to the peripheral vascular (PV) field."

LAVA is led by co-principal investigators Dr. Bulent Arslan at the Rush University Medical Center in Chicago and Dr. Mahmood Razavi at St. Joseph Heart and Vascular Center in Orange, California. The study population will include subjects with active arterial bleeding from the peripheral vasculature.

"We are thrilled for the launch of the LAVA Study, which has the potential to lead to the first FDA-approved liquid embolic for a PV application in the U.S.," said Kevin Smith, Chief Executive Officer of Sirtex. "We are proud to partner with BlackSwan on its clinical journey and look forward to the potential expansion of treatment options in the endovascular field for interventionalists and patients in need."

The LAVA Study will assess the primary safety endpoint of a composite of freedom from 30-day major adverse events and the primary effectiveness endpoint of clinical success, defined as absence of bleeding from the target lesion after embolization with the Lava™ LES, without the need for emergency surgery, re-embolization or other target lesion reinterventions within 30 days of the index procedure.

"Currently there is no liquid embolic agent that is indicated for PV applications in the U.S. Lava™ has key differentiators of optimized radiopacity, availability in two viscosities, reduced preparation time and

controlled delivery, which can enable treatment of a wide array of PV diseases," said Suresh Pai, Chief Executive Officer of BlackSwan. "Moving the LAVA Study forward advances our mission to provide the interventional community with the tools they need that drive safe, effective and value-based treatments. We're eager to discover the findings."

The LAVA Study enrollment follows the strategic collaboration Sirtex and BlackSwan entered in December 2020. Under the collaboration, Sirtex made a significant equity investment in exchange for preferred shares in BlackSwan, as well as an option to purchase the remaining shares of the company at an agreed price.

About BlackSwan Vascular
BlackSwan Vascular, Inc. is a privately held company based in Hayward, CA focused on the development of liquid embolic products tailored for use in peripheral vascular applications. The company was founded in 2017 by Suresh Pai and Celso Bagaoisan of LamaMed, LLC, a med-tech venture studio with a successful track record of capital efficient product development from concept to commercialization, and Sanjay Shrivastava of U.S. Vascular, LLC, a privately held company engaged in developing and commercializing vascular medical devices.

About Sirtex
Sirtex is a global healthcare business with offices in the U.S., Australia, Europe and Asia, working to improve outcomes in people with cancer. Sirtex's current lead product is a targeted radiation therapy for liver cancer called SIR-Spheres® Y-90 resin microspheres. More than 100,000 doses have been supplied to treat patients with liver cancer at more than 1,400 medical centers in over 50 countries. For more information, visit www.sirtex.com. SIR-Spheres® is a registered trademark of Sirtex SIR-Spheres Pty Ltd.

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