Micro Medical Solutions Receives FDA IDE Approval for Pivotal Clinical Trial of MicroStent

Lead Author: none given

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Micro Medical Solutions

WILMINGTON, Mass., June 24, 2019 — Micro Medical Solutions (MMS)** announced today that it has received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA). IDE approval allows MMS to initiate a U.S. pivotal clinical trial to evaluate MicroStent’s** safety and efficacy. MicroStent has already obtained CE Mark approval for use in the EU.

MicroStent is a vascular stent specifically designed to achieve and maintain vessel patency and improve blood flow in order to reduce below-the-knee amputations for patients with critical limb ischemia (CLI) resulting from peripheral artery disease (PAD). Last fall, MMS completed a 3-center, 15-patient feasibility study of MicroStent in which MicroStent met all primary endpoints for both safety and efficacy.

The study demonstrated in the device-related per protocol population that 90.9% of subjects had primary patency at 6 months post-index procedure, which is a composite of 90.9% subjects with freedom from occlusion, while 100% were free from a clinically driven target lesion revascularization. The study also showed 100% of subjects had freedom from the primary safety endpoint at 6 months post-index procedure, which is a composite of 100.0% subjects with freedom from death and 100% freedom from MALE (major adverse limb events) in the same population.

The FDA has granted IDE status based on these outcomes. MMS will immediately initiate the process to begin enrollment in the clinical trial, called the STAND study (A Clinical Evaluation of the MicroStent Peripheral Vascular Stent in subjects with Arterial Disease Below the Knee).

“Because CLI represents the most severe clinical manifestation of PAD, we are excited to have a device that offers physicians multiple access points, as well as a trial that allows for re-intervention to effectively treat and lessen the impending limb and tissue loss,” said the study’s lead investigator, Dr. Robert E. Beasley of Mount Sinai Medical Center in Miami Beach, Florida.

Dr. Jihad A. Mustapha, an interventional cardiologist specializing in minimally invasive, non-surgical therapy for heart and peripheral vascular disease at Advanced Cardiac & Vascular Centers for Amputation Prevention in Grand Rapids, Michigan, added, “For patients with PAD, the risk of amputation is high, particularly if they have CLI. Amputees face decreased quality of life, as well as amputation-associated mortality. I look forward to the clinical trial for MicroStent because we need new solutions to help save CLI patients from amputation.”

“IDE approval for the pivotal clinical study of MicroStent is an encouraging step forward in our efforts to bring this technology to patients with CLI in the U.S. who face the potential for amputation,” Micro Medical Solutions CEO, Gregory Sullivan said. “MMS developed the MicroStent platform in response to these patients’ needs, and we are excited to move closer to putting MicroStent in the hands of U.S. interventionalists treating CLI.”

The STAND trial (Clinical Evaluation of the MicroStent Peripheral Vascular Stent in Subjects with Arterial Disease Below the Knee) is a randomized, multicenter pivotal clinical study of the MicroStent device. This important step toward FDA approval of MicroStent will include approximately 200 patients at a maximum of 25 sites across the U.S.

About Critical Limb Ischemia
Peripheral artery disease and critical limb ischemia (CLI) affect millions each year. It has been estimated that nearly 25% of CLI patients will undergo major amputation,¹ and amputations due to
CLI continue to escalate. \(^2\) For more information on CLI, visit www.micromedicalsolutions.net.


About Micro Medical Solutions
Micro Medical Solutions is on a mission to provide solutions to some of the most pressing unmet needs in microvascular intervention by helping to significantly reduce the rate of amputations, improve clinical outcomes and patient quality of life, and minimize the financial and human costs associated with the treatment of peripheral artery disease and critical limb ischemia. For more about Micro Medical Solutions, visit www.micromedicalsolutions.net.

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