Alucent BIOMEDICAL

Press Release

Alucent Biomedical Announces FDA Approval to Proceed with Natural Vascular Scaffolding Clinical Trial

SALT LAKE CITY – Jan. 9, 2020 – Alucent Biomedical Inc. has received U.S. Food and Drug Administration approval to proceed with a Phase 1 clinical trial to evaluate the safety and efficacy of its revolutionary Natural Vascular Scaffolding (NVS) technology. The therapy is designed to treat peripheral artery disease (PAD) of the lower extremities, a painful and debilitating condition affecting over 200 million people worldwide.

The Alucent NVS Vessel Restoration system with Photoactivated Linking combines standard angioplasty with linking of the structural proteins in the wall of a blood vessel. The intervention is designed to deliver immediate restoration of the vessel's lumen and sustained improvement of blood flow, without the introduction of a foreign implant, such as a metallic stent, into the patient's body. Because there is no rigid foreign material, the arterial wall has the potential to retain its natural functionality and flexibility, and avoid the complications of permanent stents. Alucent NVS photoactivated linking is also designed to mitigate the well-known adverse effects of angioplasty, such as vessel recoil. Sustained, improved blood flow is expected to result in pain relief, limb preservation and an improved quality of life for patients.

"FDA approval to commence human clinical testing allows us to move this revolutionary therapy into PAD patients, many of whom are in acute need of a better and more durable alternative to currently available treatments," said Myles Greenberg, M.D., Alucent's CEO.

Preclinical testing of NVS in animal studies has shown acute and long-term safety and patency without the pro-inflammatory and mechanical risks of placing a rigid foreign implant into the blood vessel.

"Alucent NVS is a novel and disruptive medical therapy that may promote better clinical outcomes in patients with symptomatic femoropopliteal atherosclerosis without the use of a metallic implant. Moreover, given the novel nature of this therapy, which in animal models was able to restore vessel wall architecture, it has the potential to dramatically improve quality of life in patients with peripheral arterial disease", says Krishna Rocha-Singh, M.D., FACC, chief scientific officer at HSHS St John's Prairie Heart Institute in Springfield, IL, and chief medical advisor of Alucent Biomedical.

Enrollment for the Phase 1 clinical trial is expected to begin in Q1 2020. Up to 15 subjects will be enrolled across five research sites, including the Cardiovascular Institute of the South in Houma, La., and the Wellmont Hollston Valley Medical Center in Kingsport, Tenn.

About Alucent Biomedical
Founded in 2017, Alucent Biomedical is a privately held biomedical company dedicated to developing and commercializing its breakthrough Natural Vascular Scaffolding (NVS) technology for the treatment of vascular disease. NVS uses photoactivated protein linking of the vessel's native structural proteins to open vessels and keep them open – without the use of permanent implants. Alucent Biomedical was founded by the Avera Research Institute, part of the multistate Avera Health System, in 2017. For more information, visit alucentbiomedical.com.

MEDIA CONTACT: Diana Soltesz
Nobles Global Communications
diana@noblesgc.com • 818-618-5634