Alucent BIOMEDICAL

Press Release

Innovation Spotlight: Alucent Biomedical | Can we Make 'Stents' Obsolete?

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Interview by Kym McNicholas, The Way To My Heart

As part of our ongoing Vascular Innovation Series in conjunction with The Way to My Heart, journalist Kym McNicholas interviewed Alucent Biomedical CEO, Dr. Myles Greenberg.

Treatment for vascular blockages is getting a much-needed innovation makeover. Alucent's first area of focus is one the most debilitating vascular diseases –peripheral artery disease, plaque build-up in mainly the legs that narrows blood flow causing excruciating pain. Their hope is to ultimately make the well-known 'stent,' currently used to maintain diseased arteries and veins open, obsolete. Stents can sometimes trigger an inflammatory response leading to more build-up in the artery that blocks flow, compromising their lasting impact. Alucent has designed a more natural option to keep the vessel open: technology activated by a deep blue light that creates a scaffolding inside the vessel. In this interview, CEO Dr. Myles Greenberg describes this exciting new technology and the path to patients, with first-in-human clinical trials launching earlier this year.

What is the story behind the technology? Where did it originate?

The AlucentNVS technology was developed under Avera Health, a five-state, nonprofit health system based in Sioux Falls, S.D. Ron Utecht, a former chemistry professor at South Dakota University, led the therapy's development at Avera, working under the Alumend organization, a technology development subsidiary of Avera Health.

What need does it address?

Peripheral artery disease (PAD) is a debilitating, painful and highly prevalent condition in which arteries outside of the heart, frequently in the lower extremities, become narrowed or blocked due to a build-up of plaque, restricting blood flow to the limb or extremity. Affecting eight to 10 million people in the U.S., and 200 million people worldwide[i], PAD's primary risk factors include obesity, high cholesterol, hypertension, diabetes and tobacco use. The prevalence of PAD rises with age, from five percent at age 60 to 20 percent at age 80.

The most commonly used treatments for PAD include angioplasty, stenting, and paclitaxel-coated devices. However, a significant unmet need still exists for the treatment of PAD, as a number of studies have shown that balloon angioplasty has a failure rate of more than 60 percent at twelve months. This is especially true in the case of calcified or long lesions as well as those treatments complicated by arterial dissection. Many patients end up with limb amputations due to failures of current therapies.

What is the potential for patient impact?

AlucentNVS 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 may result in pain relief, limb preservation, a reduction in reinterventions and an improved quality of life for patients.

If you have a specific example of how your technology has helped a patient or testimonials and are able to share, we would love to include it. – N/A at this time.

Where is the technology in development and what is next for the company?

We began enrolling patients in our ACTIVATE I first-in-human trial in May of 2020. The phase I study is evaluating the safety and efficacy of the AlucentNVS technology in patients with PAD of the lower extremities. The first patients were enrolled at Ballad Health Wellmont Hospital Valley Medical Center in Kingsport, Tenn. Up to 15 patients will be enrolled across five clinical sites.

Our ACTIVATE I trial is about one-third enrolled and we expect it to be completed. by the end of the year. It's a prospective, nonrandomized, multicenter, open-label study that will assess the safety, pharmacokinetics and preliminary efficacy in applying AlucentNVS therapy to de novo lesions in the superficial femoral artery (SFA) and the proximal popliteal artery (PPA) during percutaneous transluminal angioplasty in patients with claudication due to obstructive SFA and PPA atherosclerosis.

The primary endpoints are freedom from all-cause mortality, target limb major amputation and target lesion revascularization and AlucentNVS drug plasma concentrations.

We are also in the process of finalizing the protocol for a larger IDE clinical trial with our intended commercial AlucentNVS system. The study is slated to start in mid-2021 and will include up to 100 subjects at up to 15 U.S. medical centers.

That study will also focus on lower-extremity PAD, with patients followed for 12 months.

Anything else we should know?

We are excited to have just closed $35 million Series B financing round led by a large multinational strategic investor and joined by another new investor, Fresenius Medical Care Ventures. The funding will be used to support the completion our two clinical trials.

We thank all of our investors for their enthusiasm and unwavering support. The Series B funding will allow us to continue to explore the potential of AlucentNVS to improve long-term clinical outcomes and enhanced quality of life for those with vascular disease.

For an in-depth look into Alucent shares more with Emmy Award-winning Journalist Kym McNicholas in this video interview below:

Watch Here!

i Caradu, Caroline et al. Systematic review and updated meta-analysis of the use of drug-coated balloon angioplasty versus plain old balloon angioplasty for femoropopliteal arterial disease. Journal of Vascular Surgery. Volume 70, Issue 3, 981-995.e10.