Efemoral Medical Announces Successful First-In-Human Use of The Efemoral™ Vascular Scaffold System

New bioresorbable treatment option aims to improve outcomes for patients suffering from peripheral arterial disease

LOS ALTOS, CA – December 14th, 2020 – Efemoral Medical, developer of advanced interventional bioresorbable therapies, today announced the first-in-human (FIH) use of the company's Efemoral™ Vascular Scaffold System (EVSS) with FlexStep™ Technology in the EFEMORAL I FIH clinical study. Designed to address a broad range of patients, this innovative technology offers a new approach to treat peripheral arterial disease (PAD), alleviate symptoms, and avoid reintervention for a historically challenging patient population.

The EVSS with FlexStep Technology was specifically developed to address the anatomical challenges and complex biomechanics of patients with symptomatic PAD. The patented FlexStep Technology, through the use of inter-scaffold spaces, combines flexibility with support to accommodate tortuosity and skeletal movement, while the balloon-expandable deployment system easily opens vessels and sustains healthy blood flow. The novel bioresorbable scaffold with long-term sirolimus elution aims to deliver therapeutic benefits across all lesion lengths and morphologies, prevent restenosis, and maintain patency while leaving no permanent implant behind.

"I am pleased to enroll the first patient in the EFEMORAL I study," commented Dr. Andrew Holden, Principal Investigator and Director of Interventional Radiology at Auckland City Hospital in New Zealand. "The treatment of peripheral arterial disease remains challenging as current therapies are often only temporarily effective. The system was easy to use and its unique design allows the artery to bend freely. This device has the potential to be the first safe and effective bioresorbable stent for femoro-popliteal disease."

PAD, also known as "poor circulation" or "hardening of the arteries," is a global plague. Worldwide, it affects approximately 202 million people[1], including over 8.5 million people in the United States[2]. If left untreated, PAD can lead to severe disability and extremity amputation. Effectiveness of current interventional treatment remains limited with up to 50% of conventional endovascular procedures complicated by failure or recurrence within the first year.[3]

"I would like to thank Dr. Holden and the entire team for their efforts and collaboration in achieving this significant milestone," said Christopher Haig, Co-Founder and CEO of Efemoral Medical. "Efemoral celebrates our next step as a clinical-stage company, and while still early in the development process, we are excited about the potential of our technology to offer a durable clinical solution to patients and physicians."

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6377796/

[2] https://www.heart.org/en/health-topics/peripheral-artery-disease/pad-toolkit

[3] https://www.researchgate.net/publication/260118801_Nitinol_Self-Expanding_Stents_vs_Balloon_Angioplasty_for_Very_Long_Femoropopliteal_Lesions

About Efemoral Medical, Inc.

Efemoral Medical, Inc. is developing next-generation bioresorbable solutions to treat patients with vascular disease. The company's initial product, the Efemoral Vascular Scaffold System (EVSS) with FlexStep Technology, is designed to offer a dedicated strategy for PAD interventions. The Efemoral Vascular Scaffold System (EVSS) is an OUS Investigational Device only.
To learn more, please visit efemoralmedical.com.

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