Efemoral Medical Releases Positive Long-Term Results from EFEMORAL I

Initial 20 Patients Enrolled in the First-in-Human Trial Had a 0% Rate of Reintervention.

LOS ALTOS, CA – April 23, 2025 – The initial long-term results from EFEMORAL I were presented today by Principal Investigator Prof. Andrew Holden (Auckland City Hospital, Auckland, New Zealand) at the Charing Cross Symposium in London, UK. EFEMORAL I is a first-in-human clinical trial evaluating the performance of the Efemoral Vascular Scaffold System (EVSS) for the treatment of patients suffering symptomatic peripheral arterial occlusive disease from atherosclerosis of the femoropopliteal artery. The results from the initial 20 patients enrolled across four sites in Australia and New Zealand were presented. The key findings included:

- Mean lesion length of 5.1 ± 2.0 cm
- 0 ± 15% post-procedure residual stenosis
- 0% acute/subacute thrombosis
- 0.41 ± 1.0 mm late lumen loss at 6 months (angiographic subset, n=10)
- 4.74 ± 0.86 mm mean minimal lumen diameter at 6 months (angiographic subset, n=10)
- Median follow-up of 2 years
- 100% primary patency at 3 years
- 100% freedom from target lesion revascularization at 3 years
- Sustained improvement in clinical outcome and walking tolerance at 3 years

“In this first patient experience, I found the EVSS to be simple to deploy and strong enough so that I can fully restore the original arterial lumen diameter at the time of the procedure. Furthermore, it elutes a relatively high dose of Sirolimus over several months, leading to excellent long-term outcomes, all without the need for a permanent implant,” stated Prof. Holden. “I’m looking forward to expanding my use of this device in more patients with more complex lesions.”

The EVSS offers a new approach to treating peripheral arterial disease (PAD) by addressing the specific anatomical challenges and complex biomechanics of patients with athero-occlusive disease in the leg. Through the use of inter-scaffold spaces, the patented FlexStep Technology 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 restore normal vessel diameter at the time of the procedure, deliver therapeutic benefits across all lesion lengths and morphologies, prevent restenosis, and maintain patency while leaving no permanent implant behind.

"Compared to balloon angioplasty or self-expanding nitinol stents that are commonly used to treat patients with narrowing in their femoropopliteal artery, balloon expandable scaffolds with high radial strength, such as the EVSS, allow for a more complete expansion of the vessel at the index procedure,” said Lewis B. Schwartz, MD, Co-Founder and CMO of Efemoral Medical. “A low residual stenosis means the lumen of the vessel has been restored to its original diameter and is a predictor of favorable long-

term outcomes. The 0% post-procedure residual stenosis in EFEMORAL I is the lowest ever reported for a femoropopliteal trial, while the mean minimal lumen diameter of 4.74 mm at 6 months is the highest ever reported."

" The EVSS represents a new paradigm in peripheral interventions," said Christopher Haig, Co-Founder and CEO of Efemoral Medical. "It's easy to deploy, has high radial strength, can be made in longer lengths, and offers the promise of durable outcomes without the need for a permanent implant."

About Peripheral Arterial Disease (PAD)

PAD, also known as "poor circulation" or "hardening of the arteries," is a global plague. Worldwide, it affects approximately 200 million people[1], including an estimated 20 million people in the United States[2]. Left untreated, PAD can lead to severe disability and extremity amputation. The 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]

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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[2] Yost, **The True Prevalence of PAD and the Economics of Major Amputation** Endovascular Today, May 2021
[3] https://www.researchgate.net/publication/260118801_Nitinol_Self-Expanding_Stents_vs_Balloon_Angioplasty_for_Very_Long_Femoropopliteal_Lesions