VERIGRAFT Achieves Regulatory Milestone in CVI Trial

Regulatory green light granted as VERIGRAFT completes recruitment in Phase I/II trial of its personalised vein graft for chronic venous insufficiency.


Petter Björquist, CEO, VERIGRAFT

GOTHENBURG, SWEDEN, May 27, 2025 /EINPresswire.com/ -- VERIGRAFT AB, a Swedish biotechnology company specialising in personalised tissue-engineered transplants, today announces a major regulatory milestone in the clinical development of its lead product, the Personalized Tissue Engineered Vein (P-TEV) for the treatment of Chronic Venous Insufficiency (CVI).

The Spanish Medicines Agency (AEMPS) has approved a formal amendment to the company's ongoing Phase I/II clinical trial (TECVI-1), confirming that patient recruitment has been successfully completed and acknowledging the strong safety profile of the P-TEV technology. The regulatory green light allows VERIGRAFT to officially conclude the recruitment phase and begin preparations for late-stage clinical development.

> "This is a critical moment for VERIGRAFT and for the millions of patients suffering from chronic venous insufficiency without effective long-term treatment options."
>
> *Dr Petter Björquist, CEO of VERIGRAFT*

Severe CVI affects more than four million people in the US and Europe alone, often resulting in chronic pain, leg ulcers, immobility, and significantly reduced quality of life. VERIGRAFT's P-TEV, a biologically personalised vascular graft created from decellularised human veins seeded with a patient's own cells, represents a potential curative option for patients with severe CVI.

The approval, granted on May 14, 2025, is based on interim safety assessments that demonstrate excellent biocompatibility and no significant adverse

events related to the product. The trial, which includes patients in Spain, has been conducted in close collaboration with leading vascular surgeons and academic medical centres.

This milestone further strengthens VERIGRAFT's position in the field of Advanced Therapy Medicinal Products (ATMPs) and regenerative medicine, and aligns with the company's broader strategy to advance standardised, GMP-compliant tissue therapies for unmet medical needs.

As the company prepares for the next development phase, including regulatory interactions and study design for pivotal efficacy trials, engagement with strategic partners and investors will be a key focus.

About VERIGRAFT
VERIGRAFT is a Swedish biotech company developing GMP-compliant, personalised tissue theraputics (ATMPs). Its lead product, the P-TEV, is undergoing clinical trials for Chronic Venous Insufficiency. The platform combines patient-derived cells with decellularised human tissue to deliver safe, individualised vascular grafts. The company has a strategically focused R&D pipeline of personalized tissues, targeting areas such as cardiovascular and neuronal disease and is led by a team of experienced scientists and entrepreneurs, backed by investors from Europe, Asia and the US. www.verigraft.com

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