

Veinsound announces the successful launch of EASY-VEIN NT, a first-in-human investigation of AI-focused ultrasound for the treatment of chronic venous insufficiency and varicose veins

Study authorized under the EU Medical Device Regulation (EU) 2017/745.

First procedures completed as planned, in an office setting and without anesthesia.

Study completion is expected in Q1-2027.

Lyon, France – September 16, 2026 - Veinsound, an AI-Medtech company specializing in breakthrough AI-Focused Ultrasound (AIFU) treatments for chronic venous insufficiency (CVI) and varicose veins, today announced the successful launch of its First-in-Human (FIH) clinical trial EASY-VEIN NT. The study is conducted at leading vascular center in Europe, with the favorable opinion of the National Bioethics Committee and the authorization of the Romanian National Agency for Medicines and Medical Devices (ANMDDMR). To date, the first four patients have been treated and early positive clinical observations reinforce Veinsound's potential to bring a disruptive solution for venous diseases. *"Treating the first patients marks a significant milestone in our development. This helps assess whether AIFU can treat CVI and the great saphenous vein, in an office setting, without heat, needles or catheters. The value proposition we have championed from the start —a simple, fast, anesthesia-free and in-office treatment —is now becoming a clinical reality. I warmly thank the patients and the investigators who make this study possible,"* says **Dr. Thomas CHARREL**, Chief Executive Officer of Veinsound.

GROUNDBREAKING CLINICAL RESULTS

To date, the principal investigator has treated four patients using AIFU system. *"As a clinician, I'm always looking for innovations that improve patient outcomes while simplifying procedures. The AIFU device delivers on both fronts. Precision and simplicity observed in the first treated patients are impressive and highly encouraging. I'm confident this technology will set a new standard in venous care"* declares **Dr. Zoltan GALAJDA**, Professor of cardiovascular surgery and principal investigator.



AIFU procedure at Sanconfind Medical Center, Câmpina, Romania, on Sept-8, 2026.

Following completion of the safety cohort, the first patients in the performance group have been treated along their Great Saphenous Vein (GSV) in less than 12 minutes without anesthesia. *"The first patients treated with AIFU technology showed promising results, with smooth and complication-free procedures. Preliminary observations at 1 week post-treatment - including vein occlusion and vein-wall remodeling - are very encouraging. If these preliminary results are confirmed in this study, AIFU will be a game-changer for physicians and patients who want effective treatment without injection, surgery or downtime"* completes **Dr. René MILLERET**, Vascular Surgeon and Co-Investigator.

Early positive outcomes highlight the potential to offer a safe, rapid, and highly accessible technic in the near future. *"The launch of our FIH trial and these early positive observations represent a major milestone for Veinsound and for patients suffering from CVI. Our mission has always been to democratize access to high-efficacy, non-invasive treatments, and these results confirm that we are on the right path. With the support of our clinical partners and the dedication of our team, we're one step closer to bringing this innovative technology to market and treating hundreds of millions of patients worldwide"* adds **Dr. Stéphane LAVALLEE**, Chairman of the Board.

ABOUT CHRONIC VENOUS INSUFFICIENCY

According to the World Health Organization (WHO) and the European Society for Vascular Surgery (ESVS), CVI affects up to 20% of the population worldwide, with current treatments often requiring invasive procedures, anesthesia, or lengthy procedures and recovery times. Veinsound's non-invasive, office-based AIFU technology addresses these limitations by offering:

- **No incisions, needles, or catheters:** Reduces infection risks and patient discomfort.
- **No thermal damage:** Preserves surrounding tissues and avoids anesthesia,
- **Rapid procedure:** Treatment completed in less than 12 minutes, with immediate discharge.
- **Cost-effective:** Reduces healthcare costs by eliminating the need for operating rooms.

ABOUT VEINSOUND

Veinsound is an AI-Medtech company founded by a team of experts in vascular and AI-Focused Ultrasound (AIFU) technology. Based on strong academic research (LabTAU, INSERM, France), the company has developed a robust IP portfolio (5 patent families) for the treatment of CVI and other vascular conditions. Veinsound has received €3.7M in funding from investors and non-dilutive grants, including support from 50 physician-investors who believe in its transformative potential. Veinsound could disrupt a significant portion of the global venous disease market, estimated at €10 billion.

MEDIA CONTACTS

Thomas CHARREL
thomasc@veinsound.com
[+33 675 322 238](tel:+33675322238)
www.veinsound.com

Benoit MARTIN
benoit@digiobs.com
[+33 666 027 710](tel:+33666027710)
www.digiobs.com

ABOUT THIS ANNOUNCEMENT

This press release contains forward-looking statements based on current clinical observations. No conclusions can be drawn on safety or efficacy until the trial is completed and data are peer-reviewed. Actual and future results may vary, including clinical trial outcomes, regulatory approvals, and market conditions. The device of Veinsound company is an investigational product under clinical evaluation in Europe only. This device is not commercially available and has not received CE-Mark or FDA clearance.