

16 December 2024

AOTI, INC. (the "Company" or "Group" or "AOTI")

Patient Enrolment Commences for VLU Clinical Trial of TWO₂ therapy

AOTI, INC. (AIM: AOTI), a medical technology group focussed on the durable healing of wounds and prevention of amputations, has commenced enrolling patients in the USA for a multi-national, prospective, randomized, double-blinded, placebo-controlled trial to evaluate Topical Wound Oxygen (TWO₂) therapy in the treatment of chronic Venous Leg Ulcers (VLUs) (the **VaLUe** trial). This 212 patient study is intended to demonstrate the complete durable healing efficacy of TWO₂ for this ulcer type using a similar study design to the award-winning Frykberg et al. clinical trial for diabetic foot ulcers.¹

VLUs are painful, chronic leg sores caused by venous hypertension and resultant tissue swelling (edema) and damage. They are the leading cause of wounds on the leg and represent a significant burden on patients, caregivers, healthcare systems and related economies. VLUs afflict approximately 2% of the world's population, with 60% progressing onto a chronic nonhealing wound.² VLUs have extremely high rates of recidivism, with the recurrence of the ulcers that heal reported as high as 75%. With this cycle of poor healing and re-ulceration, patients can suffer for decades leading to poor quality of life and a significant financial burden on the healthcare systems.³

AOTI's multi-modality TWO₂ therapy is the only topical oxygen approach that combines both cyclical non-contact compression with higher partial pressure oxygen delivery around the limb and wound. This cyclical pressure pattern mimics a healthy body's calf pump, as well as the pressure applied by conventional compression dressing (CCD), the only currently accepted VLU treatment option. Additionally, as TWO₂ therapy can be applied by the patient at home over their existing CCDs, it does not require additional health resources, which greatly improves patient compliance and access to care.

An earlier 132 patient, vascular surgeon-led, controlled cohort study demonstrated the significant durable healing potential of TWO₂ therapy in refractory VLU when compared to CCD, reporting a 76% vs 46% complete healing efficacy at 12 weeks (p <0.0001), and substantial reductions in VLU recurrence over three years, 6% vs 47% (p <0.0001).⁴ A recent late-breaking abstract, presented at the prestigious VEITH symposium, which explored the real-world efficacy of TWO₂ therapy in treating 2,088 patients with wounds of varying etiologies and an average of 13.5 months duration, showed overall that 76% reached complete healing within an average of 4.4 months of treatment with TWO₂, with a subset of 193 refractory VLUs reaching 72% complete healing within an average of 4.6 months of TWO₂ therapy, and demonstrating only 0.5% recurrence.⁵

Dr. Mike Griffiths, Chief Executive Officer and President of AOTI, INC., commented: *"We know from earlier studies and our treatment of hundreds of VLU patients at home daily that TWO₂ therapy has dramatic durable healing benefits in VLUs, which are estimated to afflict as many 6 million people in the USA alone. VLU patients are sometimes forgotten due to limited effective treatment options, but the disease inflicts enormous pain and suffering, in many cases for decades, with considerable associated economic burden. TWO₂ has outstanding evidence to support its use to heal Diabetic Foot Ulcers (DFU) more durably and the VaLUe study which will be conducted by leading vascular surgeons from across the USA and Europe, is designed to establish a similar level of evidence in healing VLUs."*

1. Frykberg et al., A multinational, multi-center, randomized, double-blinded, placebo-controlled trial to evaluate the efficacy of cyclical Topical Wound Oxygen (TWO₂) therapy in the treatment of chronic diabetic foot ulcers: the TWO₂ study; Diabetes Care 2020; 43: 616 - 624.

2. Venous leg ulcers. Nelson EA, Adderley U. 2016, BMJ Clin Evid., Vol. 2016:1902.

3. Prevalence and incidence of venous leg ulcers-a protocol for a systematic review. Probst, S et al. 2021, Systematic reviews vol. 10,1 148. 12 May. 2021, doi:10.1186/s13643-021-01697-3, Vol. 10, p. 148.

4. Technical and clinical outcome of topical wound oxygen in comparison to conventional compression dressings in the management of refractory nonhealing venous ulcers. Tawfik WA, Sultan S. 2013, Vasc Endovascular Surg., Vol. 47(1).

5. Compression, Oxygen, and Humidification - Improves Venous Wound Healing and Reduces Venous Ulcer Recurrence. J. Lohr. VEITH Symposium 2024; <https://www.veithsymposium.org/current/abstracts/vei/1255.pdf>

END

Peel Hunt LLP (Nominated Adviser and Broker)
Dr. Christopher Golden, Patrick Birkholm

+44 (0)20 7418 8900

FTI Consulting (Financial PR & IR)
Ben Atwell, Simon Conway,
Natalie Garland-Collins, Alex Davis

+44 (0)20 3727 1000
AOTI@fticonsulting.com

ABOUT AOTI, INC.

AOTI, INC. was founded in 2006 and is based in Oceanside, California, US and Galway, Ireland, providing innovative solutions to resolve severe and chronic wounds worldwide. Its products reduce healthcare costs and improve the quality of life for patients with these debilitating conditions. The Company's patented non-invasive Topical Wound Oxygen (TWO₂[®]) therapy has demonstrated in differentiating, robust, double-blinded randomised controlled trials (RCT) and real-world evidence (RWE) studies to more-durably reduce the recurrence of Diabetic Foot Ulcers (DFUs), resulting in an unprecedented 88 per cent reduction in hospitalisations and 71 per cent reduction in amputations over 12 months. TWO₂[®] therapy can be administered by the patient at home, improving access to care and enhancing treatment compliance. TWO₂[®] therapy has received regulatory clearance from the US (FDA), Europe (CE Mark), UK (MHRA), Health Canada, the Chinese National Medical Products Administration, Australia (TGA) and in Saudi Arabia. Also see www.aotinc.net

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@seg.com or visit www.ms.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

UPDFFMESIELSEIE