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

AOTI announces US FDA 510(k) Clearance of NEXA™ NPWT System for use in the home care setting

Extension to Indications for Use follows submission of results from a human factors study evaluating the safe and effective use of the device in the home care setting

AOTI, INC., a medical technology group with a mission to help all people with chronic conditions get back to living their lives to the fullest, through the durable healing of wounds and prevention of amputations, is pleased to announce that the US FDA has issued 510(k) Clearance (K241515) for the Company's NEXA™ Negative Pressure Wound Therapy (NPWT) System to include its use in the home care setting. The labelling for the device now includes the extended indications of *"for use in acute, extended and home care settings …*" In the US, the initial target market for the System has been long term care. This new clearance will allow for marketing of this unique System across all care sites, including into the expanding home care setting. The home care setting indication already exists in the international approvals for the device.

The NEXA™ NPWT System was developed to provide clinically proven negative pressure therapy for patients with chronic or acute wounds, with a simpler, more portable and affordable device. The NEXA™ NPWT System is differentiated from other systems on the market as it is the only multi-week disposable NPWT system that delivers the performance of traditional NPWT, at a lower cost.

AOTI markets two product families in the US and International markets. Its proprietary TWO_2® therapy system is already the global market-leader in the topical oxygen wound therapy segment and the Company recently acquired the complementary NEXA™ NPWT platform to add to this offering. The total advanced wound care market segment that the Group's products address is estimated to be $12 billion.[1]

Dr. Mike Griffiths, Chief Executive Officer and President of AOTI, INC. commented: *"I am delighted that the FDA has granted clearance for our NEXA™ NPWT device such that it can now be marketed for use in the home care setting too, bringing it in line with the approvals we already have in international markets. We continue to believe that the NEXA™ NPWT System offers significant capabilities, in a more cost-effective platform, to transition patients more effectively from hospital to the community and reduce the risk of subsequent re-admission due to complications with their wounds. I would like to thank the entire team at AOTI for all their hard work and diligence in providing a thorough submission to the Agency such that this important clearance was received so expeditiously."*

AOTI recently raised net proceeds of £13.5 million (c.$17.5 million) through an initial public offering ("IPO") on the AIM market on 18 June 2024.

1. SmartTRAK 2021 WW Advanced Wound Care Market; and Market Watch Hyperbaric Oxygen Therapy (HBOT) Market Size 2023

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AOTI, INC.
Dr. Mike Griffiths, Chief Executive Officer
Jayesh Pankhania, Chief Financial Officer
+44 (0)20 3727 1000
ir@aotinc.net

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, Alex Davis
+44 (0)20 3727 1000
AdvancedOxygenTherapy@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 (TWO_2®) 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. TWO_2® therapy can be administered by the patient at home, improving access to care and enhancing treatment compliance. TWO_2® 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

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