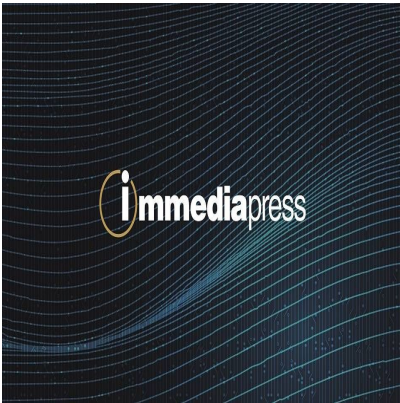




Lenire Now Included in U.S. ENT Clinical Practice Guidelines – First New Treatment Added by American Academy of Otolaryngology Since Establishment of the Academy’s Tinnitus Guidelines

Descrizione

COMUNICATO STAMPA – CONTENUTO PROMOZIONALE

DUBLIN, Oct. 16, 2026 /PRNewswire/ – The American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF) has included Lenire (bimodal neuromodulation) as a treatment option in the Academy’s new Clinical Practice Guidelines for Tinnitus.

Bimodal neuromodulation is the only new treatment recommendation added to the AAO-HNSF guidelines since their establishment in 2014. Building on the FDA’s landmark approval of Lenire in 2023 (the first and only bimodal neuromodulation device approved by the FDA), further establishes Lenire as a new standard of care for tinnitus in the U.S.A.

The AAO-HNSF guidelines help ENTs across the United States to clinically evaluate and manage tinnitus in everyday care. The guidelines – emphasize interventions and therapies deemed beneficial – and directs American ENTs – to avoid treatments that are time-consuming, costly, inaccessible, and ineffective.

– This is another historic first for our company, our technology and for the field of tinnitus treatment, – said Neuromod Founder, Dr. Ross O’Neill Ph.D. – Lenire being included in the American Academy of Otolaryngology’s guidelines, means that the 12,000-plus practicing ENTs in the U.S. now have a new safe and effective treatment to recommend to the tens of millions of Americans suffering from tinnitus.

Robust Evidence Underpins American Academy of Otolaryngology Decision on Lenire

US ENTs can now confidently recommend Lenire knowing that it has been reviewed by the Academy’s panel of tinnitus experts.

Lenire combines sound stimulation with mild electrical stimulation to the surface of the tongue (bimodal neuromodulation) to relieve the symptoms of tinnitus. Lenire has been proven effective and inherently safe in three large-scale clinical trials^{1,2,3} and validated in a growing body of real-world clinical outcomes.^{4,5}

Lenire's landmark FDA Approval in March 2023 was based on the pivotal TENT-A3 controlled clinical trial and confirmatory real-world evidence. The results were published in Nature Communications and is in the 99th percentile most-viewed in articles tracked by Nature.

Since then, tens of thousands of American patients have been successfully treated with Lenire in clinics across the United States. The company plans to support these clinicians to continue to publish this growing body of real-world evidence to firmly establish Lenire as a leading standard of care.

Results in the first peer-reviewed real-world paper published in Nature Communications Medicine reported 91.5% of tinnitus patients had a clinically significant reduction in tinnitus. The second real-world retrospective analysis published in The American Journal of Audiology reported that 81.8% of patients with bothersome tinnitus reported a clinically significant reduction in tinnitus.

“The inclusion of bimodal neuromodulation in the AAO-HNSF Clinical Practice Guideline for Tinnitus reinforces the rigorous and large-scale clinical evidence for Lenire as a treatment for patients seeking help for their bothersome tinnitus,” said Neuromod Chief Scientific Officer, Professor Hubert Lim. “Neuromod is committed to further expanding upon the large evidence base for Lenire to make it more effective and accessible for tinnitus patients worldwide.”

Lenire is available via qualified healthcare professionals in the United States of America, Canada, Europe, and Australia. It is also a treatment option through the United States of America Veterans Affairs.

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About Neuromod Devices

Neuromod Devices is a global medical technology company with offices in Ireland and North America. The company specializes in the design and development of neuromodulation technologies to address the clinical needs of tinnitus patients.

Neuromod has completed extensive clinical trials that confirmed the safety and effectiveness of its non-invasive bimodal neuromodulation tinnitus treatment device, Lenire. For more information about Neuromod, visit www.neuromod.com.

About Lenire®

Lenire® is the first non-invasive bimodal neuromodulation tinnitus treatment device. Bimodal neuromodulation stimulates nerves using two paired stimuli to drive significant relief from tinnitus.

Lenire combines audio stimulation with stimulation to the surface of the tongue that is delivered through a proprietary device trademarked as Tonguetip®.

An appropriately qualified healthcare professional, such as an ENT or audiologist, prescribes Lenire following a comprehensive audiological examination. Patients then complete treatment as advised from the comfort of their own home.

Lenire is backed by the largest volume of clinical research for a tinnitus treatment device. This research has been validated in peer-reviewed and published analyses of tinnitus patients treated with Lenire at independent clinics.

Lenire® has CE-mark certification and is the first and only bimodal neuromodulation to be awarded a De Novo Approval Grant from the US FDA.

References

View original content to download multimedia:<https://www.prnewswire.co.uk/news-releases/lenire-now-included-in-us-ent-clinical-practice-guidelines-first-new-treatment-added-by-american-academy-of-otolaryngology-since-establishment-of-the-academy-s-tinnitus-guidelines-302911308.html>

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