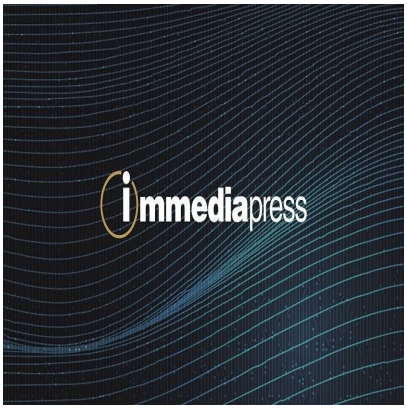

Lenire Shows Consistent Positive Results for U.S. Tinnitus Patients in 2nd Peer-Reviewed Real-World Study

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

NEW YORK, Feb. 17, 2026 /PRNewswire/ â?? The American Journal of Audiology has peer-reviewed and published the positive outcomes of U.S. tinnitus patients treated with Lenire, the only FDA approved tinnitus treatment device of its kind.

Results in the paper titled: â??Bimodal Neuromodulation for Tinnitus in a Clinical Practice Setting: Clinically Significant Benefit for Patients with Moderate or Worse Symptomsâ?• reported 81.8% of patients with bothersome tinnitus had a clinically significant reduction in tinnitus when treated with Lenire.1,2

These results are consistent with previously published Lenire treatment outcomes3, showing repeatable success for tinnitus patients in real world clinical settings. In addition to being supported by the largest body of clinical trial data in its field, Lenire is now underpinned by the most extensive real-world evidence of safety and effectiveness, following publication of this research in The American Journal of Audiology.

The paper, authored by Dr. Craig Kasper Au.D of New York Hearing Doctors (NYHD) et al, analyzed the results of 140 tinnitus patients who were fitted with Lenire at NYHD between May 1, 2023, and January 19, 2024.

Read the Paper: https://pubs.asha.org/doi/10.1044/2025_AJA-25-00090

Tinnitus is commonly known as ringing in the ears but can manifest as hissing, buzzing, and other persistent sounds. The condition afflicts an estimated 25 million American adults4, with an estimated 2.5 million tinnitus patients living in New York alone.5

Lenire uses bimodal neuromodulation to treat tinnitus. Bimodal neuromodulation is the simultaneous stimulation of two nerves for therapeutic purposes. Lenire plays audio tones via headphones while delivering mild energy pulses to the surface of the tongue to treat tinnitus. Under the care of an audiologist with tinnitus expertise, patients with bothersome tinnitus typically use the device at home for two 30-minute sessions daily for approximately 12 weeks.

Results Consistent with Real World Research and Clinical Trials

This paper is the second in a series of planned, real-world evidence publications that have been compiled from thousands of U.S. tinnitus patients that have been successfully treated with Lenire.

The analysis found that at the interim check-up, after six weeks of treatment with Lenire, 72.6 percent of patients with bothersome tinnitus had a clinically meaningful reduction in tinnitus.1,2 After 12-weeks, 81.8% of patients with bothersome tinnitus had a clinically meaningful reduction.1,2

Patients reported a mean reduction of 23.8 points on the Tinnitus Handicap Inventory (THI) after 12-weeks, greater than three times the threshold for clinically significant reduction.1,2 As a result, the majority of patients with bothersome tinnitus reported they were no longer severely impacted by their tinnitus following 12-weeks of Lenire, according to tinnitus severity grading guidelines.1,2, 11

â??New York Hearing Doctors stay on the cutting-edge of tinnitus care through the introduction of modern technologies like Lenire and leveraging research to consistently refine our treatment methodologies,â• said NYHD founder, Dr. Craig Kasper, Au. D. â??The combination of our personalized approach to tinnitus care and the remarkable effectiveness of Lenire, we are seeing life-changing treatment outcomes for our patients.â•

â??Lenire was nothing less than a game-changer in my life. I went from debilitating, almost catastrophic tinnitus, that required medication to treat the depression and anxiety, to being able to enjoy life again after four months of Lenire.â• said Richard Bistrong, tinnitus patient at New York Hearing Doctors, â??Three years later, I can enjoy my life and not worry about my tinnitus. This has impacted not only my well-being but my loved ones as well. For anyone that is looking for relief, that is based in science and patient results, I would encourage you to seek your local Lenire Provider as soon as possible to learn more about Lenire.â•

The evidence in this paper is consistent with the first peer-reviewed real-world analysis of U.S. tinnitus patients treated with Lenire and Lenireâ??s large-scale clinical trials.3,6,7,8

The first real world analysis of U.S. patients treated with Lenire, which was peer-reviewed and published in Nature Communications Medicine, showed that 91.5% who used Lenire had a clinically significant reduction in tinnitus after 12-weeks of Lenire.3 This consistency demonstrates the effectiveness of a typical treatment protocol with Lenire in a real-world clinical setting.

FDA Approval in March 2023 was facilitated by Lenireâ??s controlled, TENT-A3 clinical trial. The results were published in Nature Communications, a journal from the same portfolio. The paper remains in the 99th percentile of more than 250,000 tracked Nature articles.

TENT-A3 included 112 trial participants and demonstrated Lenireâ??s clinical superiority to sound-only therapy, a widely used treatment for tinnitus. Nearly 89% of trial participants said they would recommend Lenire as a tinnitus treatment.6

According to Neuromod Devices founder and CEO, Dr. Ross Oâ??Neill, who was Lenireâ??s principal inventor, â??The consistency of the real-world outcomes of US tinnitus patients treated with Lenire with our large-scale clinical trials demonstrates the replicability and scalability of Lenire as a tinnitus treatment option for the over 740 million people worldwide living with tinnitus.â•

â??By working closely with our network of providers, we are seeing market-surpassing patient outcomes, improving clinical best practices, and a rapidly growing body of robust real-world evidence positioning Lenire and bimodal neuromodulation as a leading tinnitus treatment option.â•

Lenire is available through specialized tinnitus clinics in the United States of America and Europe. Lenire is also a treatment option through the US Department of Veterans Affairs.

References and Notes

About Neuromod

Founded in 2010, Neuromod Devices is a global medical technology company with offices in Ireland, and the United States of America. Neuromod specializes in the design and development of neuromodulation technologies to address the clinical needs of underserved patient populations who live with chronic and debilitating conditions.

The lead application of Neuromodâ??s technology is in the field of tinnitus, where Neuromod has completed extensive clinical trials to confirm the efficacy of its non-invasive neuromodulation platform in this common disorder. For more information visit www.neuromoddevices.com.

About LenireÂ®

LenireÂ® is the first non-invasive bimodal neuromodulation tinnitus treatment device shown to soothe and relieve tinnitus in large-scale clinical trials.

Bimodal neuromodulation is the stimulation of nerves with two paired stimuli for therapeutic purposes. The tinnitus treatment device that was used in the study, known as Lenire, was developed by Neuromod Devices. It consists of wireless (Bluetooth Â®) headphones that deliver sequences of audio tones to both ears, combined with electrical stimulation pulses delivered to the surface of the tongue via 32 electrodes on a proprietary device trademarked as TonguetipÂ®. The deviceâ??s settings can be configured to provide treatment with different combinations of audio and electrical stimuli.

The timing, intensity and delivery of the stimuli are controlled by an easy-to-use handheld controller that each participant is trained to use prior to continuing treatment from home. Patients with tinnitus are prescribed Lenire by an appropriately qualified healthcare professional, such as an Audiologist or ENT Surgeon, after an assessment for suitability and can complete treatment from home in between follow-up appointments with their clinician.

LenireÂ® has CE-mark certification for the treatment of tinnitus under the supervision of an appropriately qualified healthcare professional in Europe and has received a De Novo Approval Grant by the US FDA.

About Tinnitus

Tinnitus, which is commonly known as â??ringing in the earsâ??, is a complex neurological condition that causes a perception of sound when there is no external source. It is estimated that at least 25 million Americans are currently living with tinnitus.3 Tinnitus is also the most prevalent service-connected disability compensated for by The United States Veterans Administration (VA), with more than 3.2 million veterans compensated in 2024.9

About Dr. Craig Kasper Au. D.

Dr. Craig Kasper, Au. D. is the founder and managing director of audiology clinic, New York Hearing Doctors | Institute for Hearing and Balance and New York Hearing Doctors | Tinnitus Care, based in New York.

He earned his Doctorate of Audiology from the University of Florida and holds a masterâ??s degree with clinical honors from the State University of New York at Buffalo.

Dr. Kasperâ??s extensive experience includes a Clinical Fellowship and clinical practice in the Department of Otolaryngology/Head & Neck Surgery at New York-Presbyterian Medical Center. A Distinguished Fellow of the National Academies of Practice, he is also a Fellow of the American Academy of Audiology (AAA), and a member of the Academy of Doctors of Audiology (ADA).

Dr. Kasperâ??s contributions extend beyond clinical practice; he has authored scholarly articles published in prestigious peer-reviewed journals such as Hearing Research and Laryngoscope and has been an invited presenter for professional conferences since the start of his career. Committed to public health education, he has also frequently served as a resource for the popular media on topics related to hearing health and wellness.

Photo â?? https://mma.prnewswire.com/media/2904615/Neuromod_Devices_CEO.jpg

View original content:https://www.prnewswire.co.uk/news-releases/lenire-shows-consistent-positive-results-for-us-tinnitus-patients-in-2nd-peer-reviewed-real-world-study-302689358.html

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