

Neurolief's Digital Therapeutics Neuromodulation System May Challenge Medication Therapies for the Treatment of Migraine

Study shows 76% of patients treated with Relivion achieved headache pain relief at 2 hours

TAMPA, FL, USA, June 9, 2022 /EINPresswire.com/ -- <u>Neurolief</u>, a neurotechnology innovator, today announces the publication of the <u>SP301</u> study in the Pain and Therapy Journal that demonstrates the safety and efficacy of <u>Relivion</u> MG, Neurolief's CE-marked and FDA cleared wearable neuromodulation system for at-home treatment of migraine with remote physician monitoring. The study is the first to prove that external concurrent stimulation of both the occipital and trigeminal nerves can effectively treat migraine pain, with 76% of patients achieving headache relief within 2 hours compared to 31.6% of patients in the sham group.

"The results of this study are extremely promising", said Daniel Oved, MD, Ramat-Aviv Medical Center, Tel Aviv, Israel, who was the principal investigator of the study. "With Relivion, patients now have access to an effective and safe non-drug therapy they can use at home, allowing them to return to their normal lives."

The SP301 study determined that a self-administered treatment protocol using the Relivion home based technology can provide a clinically significant safe and effective reduction of migraine-related pain. The device was shown to be significantly effective across all of the study's pre-defined end points and demonstrated clinically significant outcomes for pain relief and pain freedom at 2 hours, two of the most important clinical outcomes in the treatment of acute migraine:

•I6.2% of the study subjects reported headache relief at 2 hours in the active treatment group, while only 31.6% of the subjects treated with the sham device reported relief which represents a therapeutic gain of 44.6%

•42.9% of the study subjects (initiating the treatment at a moderate/severe pain level) reported pain freedom at 2 hours in the active treatment group while only 10.5% of the subjects treated with the sham device reported freedom from pain, representing a therapeutic gain of 32.4%

The clinical results achieved with Relivion MG appear to compare favorably with previous studies

for oral triptans, as demonstrated by 76% headache relief at 2 hours post treatment in the current study compared to 42-76% reported for oral triptans. Additionally, recent studies of the new medications for acute treatment of migraine have even more modest pain relief numbers compared to eCOT-NS (60.7% and 59.3% at 2 hours). As the selection criteria and outcome measures may vary, comparing the results of separate studies should be done with caution.

About Relivion

Relivion harnesses the power of the body's natural electricity to treat migraine, reducing the need for drug therapies. This breakthrough technology applies a mild electrical impulse directly to 6 nerve branches associated with migraine pain. The Relivion is the first system to provide combined neurostimulation of both the occipital and trigeminal nerves without requiring surgical implantation, thus allowing the patient to treat in the comfort of their own home.

"The Relivion neuromodulation technology combined with the system's remote monitoring platform has the opportunity to revolutionize the way migraine disease is managed", said Amit Dar, Neurolief's co-founder and CTO. "The publication of this data brings us one step closer to making Relivion more accessible to patients suffering from a wide range of neurological and neuropsychiatric disorders like migraine."

Relivion MG for treatment of acute migraine is FDA cleared and has CE mark. Neurolief has begun its commercialization process through a limited market release in the United States.

About Neurolief

Dedicated to bringing relief to patients suffering from chronic neurological and neuropsychiatric disorders, Neurolief is creating a digital therapeutics platform of wearable, clinically-proven neuromodulation solutions. This technology, which is made to be worn like a headset, is intended to offer highly-effective, safe treatment options that work either as an adjunct to current pharmaceutical therapies or as a stand-alone alternative to these therapies. It is designed to concurrently neuromodulate major neural pathways in the head and thereby affect brain regions that are involved in control and modulation of mood and pain. Neurolief's technology is currently used for patients with migraine, being studied for major depression and planned for future indications to include insomnia, ADHD and additional chronic pain and neuropsychiatric disorders. The company is based in Israel, with US operations in Tampa, FL, and is made up of highly experienced professionals with a proven track record in neurosciences, neuromodulation technology and the neurotech devices industry.

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