# Neurolief Announces Publication of the RIME Pivotal Study for Relivion MG – a Digital Therapeutics Platform for Migraine

*Results of clinical study demonstrate non-invasive combined occipital and trigeminal neuromodulation system may offer pronounced benefit for migraine patients.*

TAMPA, FL, UNITED STATES, June 29, 2022 /EINPresswire.com/ -- Neurolief, a neurotechnology innovator, today announces publication of the RIME US pivotal trial results in Headache, The Journal of Head and Face Pain, that demonstrate the safety and efficacy of Relivion MG, a novel external brain neurostimulation system for self-administered treatment of migraine.
The study met all its endpoints with statistical and clinical significance, with Relivion demonstrating the ability to be a viable non-drug alternative to first-line acute medication treatments.

“The results of this study are extremely promising for those seeking an effective, drug-free therapy for migraine”, said Stewart J. Tepper MD, Professor of Neurology at the Geisel School of Medicine at Dartmouth, who was the principal investigator of the study. Relivion, targets the 2 major neural pathways responsible for migraine, thereby creating a synergistic neuromodulatory effect that maximizes the clinical benefits. “This may explain why it is the only neuromodulation technology that was able to demonstrate statistically significant results for complete freedom of migraine symptoms, in a pivotal, regulatory sham-controlled clinical trial”, added Dr. Tepper.

Relivion harnesses the power of the body’s natural electricity to treat migraine, removing the need for drug therapies. This breakthrough technology applies a mild electrical impulse directly to 6 nerve branches associated with migraine pain.  Combined neurostimulation of both the occipital and trigeminal nerves was previously possible only with surgically implanted devices. The Relivion is the first system to provide such combined neural stimulation without requiring surgical implantation.

The RIME study was a multi-center, prospective, randomized, double-blind, placebo-controlled clinical trial, conducted at leading clinical centers in the US and Israel. It evaluated the safety and efficacy of the device with 131 patients who met the International Classification of Headache Disorders (ICHD-3) criteria of migraine with or without aura.

•At 2 hours after treatment, 46% of patients in the active group reached complete pain freedom compared to only 12% in the control group.

•  75% of patients in the active group reached complete freedom of “Most Bothersome Symptom” (MBS- either phonophobia, photophobia, or nausea) 2-hours after treatment, compared to 47% in the control group.

•  47% of patients in the active group demonstrated freedom from both pain and MBS while only 11% of patients in the control group, a remarkable 4.25-fold difference between active treatment and control.

•  Pain relief was also significantly higher in the active group than in the control group at 2 hours after treatment (60% vs. 37%).

•  No serious adverse events were reported.

“The results from the RIME study bring us one step closer to being widely accepted as first-line therapy for patients suffering from migraine ", said Amit Dar, Neurolief’s Co-founder and CTO. "We believe that an effective, non-drug first-line therapy, will substantially contribute to the management of this debilitating disease.”

The authors noted the results of the RIME trial suggest that in the most clinically important endpoints - pain freedom and MBS freedom - Relivion may have a greater effect than other neuromodulation technologies for the treatment of migraine. Relivion’s adverse event profile suggests it is likely more tolerable than triptans due to the absence of systemic side effects for the acute treatment of migraine. In addition, Relivion’s remote monitoring capabilities enable healthcare providers the ability to optimize the treatment to reflect patients’ personal needs and enhance their quality of life.

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

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 with current pharmaceutical therapies or may provide an 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 the control and modulation of mood and pain. Neurolief’s technology is currently studied for patients with migraine and major depression, and future indications may 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.

Megan Eckerman
Neurolief
+1 206-419-9029
email us here

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