Dr. Reddy's subsidiary betapharm, and Theranica launch Nerivio® in Germany to provide patients with drug-free migraine treatment

Wednesday 10 April, 2024

- *The launch in Germany through its step-down subsidiary betapharm marks Dr. Reddy's entry into digital therapeutics in Europe.*
- *Nerivio® is the first REN (Remote Electrical Neuromodulation) wearable, FDA-cleared, and CE-marked for acute and/or prevention migraine (with or without aura) treatment for adults and adolescents (? 12 years).*
- *Nerivio® is worn on the upper arm during treatment and controlled by a smartphone app, making it comfortable and portable.*
- *Starting with Germany, followed by Spain and the UK, Dr. Reddy's plans to further increase access to Nerivio® in European countries.*

Augsburg; April 10, 2024 – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; along with its subsidiaries together referred to as "Dr. Reddy's"), a global pharmaceutical company, announced the launch of the Nerivio® Remote Electrical Neuromodulation (REN) wearable through its subsidiary betapharm. Nerivio® is a United States Food and Drug Administration (USFDA), and CE-marked device that uses Remote Electrical Neuromodulation (REN) to prevent and treat migraine. The novel wearable device is a drug-free treatment made by Theranica, a neuromodulation therapeutics company based in Israel and the USA.

The current best estimate of global migraine prevalence is 14–15%, and, in terms of burden, migraine accounts for 4.9% of global ill health, quantified as years lived with disability[1]. Around 8 to 10 million people in Germany are affected, 14.8% of women and 6.0% of men[2].

Nerivio® is a prescription-based, non-invasive device intended for acute and prophylactic (preventive) treatment of migraine with or without aura[3] for adults and adolescents aged 12 years and older. Nerivio® can be worn on the upper arm and controlled by a smartphone app. Each device has an in-built capability for providing 18 treatment sessions, each 45 minutes long. It is to be used within 60 minutes of the onset of headache or aura for acute treatment of migraine or every alternate day for prevention of migraine. The device uses the Remote Electrical Neuromodulation (REN) mechanism to activate conditioned pain modulation (CPM), specifically by stimulating nociceptive neural receptors under the skin of the arm. This initiates a natural pain-relieving process in the brainstem, causing a global effect of pain inhibition that affects the source of migraine pain in the brain[4].

"Neuromodulation offers a significant advancement in migraine treatment," says **Dr. Arne May, a leading researcher in the Department of Systems Neuroscience at the University of Hamburg and Head of the headache outpatient clinic of the University Clinic of Hamburg**. *"For decades, medication has been the mainstay of migraine management. However, many patients experience side effects or limited efficacy with these medications. Neuromodulation technologies offer a much-needed alternative. Such a modern neuromodulation technology is Nerivo®. By stimulating specific neural pathways, Nerivio can trigger the brain's natural pain-relieving mechanisms, which were found to be deficient among migraine patients, without introducing chemical substances into the system. This drug-free approach holds particular promise for vulnerable populations such as adolescents and women of childbearing age, who may not be able to take conventional migraine medications."*

Patrick Aghanian, Chief Executive Officer of Dr. Reddy's Europe, commented, *"Starting with Germany, we are excited to introduce Nerivio®*
in Europe as a new drug-free innovation that can help migraine patients. Remote Electrical Neuromodulation (REN) has the potential to reduce the number of pills patients need to take and decrease their dependence on non-specific medication for chronic or hard-to-treat diseases[5]. Worn on the upper arm and controlled by a smartphone app, makes it comfortable, discreet and portable. We believe that gives patients the freedom to focus on their daily activities while wearing it, addressing the unmet clinical need for more convenient migraine treatment, which significantly impacts well-being and quality of life."

Clinically proven in multiple clinical trials[6], the drug-free REN wearable is suitable for a wide range of migraine patients, especially those who seek an individual treatment opportunity, a drug-free therapy, failed to control their migraine with medications, or with poor tolerance or contraindication to medications. In addition, sensitive populations such as adolescents, women of childbearing age groups, and patients

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at risk of medication overuse headaches could benefit from Nerivio®[7]. Studies show that Nerivio® is well tolerated with no systemic side effects or concern for medication overuse. It has been evaluated in robustly designed pivotal studies conducted in the U.S and Israel in patients seeking effective acute or preventive treatment of migraine. Nerivio® has proven efficacy in not only effectively providing relief from pain but also from associated migraine symptoms such as nausea or vomiting, phonophobia, and photophobia. It has been shown to reduce the need for drugs used for abortive treatment.

In August 2023, Nerivio® received an expanded CE mark approval under MDR European regulation as a dual-use (acute and/or prevention) migraine treatment for adolescents and adults. The launch in Germany is the result of multiple exclusive agreements signed between Dr. Reddy's European subsidiaries and Theranica for the commercial marketing and distribution of Nerivio® in Germany, Austria, Czech Republic, Denmark, Finland, France, Italy, Norway, Poland, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom[8] . These markets will likely follow with planned launches in Spain and the UK between May and June.

The product has already been presented in Germany at the DGN Kongress 2023, organized by the German Association of Neurology in Berlin, following a successful launch in India in November 2023.

The prescribed Nerivio® REN wearable is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12 years and older. Patients are advised to consult their physician or neurologists on the use of the device and management of migraine. More information (in German only) can be found on www.nerivio.de

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: www.drreddys.com.

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[1] Steiner, T.J., Stovner, L.J. Global epidemiology of migraine and its implications for public health and health policy. Nat Rev Neurol 19, 109–117 (2023). https://doi.org/10.1038/s41582-022-00763-1

[2] Porst et al. J Health Monitoring 2020 5(S6):2–26

[3] Symptoms or sensations, such as flashing lights or zigzag lines or loud sound, which typically precede migraine headache

[4] Nir R-R, Yarnitsky D. Conditioned pain modulation. Curr Opin Support Palliat Care 2015; 9:131-137 https://doi.org/doi:10.1097/SPC.0000000000000126; Yarnitsky D et al. Remote Electrical Neuromodulation (REN) Relieves Acute Migraine: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial. Headache 2019; 59:1240-1252 https://doi.org/doi:10.1111/head.13551

[5] Marmura: Incorporating Remote Electrical Neuromodulation (REN) Into Usual Care Reduces Acute Migraine Medication Use: An Open-Label Extension StudyFront. Neurol., 07 April 2020 Sec. Headache and Neurogenic Pain Volume 11 - 2020 | https://doi.org/10.3389/fneur.2020.00226

[6] Migraine Headache Treatment - Nerivio | Clinical Trials

[7] Babaei M, Rapoport AM. Expert Review of Medical Devices. 2023 May 12:1-5.

[8] CE mark:

| Europe agreement:

| India agreement:

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