## **Press Release**



## DR. REDDY'S LABORATORIES LTD.

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## Dr. Reddy's rolls out Nerivio®, a USFDA-approved drug-free non-invasive migraine management device, in India

- Nerivio® is the first and only USFDA approved device to use Remote Electrical Neuromodulation (REN) to prevent and treat migraine
- It is a drug-free wearable, and intended for acute and prophylactic (preventive) migraine in patients aged 12 years and above
- The device is accompanied by a user-friendly app that comes with in-built features such as interactive migraine diary to log symptoms, track responses and share insightful analytics
- Additionally, the device is backed by Dr. Reddy's patient support programme for complete migraine care
- Safe and well-tolerated with no systemic side-effects or concern of overuse, unlike medication
- Marks Dr. Reddy's entry into digital therapeutics as part of its innovative products business, having earlier ventured into e-commerce through 'Celevida Wellness', and entered into collaborations with Jiangsu Hengrui & Junshi Lifesciences respectively to bring novel molecules such as pyrotinib to India and toripalimab to India and select emerging markets

**Hyderabad India; November 16, 2023** – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; hereafter referred to as "Dr. Reddy's"), a global pharmaceutical company, announced the roll-out of Nerivio® in India, a state-of-the-art United States Food and Drug Administration (USFDA) approved wearable therapy device for drug-free management of migraine.

Migraine is a global health challenge, affecting around 30% of adults on 15 or more days per month, impacting 1.7% to 4% of the population<sup>1</sup>. Migraines are known to have a disproportionate impact on women, who constitute approximately 60% of the 213 million migraine sufferers in India alone<sup>2</sup>.

Nerivio® is a prescription-based non-invasive device intended for acute and prophylactic (preventive) treatment of migraine with or without aura<sup>3</sup> for adults and adolescents aged 12 years and above. Nerivio® can be worn on the upper arm. Each device has in-built 18 x 45-minute treatment sessions. It is to be used within 60 minutes of onset of headache for acute treatment of migraine or every alternate day for

<sup>&</sup>lt;sup>1</sup> https://www.neurologyindia.com/article.asp?issn=0028-3886;year=2021;volume=69;issue=7;spage=4;epage=9;aulast=Krishnan <sup>2</sup> https://en.gaonconnection.com/india-migraine-stroke-2019-lancet-health-air-pollution-blood-pressure-headache-health-

https://en.gaonconnection.com/india-migraine-stroke-2019-lancet-health-air-pollution-blood-pressure-headach neurological-disorders/

<sup>&</sup>lt;sup>3</sup> Symptoms or sensations, such as flashing lights or zigzag lines or loud sound, which typically precede migraine headache

prevention of migraine. The device uses the Remote Electrical Neuromodulation (REN) mechanism to specifically activate conditioned pain modulation by stimulating nerve endings. This initiates a natural pain-relieving process in the brainstem, causing a global effect of pain inhibition that affects the original source of migraine pain in the head4.

M.V. Ramana, Chief Executive Officer, Branded Markets (India and Emerging Markets), Dr. Reddy's said, "The roll-out of Nerivio® marks our entry into digital therapeutics (DTx). It is an area that is seeing increasing adoption by physicians as well as patients due to its potential to reduce pill burden and decrease dependency on non-specific medication in chronic or hard-to-treat diseases. Given the migraine disease burden, its associated symptoms, lack of effective treatment and impact on well-being, quality of life and productivity, we are happy to bring Nerivio® to India. It is USFDA-approved, drug-free, noninvasive, first-of-its-kind product for migraine in India and offers a favourable safety profile. We believe this product meets a genuine unmet clinical need among migraine patients. We look forward to receiving patient and HCP feedback on it. While our core generics business continues to drive our current growth, Nerivio® as DTx joins our e-commerce venture 'Celevida Wellness', and our recent deals to bring novel molecules such as toripalimab and pyrotinib to India, as part of our innovative products initiatives in India aimed at improving patient well-being and outcomes."

The unique device is accompanied by the Nerivio app, which is user-friendly and freely available on Google Play Store and the Apple app store for download. The app can be used to control the intensity levels of the device. It also has an interactive migraine diary which can be used to log symptoms, track responses and share insightful analytics. The app also includes an interactive GIER (guided, imagery, education and relaxation) protocol which, if used with Nerivio®, significantly increases the response rates.

As part of its patient support programme for Nerivio, Dr. Reddy's offers M-Free, a comprehensive support system that enhances and streamlines the journey of the patients. M-Free includes services such as onboarding and counseling of patients, device demonstrations, doorstep delivery, flexible payment options, informative content, and dedicated customer care to help patients get the most out of the device.

Clinically proven<sup>5</sup> and safe, Nerivio® is suitable for a wide range of patients, including those who prefer drug-free options, individuals with contraindications to medications or poor medication tolerance, sensitive populations such as adolescents, women of vulnerable age groups and patients at risk of medication overuse headache<sup>6</sup>. Studies show that Nerivio® is safe and 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., in patients seeking effective acute or preventive treatment of migraine. Nerivio® has proven efficacy in not only effectively treating relief of pain but also associated symptoms in migraine such as nausea, vomiting etc. It has been shown to reduce the need for drugs used for acute treatment in nearly 9 out of 10 patients. Being an effective non-invasive therapy, the associated systemic adverse events are not a concern. This is extremely useful in patients seeking preventive treatment of migraine since many patients experience tolerability issues with drugs, resulting in significant impact on their quality of life, when used for long time (>3 months)<sup>7</sup>.

https://nerivio.com/how-it-works/

https://nerivio.com/
https://nerivio.com/
Babaei M, Rapoport AM. Expert Review of Medical Devices. 2023 May 12:1-5.

In January 2023, Dr. Reddy's entered into an exclusive agreement with Theranica, a prescribed digital therapeutics company developing advanced neuromodulation devices for migraine and other pain conditions, for the marketing and distribution of Nerivio® in India. In August this year, Nerivio® received an expanded CE mark approval under MDR European regulation as a dual-use (acute and/or prevention) migraine treatment for adults and adolescents. Dr. Reddy's also recently signed an exclusive agreement 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<sup>8</sup>.

Nerivio® is a prescription-based product. Patients are advised to consult their neurologists on the use of the device and management of migraine. For more queries, doctors and patients can call the dedicated helpline number 1800-123-2360 (toll-free).

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: <a href="https://www.drreddys.com">www.drreddys.com</a>.

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Disclaimer: This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults, currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events, (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2023. The company assumes no obligation to update any information contained herein.

<sup>&</sup>lt;sup>8</sup> CE mark: <a href="https://www.prnewswire.com/news-releases/nerivio-ce-mark-indication-expanded-to-preventive-and-acute-treatment-of-migraine-for-adolescents-and-adults-301896254.html">https://www.prnewswire.com/news-releases/theranica-enters-into-agreement-with-dr-reddys-for-commercializing-nerivio-in-europe-301986214.html</a> | India agreement: <a href="https://www.prnewswire.com/news-releases/theranica-enters-into-agreement-with-dr-reddys-for-commercializing-nerivio-in-india-301715697.html">https://www.prnewswire.com/news-releases/theranica-enters-into-agreement-with-dr-reddys-for-commercializing-nerivio-in-india-301715697.html</a>