

Dr. Reddy's Laboratories and its U.S. subsidiary Promius Pharma announce the filing of an NDA for its migraine candidate

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HYDERABAD, India & PRINCETON, N.J.--([EON: Enhanced Online News](#))--Dr. Reddy's Laboratories Ltd (BSE: 500124, NSE: DRREDDY, NYSE: RDY) and its subsidiary, Promius Pharma, LLC today announced the filing of New Drug Application (NDA) for its migraine candidate DFN-02 with the U.S. Food and Drug Administration (USFDA).

“Acute migraine attacks are typically associated with pain and symptoms, such as nausea, photophobia, and phonophobia. It is important that an effective migraine treatment helps address associated symptoms. Equally important is having a well-tolerated treatment that provides patients a satisfactory resolution of their migraine attack.”

According to Dr. Anil Namboodiripad, Senior Vice President, Proprietary Products and President, Promius Pharma, the NDA for DFN-02 is an important step forward in the company's mission to bring solutions that address unmet needs.

“The filing of DFN-02 NDA represents our continuing commitment to bring innovative solutions in migraine treatment,” explains Dr. Namboodiripad. “Acute migraine attacks are typically associated with pain and symptoms, such as nausea, photophobia, and phonophobia. It is important that an effective migraine treatment helps address associated symptoms. Equally important is having a well-tolerated treatment that provides patients a satisfactory resolution of their migraine attack.”

In a multicenter, double-blind, randomized, placebo controlled study with 107 subjects (Clinicaltrials.gov # NCT02856802), DFN-02 has demonstrated that it can effectively treat pain and associated symptoms during a migraine attack and reduce attack-related functional disability. Data from this study show that there was a significantly higher proportion of subjects who experienced 2-hour pain freedom with DFN-02 compared with placebo: 43.8% (n=48) versus 22.5% (n=40), $p < .05$). DFN-02 was also significantly better than placebo at alleviating the patients' most bothersome symptom (MBS), including nausea, photophobia, and phonophobia (70.7% versus 39.5% MBS free at 2 hours postdose; $p < .01$). DFN-02 was well tolerated, with the following Treatment-Emergent Adverse Events: dysgeusia (n = 4), application site pain (n = 2), chest discomfort, burning sensation, rhinorrhea and malaise (n = 1 each), all mild to moderate.

Upon approval, the product will be commercialized by Promius Pharma.

About DFN-02

DFN-02 is a novel intranasal spray formulation currently patented in 11 countries (total of 13 issued patents) composed of sumatriptan 10 mg and Aegis Therapeutics, LLC permeation-

enhancing technology known as Intravail®. DFN-02 is a novel investigational intranasal formulation in development for the acute treatment of migraine with or without aura. This formulation of DFN-02 allows sumatriptan to be rapidly absorbed into the systemic circulation, and it exhibits pharmacokinetics comparable to subcutaneously administered sumatriptan.

Intravail® is a registered trademark of Aegis Therapeutics, LLC.

About Promius Pharma LLC

Promius Pharma is a wholly owned subsidiary of Dr. Reddy's Laboratories, one of the largest and most respected pharmaceutical companies in the world. With a robust commercial infrastructure and extensive research and development capabilities through its parent company, Promius Pharma is committed to bringing new products to market that meet patients' needs in dermatology and neurology. For more information, visit www.promiuspharma.com.

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: www.drreddys.com.

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.

The company assumes no obligation to update any information contained herein.

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