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Dr Reddy's, Promius Pharma file NDA for DFN-02 to treat migraine

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Dr. Reddyâ??s Laboratories Ltd 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)



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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," Namboodiripad said.

"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," he added.

In a multicentre, double-blind, randomised, placebo controlled study with 107 subjects, DFN-02 has demonstrated that it can effectively treat pain and associated symptoms during a migraine attack, the Hyderabad-based Dr Reddy's claimed in a statement.

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