

**Press Release**

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## **Promius Pharma Announces Positive Results for Phase 2 Study of DFN-02, a Novel Intranasal Formulation of Sumatriptan**

Princeton, NJ, USA. June 6, 2017 – Promius Pharma LLC announced today that its Phase 2 study of DFN-02, a novel intranasal migraine treatment under clinical development for the acute treatment of adults with migraine with or without aura, met its primary endpoint.

In this multicenter, double-blind study (Clinicaltrials.gov # NCT02856802), episodic migraine patients were randomized to receive either DFN-02 or placebo to treat a migraine attack with a moderate or severe pain level. The primary endpoint was the proportion of subjects with migraine pain freedom at 2 hours postdose (2hPF).

There was a significantly higher proportion of subjects who experienced 2hPF with DFN-02 compared with placebo: 43.8% (n=48) versus 22.5% (n=40),  $P<0.05$ . 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 2h postdose;  $P<0.01$ ). DFN-02 was well tolerated, with only 5 of 50 subjects reporting a mild or moderate adverse event.

"The positive data from this Phase 2 study indicate promise for DFN-02," said Anil Namboodiripad, PhD, Senior Vice President, Proprietary Products and President, Promius Pharma. "Scientific research, like this study, is essential to addressing the unmet needs of migraine patients."

"Patients need multiple forms of treatment to deal with episodic variability of migraine attacks," says Dr Merle Diamond, President and Managing Director of the Diamond Headache Clinic, who did not participate in this study. "DFN-02 Phase 2 results suggest that it may become a welcome option for migraine sufferers."

Additional data from the DFN-02 studies are being submitted for presentation at the International Headache Conference to be held in Vancouver in September 2017.

### **About DFN-02**

DFN-02 is a novel intranasal spray formulation composed of sumatriptan 10 mg and a permeation-enhancing excipient 0.2% 1-O-n-Dodecyl- $\beta$ -D-Maltopyranoside (DDM). This formulation of DFN-02 allows sumatriptan to be rapidly absorbed into the systemic circulation, and it exhibits pharmacokinetics comparable to subcutaneously administered sumatriptan. DFN-02 is being developed for the acute treatment of migraine with or without aura.

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 reorganisation, including related integration issues. The company assumes no obligation to update any information contained herein.

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**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](http://www.promiuspharma.com).

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