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Promius Pharma Presents Positive Results for Phase 2 Study of DFN-02, a Novel Intranasal Formulation of Sumatriptan, at 18th Congress of the International Headache Society

Princeton, NJ, USA. September 7, 2017 – Promius Pharma, LLC will present the previously announced (June 7, 2017) primary endpoint results of its Phase 2 study of DFN-02, a novel intranasal sumatriptan formulation under clinical development for the acute treatment of adults with migraine with or without aura, at the 18th Congress of the International Headache Society in Vancouver, BC, Canada, September 7-10, 2017.

In this multicenter, double-blind study (Clinicaltrials.gov # NCT02856802), 107 subjects with episodic migraine 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).

This data, previously released and presented in abstract #813, shows that 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), $P<.05$. 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; $P<.01$).

- A significantly higher proportion of subjects taking DFN-02 (38.9%; n=14/36) were pain free from 2 to 24 hours versus subjects taking placebo (13.8%; 4/29), $P=.029$
- A significantly higher proportion of subjects taking DFN-02 were free from their predose reported symptoms at 2 hours postdose compared with placebo: nausea (78.3% versus 42.1%; $P=.026$), photophobia, (71.8% versus 38.9%; $P=.005$) and phonophobia (78.1% versus 40.0%; $P=.004$)
- DFN-02 led to a greater reduction in functional disability (-1.2) compared with placebo (-0.6) at 2 hours postdose, on a 4-point scale, $P<.001$
- Subjects using DFN-02 reported significantly higher overall satisfaction at 2 hours postdose (7-point scale), $P=.003$, and at 24 hours postdose on Patient Perception of Migraine Questionnaire-Revised (PPMQ-R) total score, $P=.016$, compared with placebo-treated subjects
- Subjects using DFN-02 reported significantly higher satisfaction at 24 hours postdose on the PPMQ-R total score compared with the subjects' PPMQ-R taken at baseline about their usual migraine medication, $P=.012$

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- The proportion of subjects who had sustained headache pain freedom at 2 to 24 hours after the first dose of study medication in the first double-blind period (DB1) was significantly higher for DFN-02 than placebo (13.8% vs 38.9%, *P*=.029). The proportion of subjects who used a second dose of study medication or rescue medication between 2 to 24 hours postdose was significantly lower in the DFN-02 (12.2%) treatment group compared to placebo (48.8%), *P*<.001
- The rate of dysgeusia was low, experienced by one subject (2%) in DB1 and by 3 subjects (8.1%) in DB2, all treated with DFN-02. There were no treatment-emergent adverse events (TEAEs) reported in the placebo treatment groups

DFN-02 was well tolerated, with the following TEAEs: Dysgeusia (n = 4), application site pain (n = 2), chest discomfort, burning sensation, rhinorrhea and malaise (n = 1 each), all mild to moderate.

“Acute migraine attacks are typically associated with pain and other symptoms, such as nausea, photophobia, and phonophobia. It is important that any treatment be shown to be effective in treating pain and these symptoms to help a person get back to functionality," said Anil Namboodiripad, PhD, Senior Vice President, Proprietary Products and President, Promius Pharma. “In this study, DFN-02 has demonstrated that it can effectively treat pain and associated symptoms during a migraine attack and reduce attack-related functional disability. Patients in this study reported satisfaction with DFN-02 and it was well tolerated with few reported adverse events.”

“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.”

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 excipient known as Intravail®. 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 a novel investigational intranasal formulation in development for the acute treatment of migraine with or without aura.

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

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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.

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