**FDA Approves DFN-02 Nasal Spray For Acute Treatment of Migraine**

The mist-like nasal spray acts rapidly and is well tolerated and is formulated using Intravail to achieve blood levels similar to a 4-mg sumatriptan subcutaneous injection, resulting in rapid onset of action.

Dr. Reddy’s Laboratories and its subsidiary Promius Pharma have announced that the FDA approved DFN-02 (Tosymra) nasal spray for acute treatment of migraine with or without aura in adults.

The therapy is an intranasal spray composed of sumatriptan 10 mg and a permeation-enhancing excipient (Intravail), allowing DFN-02 to be rapidly absorbed into the systemic circulation while exhibiting pharmacokinetics comparable to subcutaneously administered sumatriptan.

“Tosymra nasal spray is formulated using a proprietary novel excipient known as Intravail to achieve blood levels similar to a 4-mg sumatriptan subcutaneous injection, resulting in rapid onset of action,” Anil Namboodiripad, PhD, president, Promius Pharma, said in a statement.1 “Independent research shows that 26% to 40% of migraine patients are not optimally controlled with their current treatment.2 For patients who suffer from the debilitating and disruptive effects of migraine, there continues to be a need for reliable and efficacious treatment options. At Promius, we are committed to developing new ways of improving patient experiences. Tosymra is a mist-like nasal spray that acts rapidly and is well tolerated.”

The new drug application submitted to the FDA was backed by a phase 2 (NCT02856802) randomized, placebo-controlled trial that demonstrated the effectiveness in treating pain and associated symptoms during a migraine attack and in reducing attack-related functional disability in 107 study participants. Eligibility criteria included those participants who have had a history of episodic migraine experiencing an average of 2 to 8 migraine attacks per month for at least the past 12 months, with no more than 14 headache days per month, and with 48 hours of headache free time between migraine headaches; those who have migraine with or without aura; and those who are willing and able to evaluate and record pain, migraine symptoms and study medication for the duration of the study, record each instance of the use of study medication and rescue medication for the duration of the study, and comply with all other study procedures and scheduling requirements. The primary outcome measure included the proportion of participants who are pain-free at 2 hours post-dose in the first double-blind treatment period.

A majority of study participants treated with DFN-02 experienced a 2-hour pain freedom compared to placebo (43.8% vs. 22.5%; P <.07). Additionally, treatment with the therapy significantly alleviated the most bothersome symptom, which included nausea, photophobia, and phonophobia, compared to placebo (70.7% vs. 39.5% most bothersome symptom-free at 2 hours post-dose; P <.01). Overall, DFN-02 was well tolerated, with the following treatment-emergent adverse effects dysgeusia (n=4), application site pain (n=2), chest discomfort, burning sensation, rhinorrhea, and malaise (n=1 each), all mild to moderate.

Similarly, to other sumatriptan products, DFN-02 is contraindicated in those with a history of coronary artery disease or coronary artery vasospasm; Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or history of hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; or severe hepatic impairment. It is not known if DFN-02 is safe and effective in children under 18 years of age.