RXADVANCE
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NEW DRUG APPROVAL

Brand Name	Nurtec™ ODT
Generic Name	rimegepant
Drug Manufacturer	Biohaven Pharmaceuticals, Inc.

New Drug Approval

FDA Approval date: February 27, 2020
Review Designation: Priority
Review Type: New Drug Application 212728

Place in Therapy

DISEASE DESCRIPTION & EPIDEMIOLOGY

A migraine is a type of headache that, in addition to pain, can be associated with nausea, vomiting, and sensitivity to light or sound. Some patients may experience an aura, which may consist of a temporary visual disturbance, or other symptoms shortly before the onset of the headache.

In the United States, more than 30 million people have 1 or more migraine headaches per year. This corresponds to approximately 18% of females and 6% of males. Migraine accounts for 64% of severe headaches in females and 43% of severe headaches in males.

Approximately 75% of all persons who experience migraines are women. Currently, 1 in 6 American women has migraine headaches. (The reported incidence of migraine in females of reproductive age has increased over the last 20 years, but this change probably reflects greater awareness of the condition.)

Before puberty, the prevalence and incidence of migraine are higher in boys than in girls. After age 12 years, the prevalence increases in males and females, reaching a peak at age 30–40 years. The female-to-male ratio increases from 2.5:1 at puberty to 3.5:1 at age 40 years. Attacks usually decrease in severity and frequency after age 40 years, except for women in perimenopause. A study by Hsu et al suggests that women aged 40–50 years are also more susceptible to migrainous vertigo. Onset of migraine after age 50 years is rare.

Efficacy

Study 1 (NCT03461757)

The efficacy of Nurtec ODT for the acute treatment of migraine with and without aura in adults was demonstrated in a randomized, double-blind, placebo-controlled trial.

The study randomized patients to 75 mg of NURTEC ODT (N=732) or placebo (N=734). Patients were instructed to treat a migraine of moderate to severe headache pain intensity. Rescue medication (i.e., NSAIDs, acetaminophen, and/or an antiemetic) was allowed 2 hours after the initial treatment. Other forms of rescue medication such as triptans were not allowed within 48 hours of initial treatment. Approximately 14% of patients were taking preventive medications for migraine at baseline. None of the patients in Study 1 were on concomitant preventive medication that act on the CGRP pathway.

The primary efficacy analyses were conducted in patients who treated a migraine with moderate to severe pain. NURTEC ODT 75 mg demonstrated an effect on pain freedom and most bothersome symptom (MBS) freedom at two hours after dosing, compared to placebo. Pain freedom was defined as a reduction of moderate or severe headache pain to no headache pain, and MBS freedom was defined as the absence of the self-identified MBS (i.e.,

photophobia, phonophobia, or nausea). Among patients who selected an MBS, the most commonly selected symptom was photophobia (54%), followed by nausea (28%), and phonophobia (15%).

In Study 1, the percentage of patients achieving headache pain freedom and MBS freedom two hours after a single dose was statistically significantly greater in patients who received NURTEC ODT compared to those who received placebo.

In Study 1, statistically significant effects of NURTEC ODT compared to placebo were demonstrated for the additional efficacy endpoints of pain relief at 2 hours, sustained pain freedom 2-48 hours, use of rescue medication within 24 hours, and the percentage of patients reporting normal function at two hours after dosing.

Pain relief was defined as a reduction in migraine pain from moderate or severe severity to mild or none. The measurement of the percentage of patients reporting normal function at two hours after dosing was derived from a single item questionnaire, asking patients to select one response on a 4-point scale; normal function, mild impairment, severe impairment, or required bedrest.

Safety

ADVERSE EVENTS

1% to 10%: Gastrointestinal: Nausea (2%)

<1%: Dermatologic: Skin rash

Hypersensitivity: Hypersensitivity reaction

Respiratory: Dyspnea

Frequency not defined: Hypersensitivity: Type IV hypersensitivity reaction

WARNINGS & PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including dyspnea, rash, and delayed serious reactions, have been reported; discontinue therapy if hypersensitivity occurs.

CONTRAINDICATIONS

Hypersensitivity to rimegepant or any component of the formulation.

Clinical Pharmacology

MECHANISMS OF ACTION

Rimegepant is a calcitonin gene-related peptide receptor antagonist.

Dose & Administration

ADULTS

Migraine, treatment: Oral: 75 mg as a single dose; maximum: 75 mg/24 hours. The safety of treating >15 migraines in a 30-day period has not been established.

Dosage adjustment for concomitant therapy: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

PEDIATRICS

Safety and effectiveness in pediatric patients have not been established.

GERIATRICS

Same as adult

RENAL IMPAIRMENTRETEVMO (SELPERCATINIB)

CrCl ≥15 mL/minute: No dosage adjustment necessary.

CrCl <15 mL/minute: Avoid use (has not been studied).

Patients on dialysis: Avoid use (has not been studied)

HEPATIC IMPAIRMENT

Mild to moderate impairment (Child-Pugh class A, B): No dosage adjustment necessary.

Severe impairment (Child-Pugh class C): Avoid use

Product Availability

DOSAGE FORM(S) & STRENGTH(S)

Nurtec ODT orally disintegrating tablets: 75 mg