

## Zavzpret<sup>™</sup> (zavegepant) – New drug approval

- On March 10, 2023, [Pfizer announced](#) the FDA approval of [Zavzpret \(zavegepant\)](#), for the acute treatment of migraine with or without aura in adults.
  - Zavzpret is not indicated for the preventive treatment of migraine.
- Zavzpret is the first FDA approved intranasal formulation of a calcitonin gene-related peptide (CGRP) receptor antagonist.
- The efficacy of Zavzpret was established in two randomized, double-blind, placebo-controlled trials (Study 1 [N = 1,269] and Study 2 [N = 792]). In both studies, patients were instructed to treat a migraine (with either Zavzpret or placebo) of moderate to severe headache pain intensity. Rescue medication (ie, 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. The coprimary endpoints were pain freedom and most bothersome symptom (MBS) freedom at 2 hours after a single dose, compared to placebo. MBS freedom was defined as the absence of the self-identified MBS (ie, photophobia, phonophobia, or nausea).
  - In Study 1, pain freedom at 2 hours was observed in 23.6% of patients receiving Zavzpret and 14.9% of patients receiving placebo ( $p < 0.001$ ). MBS freedom at 2 hours was observed in 39.6% of patients receiving Zavzpret and 31.1% of patients receiving placebo ( $p = 0.001$ ).
  - In Study 2, pain freedom at 2 hours was observed in 22.5% of patients receiving Zavzpret and 15.5% of patients receiving placebo ( $p = 0.011$ ). MBS freedom at 2 hours was observed in 41.9% of patients receiving Zavzpret and 33.7% of patients receiving placebo ( $p = 0.016$ ).
- A warning and precaution for Zavzpret are hypersensitivity reactions.
- The most common adverse reactions ( $\geq 2\%$  of patients treated with Zavzpret and greater than placebo) with Zavzpret use were taste disorders, nausea, nasal discomfort, and vomiting.
- The recommended dose of Zavzpret is 10 mg given as a single spray in one nostril, as needed.
  - The maximum dose that may be given in a 24-hour period is 10 mg (one spray).
  - The safety of treating more than 8 migraines in a 30-day period has not been established.
- Pfizer plans to launch Zavzpret in July 2023. Zavzpret will be available as a 10 mg nasal spray device (in cartons containing 6 devices).