Pfizer’s ZAVZPRET™ (zavegepant) Migraine Nasal Spray Receives FDA Approval

Friday, March 10, 2023 - 06:45am

.q4default .bwalignc { text-align: center; list-style-position: inside }.q4default .bwlistdecimal { list-style-type: decimal }.q4default .bwuline { text-decoration: underline }

ZAVZPRET is the first and only calcitonin gene-related peptide (CGRP) receptor antagonist nasal spray for the acute treatment of migraine in adults

Expands Pfizer’s migraine portfolio, which includes an oral therapy for both acute and preventive treatment, to further meet the needs of people living with this debilitating disease

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced the U.S. Food and Drug Administration (FDA) has approved ZAVZPRET™ (zavegepant), the first and only calcitonin gene-related peptide (CGRP) receptor antagonist nasal spray for the acute treatment of migraine with or without aura in adults. In its pivotal Phase 3 study, ZAVZPRET was statistically superior to placebo on the co-primary endpoints of pain freedom and freedom from most bothersome symptom at two hours post-dose. The pivotal study also demonstrated pain relief as early as 15 minutes in a prespecified secondary endpoint versus placebo.

“The FDA approval of ZAVZPRET marks a significant breakthrough for people with migraine who need freedom from pain and prefer alternative options to oral medications,” said Angela Hwang, Chief Commercial Officer, President, Global Biopharmaceuticals Business, Pfizer. “ZAVZPRET underscores Pfizer’s commitment to delivering an additional treatment option to help people with migraine gain relief and get back to their daily lives. Pfizer will continue to build its migraine franchise to further support the billions of people worldwide impacted by this debilitating disease.”

The FDA approval is based on two pivotal randomized, double-blind, placebo-controlled studies that established the efficacy, tolerability and safety profiles of ZAVZPRET for the acute treatment of migraine. In these studies, ZAVZPRET was statistically superior to placebo on the co-primary endpoints of pain freedom (defined as a reduction of moderate or severe headache pain to no headache pain) and freedom from most bothersome symptom at two hours post-dose (defined as the absence of the self-identified most bothersome symptom). The pivotal Phase 3 study published in The Lancet Neurology found ZAVZPRET showed broad efficacy by also demonstrating statistically significant superiority to placebo across 13 of 17 prespecified secondary outcome measures, including early time point endpoints (e.g., 15 and 30-minute pain relief and return to normal function at 30 minutes), return to normal function at 2 hours, and durable efficacy endpoints (e.g., 2-24 and 2-48 hour sustained pain freedom and sustained pain relief). On the 14th endpoint, return to normal function at 15 minutes post-dose, the difference between ZAVZPRET and placebo was not significant. Consequently, in keeping with the trial's statistical analysis plan, the remaining secondary endpoints were not formally tested.

"When a migraine hits, it has a significant negative impact on a person's daily life," said Kathleen Mullin, M.D., Associate Medical Director at New England Institute for Neurology & Headache. "Among my migraine patients, one of the most important attributes of an acute treatment option is how quickly it works. As a nasal spray with rapid drug absorption, ZAVZPRET offers an alternative treatment option for people who need pain relief or cannot take oral medications due to nausea or vomiting, so they can get back to normal function quickly."

ZAVZPRET was well tolerated in clinical trials. The most common adverse reactions reported in at least 2% of patients treated with ZAVZPRET and at a frequency greater than placebo were taste disorders (includes dysgeusia and ageusia), nausea, nasal discomfort and vomiting. ZAVZPRET is contraindicated in patients with a history of hypersensitivity to zavegepant or to any of its components. Hypersensitivity reactions, including facial swelling and urticaria, have occurred with ZAVZPRET in clinical studies.

ZAVZPRET is anticipated to be available in pharmacies in July 2023.

About Migraine Nearly 40 million people in the United States suffer from migraine1 and the World Health Organization classifies migraine as the second leading cause of disability in the world.2 Migraine is characterized by debilitating attacks lasting four to 72 hours with multiple symptoms, including pulsating headaches of moderate to severe pain intensity often associated with nausea or vomiting, and/or sensitivity to sound

(phonophobia) and sensitivity to light (photophobia).3

About CGRP Receptor Antagonism Small molecule CGRP receptor antagonists represent a novel class of drugs for the treatment of migraine. For acute treatment, this unique mode of action offers an alternative to other agents, including those patients who have contraindications to the use of triptans or who have a poor response to triptans or are intolerant to them. CGRP signal-blocking therapies have not been associated with medication overuse headache (MOH) or rebound headache, which can limit the clinical utility of other acute treatments.

About ZAVZPRET Zavegepant is a third generation, high affinity, selective and structurally unique, small molecule CGRP receptor antagonist and the only CGRP receptor antagonist in clinical development with both intranasal and oral formulations.

INDICATION

ZAVZPRET™ (zavegepant) is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use: ZAVZPRET is not indicated for the preventive treatment of migraine.

IMPORTANT SAFETY INFORMATION

Contraindications: Hypersensitivity to ZAVZPRET or any of its components.

Warnings and Precautions: Hypersensitivity reactions, including facial swelling and urticaria, have occurred with ZAVZPRET. If a hypersensitivity reaction occurs, discontinue ZAVZPRET and initiate appropriate therapy.

Adverse Reactions: Most common adverse reactions (occurring in ≥2% of patients treated with ZAVZPRET and greater than placebo) for ZAVZPRET vs placebo were taste disorders including dysgeusia and ageusia (18% vs 4%), nausea (4% vs 1%), nasal discomfort (3% vs 1%), and vomiting (2% vs 1%).

Drug Interactions: Avoid use with drugs that inhibit or induce OATP1B3 or NTCP transporters. Avoid use of intranasal decongestants; if unavoidable, administer intranasal decongestants at least 1 hour after ZAVZPRET administration.

Use in Specific Populations: Hepatic Impairment: Avoid use in patients with severe hepatic impairment. Renal impairment: Avoid use of ZAVZPRET in patients with creatine clearance (CLcr) less than 30 mL/min.

Please click here for full Prescribing Information.

About Pfizer: Breakthroughs That Change Patients' Lives At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice The information contained in this release is as of March 10, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about ZAVZPRET™ (zavegepant), including an approval in the U.S. for the acute treatment of migraine with or without aura in adults, the timing of anticipated availability and its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of ZAVZPRET; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when applications may be filed in particular jurisdictionsfor ZAVZPRET for the acute treatment of migraine with or without aura in adults or any other potential indications; whether and when regulatory authorities may approve any such applications for ZAVZPRET that may be pending or filed, which will depend on a myriad of factors, including making a determination as to whether the product's benefits outweigh its known risks and

determination of the product’s efficacy and, if approved, whether ZAVZPRET will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of ZAVZPRET; uncertainties regarding the impact of COVID-19 on Pfizer’s business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

References:

Buse et al. Burden of Illness Among People with Migraine and ≥ 4 Monthly Headache Days While Using Acute and/or Preventive Prescription Medications for Migraine. Journal of Managed Care & Specialty Pharmacy. 2020;26(10):1334-1343. GBD 2016 Headache Collaborators. Global, regional, and national burden of migraine and tension-type headache, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol 2018;17(11):954-976. Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. Cephalalgia. 2018;38(1):1–211.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230309005795/en/

Media Contact: +1 (212) 733-1226 PfizerMediaRelations@Pfizer.com

Investor Contact: +1 (212) 733-4848 IR@Pfizer.com

Source: Pfizer Inc.