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Pfizer Announces The Lancet Neurology Has Published Phase 3 Data for Zavegepant for the Acute Treatment of Migraine in Adults

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- *Zavegepant is the first and only calcitonin gene-related peptide (CGRP) receptor antagonist in development as an intranasal formulation studied in a Phase 3 trial*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced publication of results in *The Lancet Neurology*from the Phase 3 pivotal clinical trial of zavegepant, an investigational calcitonin gene-related peptide (CGRP) receptor antagonist nasal spray for the acute treatment of migraine. The study met its co-primary endpoints, showing that a single 10 mg dose of zavegepant was more effective than placebo for both pain freedom and freedom from the most bothersome symptom (MBS) at two hours post-dose. Additionally, zavegepant demonstrated relief from migraine pain in 15 minutes, with relief lasting up to 48 hours for many patients. Zavegepant was well tolerated, and there were no serious adverse events reported in treated participants.

“The results from this study demonstrate zavegepant’s potential as an effective acute nasal spray treatment for migraine, a neurological disorder that affects more than one billion people worldwide,” said Richard B. Lipton, M.D., Lead Author, Department of Neurology at the Albert Einstein College of Medicine. “This was the first Phase 3 clinical trial of a non-oral CGRP receptor antagonist developed for the acute treatment of migraine in adults. With this evidence of sustained treatment benefits, good tolerability and an alternative administration method, I believe zavegepant has the potential to fill an important gap in the available options for the acute treatment of migraine.”

In the trial, 1,405 people were randomized to receive a single 10 mg dose of either zavegepant or placebo. Participants historically experienced two to eight moderate or severe migraine attacks per month, and their untreated attacks lasted a mean of 30.8 hours. During the study, participants recorded their migraine headache pain intensity based on a four-point scale, identified their current MBS associated with migraine (selected from phonophobia, photophobia or nausea) and recorded their level of functional disability immediately before dosing the treated attack and at various intervals post-dose.

Zavegepant was demonstrated to be effective in the acute treatment of migraine, as measured by superiority to placebo on the co-primary efficacy endpoints of pain freedom (24% vs 15%, P<0·0001) and freedom from the MBS (40% vs 31%, P=0·0012) at two hours post-dose. Additionally, zavegepant was more effective than placebo on 13 of the 17 secondary endpoints, including treatment benefits for pain relief beginning as early as 15 minutes and sustained pain relief from two through 48 hours post-dose. On the 14th endpoint, return to normal function at 15 minutes post-dose, the difference between zavegepant and placebo was not significant. Consequently, in keeping with the analysis plan, the remaining secondary endpoints were not formally tested.

Treatment with zavegepant was also associated with higher rates of return to normal functional ability at 30 minutes post treatment and two hours.

Zavegepant was well tolerated in this study. The most common adverse events (AE) in either treatment group (? 2%) were dysgeusia (an altered sense of taste), occurring in 20.5% of zavegepant patients as compared to 4.7% of patients on placebo, nasal discomfort, occurring in 3.7% of zavegepant patients as compared to 0.8% of patients on placebo, and nausea, occurring in 3.2% of zavegepant patients and 1.1% of patients on placebo. The AE safety profile was consistent with earlier studies of zavegepant. There were no serious AEs reported in treated participants, and no signal of hepatotoxicity due to zavegepant was identified in the trial.

“The intranasal formulation for zavegepant embodies breakthrough innovation in patient-centric drug development,” said James Rusnak, M.D., Ph.D., Senior Vice President, Chief Development Officer, Internal Medicine and Hospital, Global Product Development, Pfizer. “If approved by the FDA, zavegepant has the potential to be a significant new treatment option for people with migraine, particularly those who desire fast-acting relief or would benefit from an alternative delivery method. We are excited by the momentum the publication of these study results offers, as we anticipate potentially bringing a new medical breakthrough to millions of people suffering from migraine in the U.S.”

About Zavegepant

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. The New Drug Application (NDA) was filed for intranasal zavegepant with the U.S. Food and Drug Administration for the acute treatment of migraine in adults. The Prescription Drug User Fee Act (PDUFA) goal date for completion of the FDA review of the NDA is set for 1Q2023.

About Migraine

Nearly 40 million people in the U.S. suffer from migraine[1] and the World Health Organization classifies migraine as one of the 10 most disabling medical illnesses.[2] Migraine is characterized by debilitating attacks lasting four to 72 hours with multiple symptoms, including pulsating headaches of moderate to severe pain intensity that can be 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 potentially offers an alternative to other agents, particularly for 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 headaches which can limit the clinical utility of other acute treatments.

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.

Disclosure Notice

The information contained in this release is as of February 16, 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 zavegepant, including a potential indication in the U.S. for the acute treatment of migraine with or without aura in adults, including 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, 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 any additional jurisdictions for intranasal zavegepant for acute treatment of migraine in adults or in any jurisdictions for any other potential indications for zavegepant; whether and when the FDA may approve the new drug application for intranasal zavegepant for acute treatment of migraine in adults and whether and when regulatory authorities in any jurisdictions may approve any such other applications for zavegepant that may be pending or filed, which will depend on myriad 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 zavegepant 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 zavegepant; 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, 2021 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:

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2. 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.

3. Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1–211.

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