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Pfizer and Biohaven's VYDURA® (Rimegepant) Granted First Ever Marketing Authorization by European Commission for Both Acute Treatment of Migraine and Prophylaxis of Episodic Migraine

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NEW YORK & NEW HAVEN, Conn.--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN) today announced that the European Commission (EC) has granted marketing authorization for VYDURA® (rimegepant), a calcitonin gene-related peptide (CGRP) receptor antagonist for both the acute treatment of migraine with or without aura, and prophylaxis of episodic migraine in adults who have at least four migraine attacks per month. VYDURA®, an orally disintegrating tablet, is the first medicine approved for both acute and prophylactic treatment of migraine in the European Union (EU). Migraine is a leading cause of disability worldwide with approximately one in ten people living with the condition in Europe alone. Globally, migraine disproportionately affects women by three to four times compared to men.

"There is a significant unmet need for people in the European Union living with the pain and disability caused by frequent migraines," said Nick Lagunowich, Global President, Pfizer Internal Medicine. "The comprehensive clinical program has established VYDURA's efficacy and safety as both an acute and preventive treatment of migraine. Studies in acute migraine demonstrated a rapid and long-lasting relief of migraine headache and other symptoms with a single dose, while the prevention study found a significant reduction in migraine attacks with every other day dosing. We have great confidence in the positive impact VYDURA could have on people living with this debilitating condition in the EU."

Results from the Phase 3 study published in *Lancet* demonstrated that a single dose of rimegepant provided superior pain reduction and associated symptoms of migraine at two hours compared to placebo. The prevention study, also published in *Lancet*, demonstrated that rimegepant taken every other day provided superior reduction in the number of days per month with migraine in Weeks 9 –12 of the 12-week treatment period compared to placebo, that was maintained with continued dosing during the 12-month open-label extension period.

"Today's approval marks a huge step forward for patients in Europe who are living with migraine. Migraine is often overlooked and undertreated, resulting in substantial disability with suboptimal care for patients," commented Professor Peter Goadsby, Director of the National Institute for Health and Care Research (NIHR) Clinical Research Facility and Professor of Neurology at King's College London. "VYDURA's promising efficacy and favorable benefit-risk profile spark hope for people in need of new migraine treatment options. This approval has the potential to advance the standard of care for migraine in the EU and I am hopeful it will improve the quality of life for many people living with the burden of this prevalent neurological disease."

The Marketing Authorization follows the recommendation for approval by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in February. The EC approval will be valid for all 27 EU member states as well as Iceland, Liechtenstein, and Norway and local reimbursement approval will follow. Assessment of the marketing authorization application by the Medicines & Healthcare products Regulatory Agency (MHRA) is underway and approval is expected to shortly follow in the United Kingdom.

About VYDURA® (rimegepant)
VYDURA® targets a key component of migraine by reversibly blocking CGRP receptors. CGRP is increased during a migraine attack, dilates blood vessels and is involved in nociceptor signaling. CGRP receptor antagonists work by reversibly blocking CGRP receptors, thereby inhibiting the biologic activity of the endogenous CGRP neuropeptide.

The Marketing Authorization for VYDURA® was based, in part, on the review of the results from three Phase 3 studies for acute treatment, a long-term, open-label safety study in acute treatment of migraine and a Phase 3 study with a 1-year open-label extension in the preventive treatment of migraine. VYDURA® is taken orally as needed, up to once daily, to stop migraine attacks or taken every other day to help prevent migraine attacks.

The most frequent adverse event in clinical trials with VYDURA® was nausea, occurring in 3% of patients compared to 1% with placebo, while hypersensitivity reactions including rash occurred in less than 1% of patients. Less than 2% of patients discontinued from VYDURA® due to adverse events. VYDURA® does not have addiction potential and was not associated with medication overuse headache or rebound headache in clinical trials, although overuse of any type of medicinal products for headache can make them worse.

VYDURA® is commercialized as Nurtec® and Nurtec® ODT outside Europe. It is commercialized in the U.S. for the acute treatment of migraine and for the preventive treatment of episodic migraine in adults, and ex-U.S. is approved for the acute treatment of migraine in Kuwait and the United Arab Emirates, and for acute treatment of migraine and preventive treatment of episodic migraine in Israel.

Earlier this year, Pfizer and Biohaven entered into an agreement for the commercialization of VYDURA®. Under the terms of the agreement, Pfizer has commercialization rights to rimegepant in markets outside the U.S. Biohaven continues to lead research and development globally and retains the U.S. market.

About Migraine
More than one billion people worldwide suffer from migraine. 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). There is a significant unmet need for new treatments as more than 90 per cent of people with migraine are unable to work or function normally during an attack.

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 www.Pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of April 27, 2022. 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 VYDURA® (rimegepant) 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 any applications may be filed for rimegepant in any other jurisdictions; whether and when regulatory authorities may approve any applications that may be pending or filed for rimegepant in any jurisdictions, which will depend on a 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 rimegepant 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 rimegepant; whether the collaboration between Pfizer and Biohaven will be successful; 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.

About Biohaven
Biohaven is a commercial-stage biopharmaceutical company with a portfolio of innovative, best-in-class therapies to improve the lives of patients with debilitating neurological and neuropsychiatric diseases, including rare disorders. Biohaven's Neuroinnovation™ portfolio includes FDA-approved Nurtec® (rimegepant) for the acute and preventive treatment of migraine and a broad pipeline of late-stage product candidates across three distinct mechanistic platforms: CGRP receptor antagonism for the acute and preventive treatment of migraine; glutamate modulation for obsessive-compulsive disorder, and spinocerebellar ataxia; MPO inhibition for amyotrophic lateral sclerosis; and Kv7 Ion Channel Activators (Kv7), and myostatin. More information about Biohaven is available at www.biohavenpharma.com.

Forward-Looking Statements
This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve substantial risks and uncertainties, including statements regarding the future development, timing and potential marketing approval and commercialization of VYDURA® (rimegepant). Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements. Additional important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of

Biohaven's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on February 25, 2022, and Biohaven's subsequent filings with the Securities and Exchange Commission. The forward-looking statements are made as of this date and Biohaven does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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