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Biohaven and Pfizer Receive Positive CHMP Opinion for Migraine Treatment

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NEW HAVEN, Conn. and NEW YORK – February 25, 2022 /PRNewswire/ -- Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN) and Pfizer Inc. (NYSE: PFE) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for rimegepant, a calcitonin gene-related peptide (CGRP) receptor antagonist, recommending the 75 mg dose of rimegepant (available as an orally dissolving tablet) for marketing authorization for both the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month.

The CHMP's positive opinion will now be reviewed by the European Commission (EC). The decision on whether to approve rimegepant, whose European Union (EU) trade name will be VYDURA™, will be made by the EC and would be valid in all 27 EU member states as well as in Iceland, Lichtenstein, and Norway. If approved, rimegepant will be the first oral CGRP receptor antagonist in the EU, and the only migraine medication approved for both acute and preventive treatment.

"This expression of confidence in rimegepant brings us closer to our goal of helping patients suffering from this debilitating neurological disease find appropriate treatment," said Nick Lagunowich, Global President, Pfizer Internal Medicine. "Pfizer is proud to have a strong footprint in Europe, which will help bring this important potential new treatment option to millions of adults in Europe living with migraine."

The CHMP positive opinion was based on the review of the results from three Phase 3 studies and 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. In these studies, rimegepant was safe and well-tolerated with rates of adverse events similar to that of placebo.

"The recommendation for rimegepant marks an important milestone for the migraine community," said Vlad Coric, M.D., Chief Executive Officer and Chairman of the Board of Biohaven. "Together with Pfizer, we are dedicated to helping patients and hope to provide rimegepant to patients in Europe soon, and eventually those worldwide, who are living with this debilitating disease, many of whom do not have satisfactory treatment options today."

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

About Rimegepant
Rimegepant targets a key component of migraine by reversibly blocking CGRP receptors, thereby inhibiting the biologic cascade that results in a migraine attack. A single, quick-dissolving tablet of 75 mg rimegepant provides

fast pain relief, significant pain reduction and return to normal function, and has a lasting effect of up to 48 hours in many patients. Rimegepant is taken orally as needed, up to 18 doses/month to stop migraine attacks or taken every other day to help prevent migraine attacks and reduce the number of monthly migraine days. Rimegepant does not have addiction potential and was not associated with medication overuse headache or rebound headache in clinical trials.

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

About Migraine
More than one billion people worldwide suffer from migraine and the World Health Organization classifies migraine as one of the 10 most disabling medical illnesses. 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 percent of people with migraine are unable to work or function normally during an attack.

CGRP Receptor Antagonism
Small molecule CGRP receptor antagonists represent a novel class of drugs for the treatment of migraine. CGRP receptor antagonists work by reversibly blocking CGRP receptors, thereby inhibiting the biologic activity of the CGRP neuropeptide. 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 limit the clinical utility of other acute treatments due to increases in migraine attacks that result from frequent use.

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 @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 February 25, 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 rimegepant, and a collaboration agreement between Pfizer and Biohaven for commercialization of rimegepant outside the U.S., including their 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 (including the application for rimegepant pending with the European Medicines Agency), 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 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 ODT (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, Alzheimer's disease, and spinocerebellar ataxia; and MPO inhibition for amyotrophic lateral sclerosis. 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 March 1, 2021, 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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