Pfizer Logo

Biohaven and Pfizer Announce Positive Top-Line Results of Pivotal Trial of Rimegepant for the Acute Treatment of Migraine in China and South Korea

Monday, February 14, 2022 - 07:00am

NEW HAVEN, Conn. and NEW YORK - February 14, 2022 /PRNewswire/ -- Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN) and Pfizer Inc. (NYSE: PFE), today announced positive top-line results from an Asia-Pacific, Phase 3 clinical trial of rimegepant in 1,431 adults for the acute treatment of migraine. Led by BioShin Limited, a subsidiary of Biohaven in China and South Korea, the randomized, regional, multi-center study met the co-primary endpoints evaluating the efficacy and safety of the orally dissolving tablet (ODT) formulation of rimegepant, an oral calcitonin gene-related peptide (CGRP) receptor antagonist.

This is the fourth positive Phase 3 study of rimegepant for the acute treatment of migraine and the first to be conducted in Asia Pacific. The study met its co-primary endpoints of freedom from pain ($p<0.0001$) and freedom from most bothersome migraine?associated symptom (MBS) including nausea, phonophobia or photophobia ($p<0.0001$) at 2-hours following a single oral dose of rimegepant. In the study, a single oral dose of rimegepant 75 mg provided significant relief of migraine symptoms and return to normal function at 2 hours and delivered sustained efficacy that lasted up to 48 hours for many patients. Rimegepant showed a favorable safety and tolerability profile among study participants that was consistent with prior clinical trial results in the United States. Detailed data from the study will be presented at future medical meetings to help inform ongoing and future research.

Under the terms of the collaboration agreement between Biohaven and Pfizer, 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. Rimegepant is commercialized as Nurtec® ODT in the U.S. and is the only oral CGRP receptor antagonist approved for both the acute and preventive treatment of migraine in adults. An application for the approval of rimegepant is currently under review by the European Medicines Agency with a decision expected in the first half of 2022. Rimegepant 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.

Vlad Coric, M.D., Chief Executive Officer and Chairman of the Board of Biohaven commented, "These top-line trial results clearly show the consistent clinical profile of rimegepant to relieve migraine symptoms and return patients to normal function. Through our partnership with Pfizer, we are committed to rapidly expanding the availability of rimegepant to patients around the world, particularly in Asia Pacific where migraine is a common disease and a leading cause of disability."

"It is very exciting to see the completion and positive results of the first Phase 3 study of rimegepant in Asia Pacific," said Nick Lagunowich, Global President, Pfizer Internal Medicine. "With millions of patients in the region impacted by this debilitating neurological disease, these results provide hope for a potentially new

effective acute treatment for patients in need. We are moving as quickly as possible in our effort to get this potential treatment into the hands of patients, and we look forward to working with regulatory agencies around the world to do so."

Professor Shengyuan Yu, Principal Investigator of the study and Director of the Department of Neurology, Chinese PLA General Hospital, said, "We need new, effective and safe treatment options to help improve the lives of our migraine patients in Asia and are encouraged by the positive results of this study."

Donnie McGrath, M.D., Executive Chairman of Biohaven's wholly-owned subsidiary in China, BioShin, added, "The results from this study demonstrate the effectiveness of rimegepant and highlight the potential impact for patients in Asia Pacific, if approved. I'm so proud of the BioShin R&D team who executed this study."

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. Rimegepant was approved by the U.S. Food and Drug Administration (FDA) under the trade name Nurtec ODT for the acute treatment of migraine in February 2020 and for the preventive treatment of episodic migraine in May 2021. A single dose of 75 mg Nurtec ODT 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. Nurtec ODT 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. Nurtec ODT does not have addiction potential and is not associated with medication overuse headache or rebound headache.

About NURTEC ODT
NURTEC ODT (rimegepant) is the first and only calcitonin gene-related peptide (CGRP) receptor antagonist available in a quick-dissolve ODT formulation that is approved by the U.S. Food and Drug Administration (FDA) for the acute treatment of migraine with or without aura and the preventive treatment of episodic migraine in adults. The activity of the neuropeptide CGRP is thought to play a causal role in migraine pathophysiology. NURTEC ODT is a CGRP receptor antagonist that works by reversibly blocking CGRP receptors, thereby inhibiting the biologic activity of the CGRP neuropeptide. For more information about NURTEC ODT, visit www.nurtec.com.

Indication
NURTEC ODT orally disintegrating tablets is a prescription medicine that is used to treat migraine in adults. It is for the acute treatment of migraine attacks with or without aura and the preventive treatment of episodic migraine. It is not known if NURTEC ODT is safe and effective in children.

Important Safety Information
Do not take NURTEC ODT if you are allergic to NURTEC ODT (rimegepant) or any of its ingredients. Before you take NURTEC ODT, tell your healthcare provider (HCP) about all your medical conditions, including if you:

- have liver problems,
- have kidney problems,
- are pregnant or plan to become pregnant,
- breastfeeding or plan to breastfeed.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NURTEC ODT may cause serious side effects including allergic reactions, trouble breathing and rash. This can happen days after you take NURTEC ODT. Call your HCP or get emergency help right away if you have swelling of the face, mouth, tongue, or throat or trouble breathing. This occurred in less than 1% of patients treated with NURTEC ODT.

The most common side effects of NURTEC ODT were nausea (2.7%) and stomach pain/indigestion (2.4%). These are not the only possible side effects of NURTEC ODT. Tell your HCP if you have any side effects.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1–800–FDA–1088 or report side effects to Biohaven at 1–833–4NURTEC.

See full Prescribing Information and Patient Information.

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. 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 limits 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 14, 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 jurisdictions; whether and when regulatory authorities may approve any potential 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, 2020 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 NURTEC ODT (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.

NURTEC and NURTEC ODT are registered trademarks of Biohaven Pharmaceutical Ireland DAC. Neuroinnovation is a trademark of Biohaven Pharmaceutical Holding Company Ltd.

Biohaven Dr. Vlad Coric Chief Executive Officer Vlad.Coric@biohavenpharma.com Media Contact: Mike Beyer Sam Brown Inc. mikebeyer@sambrown.com 312-961-2502 Pfizer Media Relations +1 (212) 733-1226 PfizerMediaRelations@pfizer.com Investor Relations +1 (212) 733-4848 IR@pfizer.com