Biohaven and Pfizer Complete Collaboration Transaction for Commercialization of Rimegepant and Zavegepant Outside United States

Wednesday, January 05, 2022 - 07:00am

Transaction triggers total upfront payment to Biohaven of $500 million

NEW HAVEN, Conn., and NEW YORK, January 5, 2022 /PRNewswire/ -- Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN) and Pfizer Inc. (NYSE: PFE), today announced that the parties have completed the collaboration transaction between the two companies. The transaction agreements, including Pfizer's commercialization of rimegepant and zavegepant outside of the U.S., have become effective following the receipt of required regulatory approvals and the satisfaction of other customary conditions, and BHVN shares have been issued to Pfizer. Biohaven will continue to lead research and development globally and retain rights to the U.S. market.

In connection with the closing of the equity purchase and effectiveness of the strategic transaction, Pfizer made an upfront payment to Biohaven of $500 million, consisting of $150 million cash and $350 million in the purchase of Biohaven equity. At close, Pfizer will own 3% of Biohaven. Biohaven is also eligible to receive up to $740 million in future milestones. In addition to the tiered double-digit royalties owed to Biohaven on net sales outside of the U.S., Pfizer will compensate Biohaven for a pro-rata share of certain of its sales-based milestone obligations owed to Bristol-Myers Squibb Company ("BMS"), and for the related royalties on net sales outside of the U.S. owed under Biohaven's license and funding agreements with BMS and Royalty Pharma.

"The successful closing of our collaboration agreements represent an important and exciting step in expanding the impact of rimegepant to people outside the U.S. with migraine," said Nick Lagunowich, Global President, Pfizer Internal Medicine. "We are enthusiastic about working with the Biohaven team to bring this valuable new treatment option to the millions of people across the globe suffering from migraine."

Rimegepant is commercialized as Nurtec® ODT in the U.S. and is the only oral CGRP (calcitonin gene-related peptide) 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 already 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. Zavegepant is a third generation, high affinity, selective and structurally unique, small molecule CGRP receptor antagonist delivered in an intranasal spray which recently achieved positive Phase 3 topline data in its second pivotal clinical trial for the acute treatment of migraine in adults. Zavegepant, if approved, would be the first intranasal CGRP receptor antagonist for the acute treatment of migraine in adults. Intranasal treatments like zavegepant offer additional potential benefits including ultra-rapid speed of onset and a non-oral delivery for patients who experience signigicant nausea or vomiting.

Vlad Coric M.D., Chairman and CEO of Biohaven commented, "Together we hope to establish a world-class migraine business that can deliver on our promise of providing new treatment options for people living with this debilitating disease." Dr. Coric added, "We are excited to collaborate with Pfizer given their global footprint and experience in the treatment of pain and in Women's Health, which we believe may help establish rimegepant as a leading novel treatment of migraine."

About Migraine

More than one billion people suffer from migraine worldwide, of which 75 percent are women. The World Health Organization classifies migraine as one of the 10 most disabling medical illnesses. Migraine is characterized by debilitating headache 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 large unmet need for new acute and preventive treatments, as a significant portion of migraine patients are unsatisfied with current standard of care migraine treatments due to a lack of efficacy or safety or tolerability burden.

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.

NURTEC ODT U.S. Important Safety Information Nurtec ODT (orally disintegrating tablet) 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.

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, including 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 http://www.fda.gov/medwatch or call 1-800-FDA-1088 or report side effects to Biohaven at 1-833-4Nurtec.

Please click here for full Prescribing Information and Patient Information.

About Zavegepant Zavegepant is a third generation, high affinity, selective and structurally unique, small molecule CGRP receptor antagonist from Biohaven's NOJECTION® Migraine Platform and the only CGRP receptor antagonist in clinical development with both intranasal and oral formulations. The efficacy and safety of intranasal zavegepant was shown in two pivotal clinical trials with statistical superiority to placebo on the coprimary endpoints. Previously the efficacy and safety of intranasal zavegepant was shown in a randomized controlled Phase 2/3 dose-ranging trial with more than 1000 patients treated. In December 2021, zavegepant pivotal data showed statistical superiority to placebo on a total of 15 consecutive, prespecified primary and secondary outcome measures in the acute treatment of migraine. Topline results showed ultra-rapid pain relief at the earliest measured time point of 15 minutes, return to function at 30 minutes, 2 hour freedom from pain and freedom from patients' most bothersome symptom (either nausea, photophobia or phonophobia) and sustained efficacy through 48 hours after a single intranasal dose. Biohaven plans to file a New Drug Application for zavegepant with the U.S. Food and Drug Administration in 1Q2022.

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 January 5, 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, zavegepant, and a collaboration agreement between Pfizer and Biohaven for commercialization of rimegepant and zavegepant 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 or zavegepant in any jurisdictions; whether and when regulatory authorities may approve any potential applications that may be pending or filed for rimegepant or zavegepant 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 and/or 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 rimegepant and/or zavegepant; 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 neuro-innovation 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.

Biohaven Forward-looking Statement 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 success of the collaboration with Pfizer, the receipt of milestone and other payments under the Pfizer collaboration, the future development and potential marketing approval and commercialization of Nurtec ODT(rimegepant), rimegepant or zavegepant, the potential benefits of the collaboration and the potential advantages and therapeutic benefits of Nurtec ODT, rimegepant and zavegepant. 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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