Biohaven and Pfizer Enter Strategic Collaboration for the Commercialization of Rimegepant Outside the United States

Tuesday, November 09, 2021 - 09:09am

Rimegepant, commercialized as Nurtec® ODT in the U.S., is the first and only oral CGRP (calcitonin gene- related peptide) receptor antagonist for the acute and preventive treatment of migraine Biohaven to receive tiered double-digit royalties on ex-U.S. net sales as well as upfront and milestone payments of up to $1.24 billion Biohaven and Pfizer global collaboration to be discussed on Biohaven 3Q Earnings Investor Call 8:00AM ET today

NEW HAVEN, Conn., and NEW YORK, November 9, 2021 /PRNewswire/ -- Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN) and Pfizer Inc. (NYSE: PFE), today announced a strategic commercialization arrangement for rimegepant in markets outside of the United States upon approval. Rimegepant is commercialized as Nurtec® ODT in the U.S., and is indicated for the acute treatment of migraine attacks with or without aura and the preventive treatment of episodic migraine in adults. An application for the approval of rimegepant is currently under review by the European Medicines Agency and several additional regulatory authorities outside of the U.S.

“We believe this collaboration, which brings together the winning combination of Biohaven’s Neuroscience R&D with Pfizer’s industry-leading expertise and large global footprint will help accelerate access to rimegepant for patients around the world,” said Vlad Coric MD, Chief Executive Officer of Biohaven. “With this alliance, Biohaven Pharmaceutical and Pfizer believe there is an opportunity to change the paradigm in migraine treatment and potentially establish a new standard of care.”

Under the terms of the arrangement, Biohaven would remain primarily responsible for further clinical development of rimegepant and the parties will cooperate in regulatory activities to secure approval for the product. Biohaven will continue to solely commercialize Nurtec ODT in the U.S and Pfizer would commercialize rimegepant, upon approval, in all regions outside the U.S. Additionally, per the arrangement, Pfizer gains rights outside of the U.S. to zavegepant, a third generation, high affinity, selective and structurally unique, small molecule CGRP receptor antagonist, currently being studied in an intranasal delivery and a soft-gel formulation in Phase 3 clinical trials for migraine indications.

"We are excited to join forces with Biohaven in the fight against migraine and help those patients impacted by this debilitating neurological disease," said Nick Lagunowich, Global President, Pfizer Internal Medicine. "We believe our legacy in pain and Women's Health combined with our experienced customer-facing colleagues, will enable us to maximize this opportunity with Biohaven, potentially bringing a valuable new treatment option to patients living with migraine pain."

Terms of the Arrangement

Biohaven and Pfizer are entering into a collaboration and license agreement and related sublicense agreement pursuant to which Pfizer will acquire rights to commercialize rimegepant and zavegepant outside of the U.S. Biohaven will continue to lead research and development globally and Pfizer would execute commercialization globally, outside of the U.S. Under the financial terms of all transaction agreements, Pfizer will make an upfront payment of $500 million, consisting of $150 million cash and $350 million in the purchase of Biohaven equity at a 25 percent market premium. Biohaven is also eligible to receive up to $740 million in 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 the related royalties on net sales outside of the U.S. owed under the Company's license and funding agreements with Bristol-Myers Squibb Company and Royalty Pharma.

As noted above, in connection with the transaction, Pfizer will make a $350 million investment in the common shares of Biohaven.

Closing of the license agreements and equity purchase are contingent on completion of review under applicable antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 in the U.S. and equivalents outside the U.S., and other customary closing conditions.

Biohaven and Pfizer global collaboration will be discussed on Biohaven 3Q Earnings Investor Call 8:00AM ET on November 9, 2021. To access the call, please dial 877-407-9120 (domestic) or 412-902-1009 (international). The conference call webcast and accompanying slide presentation can be accessed through the “Investors” section of Biohaven’s website at www.biohavenpharma.com.

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 root cause 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. Nurtec ODT is the #1 prescribed migraine treatment in its class with a cumulative launch to date of U.S. net revenue of approximately $336 million and with more than one million prescriptions. 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 some 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 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 November 9, 2021. 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 commercialization arrangement between Pfizer and Biohaven for markets 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; risks related to the satisfaction or waiver of the conditions to closing the transaction in the anticipated timeframe or at all; 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 closing of the collaboration with Pfizer, the receipt of upfront, milestone and other payments under the Pfizer collaboration, the investment by Pfizer in Biohaven common shares in connection with the 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.

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

Contact 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