Pfizer Logo

Pfizer to Acquire Biohaven Pharmaceuticals

Tuesday, May 10, 2022 - 06:45am

Pfizer to commercialize NURTEC® ODT (rimegepant), an innovative compound for the prevention and acute treatment of migraine, a condition with high unmet need

Expands Pfizer's innovative Internal Medicine pipeline to drive enhanced growth through 2030 and beyond

Biohaven common shareholders will receive $148.50 per Biohaven share in cash, plus 0.5 of a share of a new publicly traded company that retains Biohaven's non-CGRP pipeline compounds ("New Biohaven")

Pfizer and Biohaven to hold analyst call at 10am ET today

NEW YORK & NEW HAVEN, CONN.--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN) today announced that the companies have entered into a definitive agreement under which Pfizer will acquire Biohaven, the maker of NURTEC® ODT, an innovative dual-acting migraine therapy approved for both acute treatment and episodic prevention of migraine in adults.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20220510005676/en/

Under the terms of the agreement, Pfizer will acquire all outstanding shares of Biohaven not already owned by Pfizer for $148.50 per share in cash. Biohaven common shareholders, including Pfizer, will also receive 0.5 of a share of New Biohaven, a new publicly traded company that will retain Biohaven's non-CGRP development stage pipeline compounds, per Biohaven common share. The boards of directors of both Biohaven and Pfizer have unanimously approved the transaction. Pfizer will pay transaction consideration totaling approximately $11.6 billion in cash. Pfizer will also make payments at closing to settle Biohaven's third party debt and for the redemption of all outstanding shares of Biohaven's redeemable preferred stock. The $148.50 cash consideration represents a premium of approximately 33% to Biohaven's volume weighted average selling price of $111.70 over the three months prior to the announcement of the transaction.

The proposed transaction includes the acquisition of Biohaven's calcitonin gene-related peptide (CGRP) programs including:

- Rimegepant:
  - Approved in the United States (U.S.) under the trade name, NURTEC® ODT, for both the acute treatment of migraine and preventive treatment of episodic migraine
  - Approved in the European Union under the trade name, VYDURA®, for both acute treatment of migraine and prophylaxis of episodic migraine
- Zavegepant:
  - On track for a 2Q2022 acceptance (based on March 2022 submission) in the U.S. as an intranasal spray for the acute treatment of migraine and in development as an oral soft gel for chronic migraine prevention

- A portfolio of five pre-clinical CGRP assets

“Today’s announcement builds on our legacy of delivering breakthroughs for patients living with complex pain disorders and diseases that disproportionately impact women,” said Nick Lagunowich, Global President, Pfizer Internal Medicine. “NURTEC® ODT, which is already the #1 prescribed migraine medicine in its class in the United States, coupled with Biohaven’s CGRP pipeline, offers hope for patients suffering from migraine worldwide. We believe Pfizer is uniquely positioned to help the portfolio reach its full potential given our leading scale and capabilities, including comprehensive field force engagement with Primary Care Physicians, specialists and health systems delivering the right information at the right time.”

This agreement follows on the November 9, 2021 collaboration for the commercialization of rimegepant and zavegepant outside the United States, in connection with which Pfizer invested $350 million to acquire 2.6% of Biohaven’s common stock at $173 per share.

“We are excited to announce Pfizer’s proposed acquisition of Biohaven, recognizing the market leadership of NURTEC® ODT, our breakthrough all in one migraine therapy, and the untapped potential of our CGRP franchise,” said Vlad Coric, MD, Chairman and Chief Executive Officer of Biohaven. “Pfizer’s capabilities will accelerate our mission to deliver our migraine medicines to even more patients, while the new R&D company is well positioned to bring value to patients and shareholders by focusing on our innovative pipeline for neurological and other disorders. We believe this transaction represents significant future value creation for patients and our collective shareholders.”

Following the closing, New Biohaven will continue to operate under the Biohaven name. New Biohaven will be led by Vlad Coric, MD, as Chairman and CEO, and include other members of the current management team of Biohaven. Biohaven common shareholders will receive, for each Biohaven share, 0.5 of a share of New Biohaven distributed via a *pro rata* distribution of SEC-registered, publicly listed shares. At distribution, New Biohaven will be capitalized with $275 million of cash. New Biohaven will also have the right to receive tiered royalties from Pfizer on any annual net sales of rimegepant and zavegepant in the United States in excess of $5.25 billion.

Pfizer expects to finance the transaction with existing cash on hand.

Pfizer’s acquisition of Biohaven is subject to the completion of the New Biohaven spin-off transaction and other customary closing conditions, including receipt of regulatory approvals and approval by Biohaven’s shareholders. The companies expect the transaction to close by early 2023.

Due to the proposed transaction, Biohaven will not hold a conference call to discuss its first quarter 2022 financial results and will issue a press release and file a quarterly report on Form 10-Q with the U.S. Securities and Exchange Commission announcing those results on May 10, 2022.

J.P. Morgan acted as Pfizer’s financial advisor for the transaction with Ropes & Gray LLP acting as its legal advisor. Centerview Partners acted as Biohaven’s financial advisor for the transaction with Sullivan & Cromwell LLP acting as its legal advisor.

Investor Call Details

Pfizer and Biohaven will host an analyst and investor call today at 10am EDT to discuss the proposed transaction.

Webcast Details | Pfizer Analyst and Investor Call | May 10

When you add these details to your invite, copy the Webcast link, then right-click where you want to place it and select Keep Text Only to paste it

Webcast

- Pfizer Analyst and Investor Call
- STARTS: May 10, 2022 10:00 AM
- ENDS: May 10, 2022 11:00 AM
- WEBCAST LINK: https://pfizer.rev.vbrick.com/#/events/97005988-ae33-4a4b-b3e9-667a6f82e835
- If viewing on an iPad, iPhone or Android: Your meeting experience is completely dependent upon Internet connection or cellular signal quality in your area

Audio Conference:

Participant Event Plus Dial-In Number:
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Participant Event Plus Toll Dial-In Number:
(602) 585-9859 (outside U.S. and Canada)

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About Migraine

Around one billion people suffer from migraine across the globe, of which 75 percent are women. The World Health Organization classifies migraine as one of the 10 most disabling medical illnesses. 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. In April 2022, the European Commission (EC) granted marketing authorization for VYDURA® (rimegepant) 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. NURTEC® ODT is the #1 prescribed migraine treatment in its class with a cumulative launch to date of U.S. net revenue of approximately $650 million and with more than two 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.

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 profile of intranasal zavegepant for the acute treatment of migraine, as compared to placebo, was shown in a randomized controlled Phase 2/3 dose-ranging trial with a total of over 1000 patients who received zavegepant. In this study, zavegepant showed statistical superiority to placebo on the coprimary endpoints of 2-hour freedom from pain and freedom from a patients' most bothersome symptom (either nausea, photophobia or phonophobia). This was the second zavegepant pivotal clinical trial to meet these coprimary endpoints. Biohaven plans to file a new drug application with the U.S. Food and Drug Administration for zavegepant in the second quarter of 2022.

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,
- are 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 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 (EMA-approved as Vydura® for 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) and a broad pipeline of late-stage product candidates across five distinct mechanistic platforms: CGRP receptor antagonism for the acute and preventive treatment of migraine; glutamate modulation

for obsessive-compulsive disorder, and spinocerebellar ataxia; myeloperoxidase (MPO) inhibition for amyotrophic lateral sclerosis; Kv7 ion channel activators for focal epilepsy and neuronal hyperexcitability, and myostatin inhibition for neuromuscular diseases. More information about Biohaven is available at www.biohavenpharma.com and NURTEC® ODT at www.nurtec.com.

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.

Disclosure Notice

The information contained in this release is as of May 10, 2022.

This release contains forward-looking information about Pfizer's proposed acquisition of Biohaven, Biohaven's related spin-off of its development stage pipeline compounds, Biohaven's commercial and pipeline portfolio, including rimegepant and zavegepant, expected best-in-class and growth potential, and Pfizer's Internal Medicine portfolio and growth potential, including their potential benefits, that involve 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, risks related to the satisfaction or waiver of the conditions to closing the proposed acquisition (including the failure to obtain necessary regulatory approvals and failure to obtain the requisite vote by Biohaven shareholders) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; the possibility that competing offers may be made; risks related to the ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; risks related to diverting management's attention from Biohaven's ongoing business operation; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Pfizer's common stock, Biohaven's common shares and/or their respective operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition, spin-off or Biohaven's business; risks and costs related to the implementation of the separation of New Biohaven, including timing anticipated to complete the separation and any changes to the configuration of the businesses included in the separation if implemented; the risk that the integration of Biohaven and Pfizer will be more difficult, time consuming or costly than expected; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; future business combinations or disposals; 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; risks associated with

interim 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 drug applications may be filed in particular jurisdictions for rimegepant or zavegepant or any other investigational products; whether and when any such applications may be approved by regulatory authorities, 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, zavegepant or any such other products 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, zavegepant or any such other products; uncertainties regarding the impact of COVID-19; and competitive developments.

You should carefully consider the foregoing factors and the other risks and uncertainties that affect the businesses of Pfizer and Biohaven described in the "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results" sections of their respective Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed by either of them from time to time with the U.S. Securities and Exchange Commission (the "SEC"), all of which are available at www.sec.gov. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and Pfizer and Biohaven assume no obligation to, and do not intend to, update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law. Neither Pfizer nor Biohaven gives any assurance that it will achieve its expectations.

Additional Information and Where to Find It

In connection with the proposed transaction, Biohaven will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed transaction. The definitive proxy statement will be mailed to Biohaven's shareholders in connection with the proposed transaction. This communication is not a substitute for the proxy statement or any other document that may be filed by Biohaven with the SEC. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Any vote in respect of resolutions to be proposed at Biohaven's shareholder meeting to approve the proposed transaction or other responses in relation to the proposed transaction should be made only on the basis of the information contained in Biohaven's proxy statement. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the SEC at the SEC's web site at www.sec.gov or on Biohaven's website at https://www.biohavenpharma.com/investors.

No Offer or Solicitation

This communication is for information purposes only and is not intended to and does not constitute, or form part of, an offer, invitation or the solicitation of an offer or invitation to purchase, otherwise acquire, subscribe for, sell or otherwise dispose of any securities, or the solicitation of any vote or approval in any jurisdiction, pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law.

Participants in the Solicitation

Biohaven and certain of its directors, executive officers and employees may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Biohaven's directors and executive officers is set forth in its proxy statement for its 2022 annual meeting of shareholders, which was filed with the SEC on March 11, 2022. Other information regarding participants in the proxy solicitations in connection with the proposed transaction, and a description of any interests that they have in the proposed transaction, by security holdings or otherwise, will be included in the proxy statement described above. These documents are available free of charge at the SEC's web site at www.sec.gov and by going to Biohaven's website at https://www.biohavenpharma.com/investors.

Category: Investments

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