Pfizer Logo

Pfizer Completes Acquisition of Biohaven Pharmaceuticals

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Acquisition adds breakthrough calcitonin gene-related peptide portfolio, including NURTEC® ODT, to address needs of millions of migraine patients worldwide

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today the completion of its acquisition of Biohaven Pharmaceutical Holding Company Ltd., the maker of NURTEC® ODT (rimegepant), an innovative migraine therapy approved for both acute treatment and prevention of episodic migraine in adults.

The acquisition brings to Pfizer a portfolio of promising calcitonin gene-related peptide (CGRP) receptor antagonists including:

- Rimegepant:
  - Approved in the United States under the trade name NURTEC® ODT, in adults for both the acute treatment of migraine with or without aura and the preventive treatment of episodic migraine
  - Approved in the European Union under the trade name VYDURA® 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 4 migraine attacks per month
- Zavegepant:
  - New Drug Application (NDA) for intranasal spray for the acute treatment of migraine under U.S. Food and Drug Administration (FDA) review, with a Prescription Drug User Fee Act (PDUFA) goal date in 1Q 2023
- A portfolio of pre-clinical CGRP assets

"We are proud to build on Pfizer’s legacy of delivering breakthrough medicines for patients living with complex pain disorders,” said Aamir Malik, Executive Vice President, Chief Business Innovation Officer, Pfizer. “The success of NURTEC® ODT coupled with Biohaven’s CGRP pipeline will strengthen Pfizer’s innovative Internal Medicine pipeline through 2030, and beyond. Combined with Pfizer’s global reach, this acquisition increases our potential to bring new treatment options to patients with migraine – a disease which affects over 1 billion people worldwide.”[i]

Pfizer acquired all of the outstanding shares of Biohaven not already owned by Pfizer for $148.50 per share in cash, for a total transaction consideration of approximately $11.6 billion. As a result of the acquisition, Biohaven became a wholly-owned subsidiary of Pfizer.

Effective immediately prior to the closing of the acquisition, Biohaven completed the spin-off of Biohaven Ltd. (NYSE: BHVN), distributing Biohaven Ltd.’s shares to Biohaven’s shareholders. Biohaven Ltd., a new company that retained Biohaven’s non-CGRP development stage pipeline compounds, holds the Kv7 ion channel activators, glutamate modulation, and myostatin inhibition platforms, preclinical product candidates, and certain corporate infrastructure assets excluded from the Pfizer acquisition. Pfizer, a Biohaven shareholder, received a pro rata portion of Biohaven Ltd.’s shares in the distribution and owns approximately 3% of Biohaven Ltd.

Biohaven Ltd. will continue to trade on the New York Stock Exchange under the ticker “BHVN”.

For additional background on the acquisition, please read the announcement press release here.

About Migraine

Worldwide, more than one billion people suffer from migraine, which predominately affects women.[i] Findings from the 2019 Global Burden of Disease study indicate that migraine is one of the worlds leading causes of disability.[ii] 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).[iii]

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 adults in February 2020 and for the preventive treatment of episodic migraine in adults in May 2021. Nurtec® ODT is taken orally as needed, up to once daily for acute treatment, and every other day for preventive treatment. The maximum dose in a 24 hour period is 75 mg.

NURTEC® ODT U.S. IMPORTANT SAFETY INFORMATION

Contraindications: Hypersensitivity to Nurtec® ODT or any of its components.

Warnings and Precautions: If a serious hypersensitivity reaction occurs, discontinue Nurtec® ODT and initiate appropriate therapy. Serious hypersensitivity reactions have included dyspnea and rash, and can occur days after administration.

Adverse Reactions: The most common adverse reactions were nausea (2.7% in patients who received Nurtec® ODT compared to 0.8% in patients who received placebo) and abdominal pain/dyspepsia (2.4% in patients who received Nurtec® ODT compared to 0.8% in patients who received placebo). Hypersensitivity, including dyspnea and rash, occurred in less than 1% of patients treated with Nurtec® ODT.

Drug Interactions: Avoid concomitant administration of Nurtec® ODT with strong inhibitors of CYP3A4 or strong or moderate inducers of CYP3A. Avoid another dose of Nurtec® ODT within 48 hours when it is administered with moderate inhibitors of CYP3A4 or potent inhibitors of P?gp.

Use in Specific Populations: *Pregnancy*: It is not known if Nurtec® ODT can harm an unborn baby. *Lactation*: The transfer of rimegepant into breastmilk is low (<1%). *Hepatic impairment*: Avoid use of Nurtec® ODT in persons with severe hepatic impairment. *Renal impairment*: Avoid use in patients with end-stage renal disease.

INDICATIONS

Nurtec® ODT is indicated in adults for the:

- acute treatment of migraine with or without aura
- preventive treatment of episodic migraine

Please click here for full Prescribing Information.

About Zavegepant

Zavegepant is a third generation, high affinity, selective and structurally unique, small molecule CGRP receptor antagonist from the NOJECTION® Migraine Platform and the only CGRP receptor antagonist in clinical development with both intranasal and oral formulations. The FDA has accepted for review a New Drug Application (NDA) for zavegepant nasal spray, with a PDUFA date in 1Q 2023.

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 October 3, 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 Pfizer's acquisition of Biohaven, the spin off of Biohaven Ltd., Biohaven's commercial and pipeline portfolios, including rimegepant and zavegepant, expected growth and breakthrough 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 ability to realize the anticipated benefits of the 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; negative effects of the consummation of the acquisition on the market price of Pfizer's common stock and/or operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the acquisition, spin off of Biohaven Ltd. or Biohaven's business; risks and costs related to the implementation of the separation of Biohaven Ltd.; 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 divestitures; 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 any 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.

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.

[i] Ashina et al, Lancet; 2021; 397:1485-95
[ii] Steiner et al, The Journal of Headache and Pain; 2020; 21:137
[iii] Ferrari et al, Nature Review Disease Primers; 2022; 8(1):2

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