



**ROYALTY PHARMA**

**BIOHAVEN SECURES PRIORITY REVIEW VOUCHER (PRV) TO EXPEDITE REGULATORY REVIEW OF RIMEGEPANT ZYDIS ODT NEW DRUG APPLICATION**

*Rimegepant Zydis orally disintegrating tablet (ODT) is Biohaven's lead oral CGRP receptor antagonist drug candidate from its NOJECTION™ migraine platform*

*A priority review voucher (PRV) entitles the holder to designate a New Drug Application (NDA) for priority review and provides for an expedited 6-month review*

*The purchase of the PRV, and additional funding for general corporate uses, was funded by a sale of preferred stock to Royalty Pharma*

NEW HAVEN, Conn., March 18, 2019 /PRNewswire/ - Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN), a clinical-stage biopharmaceutical company with a portfolio of innovative, late-stage product candidates targeting neurological and neuropsychiatric diseases, including rare disorders, today announced that the company has purchased a U.S. Food and Drug Administration (FDA) priority review voucher (PRV) to use with the NDA submission of rimegepant Zydis® ODT in the second quarter of 2019. The PRV entitles the holder to designate an NDA for priority review and provides for an expedited 6-month review.



Vlad Coric, M.D, Chief Executive Officer of Biohaven commented, "This transaction highlights the important benefits to patients of the priority review voucher program – the program motivates more treatments to be developed for rare pediatric diseases and also speeds approval of potential blockbuster therapies. Millions of patients suffer from debilitating migraines and have long awaited

new treatment approaches such as an easy to use oral CGRP receptor antagonist. We are excited about the potential of bringing rimegepant Zydis ODT to patients as quickly as possible."

Biohaven entered into a definitive agreement to purchase the PRV for \$105M. The closing of the transaction is subject to customary closing conditions, including antitrust review. In addition to the purchase of the PRV, the company also announced an agreement to raise a total of up to \$200M in financing for the purchase of this PRV and general corporate uses. The financing is being provided by the sale of preferred shares to Royalty Pharma and is subject to customary closing conditions.

Royalty Pharma will provide \$125M at closing and allow the company to draw up to an additional \$75M upon FDA acceptance of the rimegepant NDA.

Pablo Legorreta, CEO of Royalty Pharma stated, "We are pleased to further support Biohaven in the development of rimegepant. In a matter of days, we worked collaboratively with Biohaven to assist in funding the strategically important acquisition of a PRV. We are providing up to \$200m of capital with a structured return that is potentially less dilutive than other alternatives.

This financing is highly flexible and responsive to the many potential future paths for a dynamic company like Biohaven."

Biohaven previously announced positive topline results from a randomized, double-blind, placebo-controlled, Phase 3 clinical trial evaluating the efficacy and safety of its Zydis ODT formulation of rimegepant. Rimegepant Zydis ODT was statistically superior to placebo on the two co-primary endpoints as well as the first 21 consecutive primary and secondary outcome measures pre-specified in hierarchical testing. Importantly, the performance of the rimegepant Zydis ODT formulation began to numerically separate from placebo on pain relief as early as 15 minutes after dosing, and this difference was statistically significant at 60 minutes ( $p < 0.0001$ ). Additionally, a significantly greater percentage of patients treated with rimegepant Zydis ODT returned to normal functioning by 60 minutes as compared to placebo ( $p = 0.0025$ ). Lasting clinical benefit was observed through 48 hours after a single dose of rimegepant on freedom from pain ( $p < 0.0001$ ), pain relief ( $p < 0.0001$ ), freedom from the most bothersome symptom ( $p = 0.0018$ ), and freedom from functional disability ( $p < 0.0001$ ). The vast majority of patients treated with rimegepant Zydis ODT (85%) did not use any rescue medications.

## **About Rimegepant**

Rimegepant is Biohaven's orally-dosed calcitonin gene-related peptide (CGRP) receptor antagonist, which the Company is developing as a treatment for migraine. Rimegepant represents a novel mechanism that targets the underlying pathophysiology of migraine without causing vasoconstriction. The efficacy and safety profile of rimegepant for the acute treatment of migraine has now been established across four randomized controlled trials to date: the three completed pivotal Phase 3 trials, and a Phase 2b trial. The co-primary endpoints achieved in the three Phase 3 trials are consistent with regulatory guidance from the U.S. Food and Drug Administration (FDA) and provide the basis for a planned submission of a new drug application (NDA) to the FDA in the second quarter of 2019.

## **About Biohaven**

Biohaven is a clinical-stage biopharmaceutical company with a portfolio of innovative, late-stage product candidates targeting neurological diseases, including rare disorders. Biohaven has combined internal development and research with intellectual property licensed from companies and institutions including Bristol-Myers Squibb Company, AstraZeneca AB, Yale University, Catalent, ALS Biopharma LLC and Massachusetts General Hospital. Currently, Biohaven's lead development

programs include multiple compounds across its CGRP receptor antagonist, glutamate modulation and myeloperoxidase inhibition platforms. More information about Biohaven is available at <http://www.biohavenpharma.com>.

### **About Royalty Pharma**

Founded in 1996, Royalty Pharma is the industry leader in acquiring pharmaceutical royalties, with over \$16 billion in royalty assets. Royalty Pharma funds innovation in life sciences both directly and indirectly: directly when it partners with life sciences companies to co-develop and co-fund products in late-stage clinical trials, and indirectly when it acquires existing royalty interests from the original innovators (academic institutions, research hospitals, foundations and inventors). The company's portfolio includes royalty interests in over 40 approved products including AbbVie and J&J's Imbruvica, Astellas and Pfizer's Xtandi, Biogen's Tysabri, Gilead's HIV franchise, Merck's Januvia, and Vertex's cystic fibrosis franchise. Royalty Pharma is also a leading investor in pre-approval royalties, having since 2011 invested over \$4 billion in royalties on pre-approval products and committed over \$900 million to direct R&D funding in exchange for royalties. More information on Royalty Pharma is available at <http://www.royaltypharma.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 that are based on the current expectations and assumptions of the Company's management. All statements, other than statements of historical facts, included in this press release regarding the Company's business and product candidate plans and objectives are forward-looking statements. Forward-looking statements include those related to: the expected timing, commencement and outcomes of the Company's planned and ongoing clinical trials, the timing of planned interactions and filings with the FDA, the timing and outcome of expected regulatory filings, the expected issuance of preferred stock to Royalty Pharma, the potential commercialization of the Company's product candidates and the potential for the Company's product candidates to be first in class or best in class therapies. The use of certain words, including "believe", "continue", "may", "on track", "expects" and "will" and similar expressions, are intended to identify forward-looking statements. 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 the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2019. The forward-looking statements are made as of this date and the Company 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.

For further information, contact Dr. Vlad Coric, Chief Executive Officer, at [Vlad.Coric@biohavenpharma.com](mailto:Vlad.Coric@biohavenpharma.com)

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