Biohaven Initiates Pivotal Trial of Novel Investigational Drug for Treatment of Migraine

September 30, 2024

- *Biohaven initiated a pivotal Phase 2 trial evaluating BHV-2100 in the acute treatment of migraine*
- *BHV-2100 is a potential first-in-class, potent, orally administered Transient Receptor Potential Melastatin-3 (TRPM3) antagonist— a novel, highly selective, and non-opioid investigational treatment being developed for migraine and other pain disorders*
- *Despite recent treatment advances, migraine remains a leading cause of disability and burden, impacting 40 million people in the US and 1 billion world-wide*

NEW HAVEN, Conn., Sept. 30, 2024 /PRNewswire/ -- Biohaven Ltd. (NYSE: BHVN) ("Biohaven"), a global clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of life-changing therapies to treat a broad range of rare and common diseases, announced today that it has initiated a pivotal Phase 2 study of the potential first-in-class, orally administered TRPM3 antagonist, BHV-2100, in the acute treatment of migraine.

Richard B. Lipton, M.D., the Edwin S. Lowe Professor and Vice Chair of Neurology at the Albert Einstein College of Medicine, and Director of the Montefiore Headache Center commented, "The burden of migraine remains high, and many patients experience inadequate relief or suffer from tolerability issues from existing therapies. There remains a need for novel treatments for migraine to lessen disease burden and disability. The TRPM3 ion channel has been implicated in the pathophysiology of migraine, and this trial is the first to assess efficacy and tolerability of a novel agent targeting this mechanism in migraine."

The pivotal Phase 2 study is a randomized, double-blind, placebo-controlled trial assessing the efficacy and safety of two doses (75 mg and 150 mg) of BHV-2100 in the acute treatment of migraine. The trial is designed to support registration with FDA-accepted coprimary endpoints of pain freedom and freedom from most bothersome symptom at 2 hours. The trial will enroll approximately 575 patients across 60 sites in the United States. Additional information can be found at www.clinicaltrials.gov/study/NCT06603623.

Beth Emerson, M.D., M.B.A., Executive Medical Director and Development Lead for Migraine at Biohaven, stated "Biohaven remains extremely committed to advancing novel therapeutic options for people suffering from migraine. Building on our deep passion, unparalleled expertise, and successful track record of developing innovative medications that are currently making a difference for migraine patients today, our team is thrilled to embark on this important program to potentially deliver a new, cutting-edge therapy for migraine. This includes a large number of patients who do not respond to existing therapies, estimated to be approximately one-third of the 40 million patients in the US who desperately need more treatment options."

BHV-2100 is a potentially first-in-class, potent, selective, orally administered TRPM3 antagonist— a novel, non-sedating non-opioid treatment for migraine and pain. BHV-2100 demonstrated excellent safety and tolerability across all doses tested in Phase 1 trials in healthy adults, without the thermoregulatory adverse events observed with other TRP antagonists or sedation associated with other pain medications. Additionally, the pharmacokinetic profile is very well-suited for use in the treatment of acute migraine. Single doses of BHV-2100 demonstrated rapid absorption and sustained concentrations above predicted efficacious levels at all doses tested after 20 minutes with maximal drug concentrations achieved at approximately 1.5 to 2 hours and a half-life of approximately 8-12 hours.

Beth Morris, Vice President of Biohaven Clinical Operations, added "Biohaven has deep expertise in running clinical trials in migraine and this study will assess an important new potential therapy for patients. I am proud of our clinical operations team for efficiently advancing this trial into Phase 2 after completing the initial Phase 1 trial earlier this year. Days matter for patients and if this study is positive, we will be one step closer to delivering another novel treatment option to better meet the needs of people with migraine: to resolve symptoms and to return to their lives quickly."

About Biohaven

Biohaven is a biopharmaceutical company focused on the discovery, development, and commercialization of life-changing treatments in key therapeutic areas, including immunology, neuroscience, and oncology. Biohaven is advancing its innovative portfolio of therapeutics, leveraging its proven drug development experience and multiple proprietary drug development platforms. Biohaven's extensive clinical and preclinical programs include Kv7 ion channel modulation for epilepsy and mood disorders; extracellular protein degradation for immunological diseases; TRPM3 antagonism for migraine and neuropathic pain; TYK2/JAK1 inhibition for neuroinflammatory disorders; glutamate modulation for OCD and SCA (spinocerebellar ataxia); myostatin inhibition for neuromuscular and metabolic diseases, including SMA and obesity; antibody recruiting bispecific molecules and antibody drug conjugates for cancer. For more information, visit www.biohaven.com.

Forward-looking Statements

This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "continue", "plan", "will", "believe", "may", "expect", "anticipate" and similar expressions, is intended to identify forward-looking statements. Investors are cautioned that any forward-looking statements, including statements regarding the future development, timing and potential marketing approval and commercialization of development candidates, are not guarantees of future performance or results and involve substantial risks and uncertainties. Actual results, developments and events may differ materially from those in the forward-looking statements as a result of various factors including: the expected timing, commencement and outcomes of Biohaven's planned and ongoing clinical trials; the timing of planned interactions and filings with the FDA; the timing and outcome of expected regulatory filings; complying with applicable U.S. regulatory requirements; the potential commercialization of Biohaven's product candidates; the potential for Biohaven's product candidates to be first-in-class therapies; and the effectiveness and safety of Biohaven's product candidates. Additional important factors to be considered in connection with forward-looking statements are described in Biohaven's filings with the Securities and Exchange Commission, including within the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The forward-looking statements are made as of the date of this news release, 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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