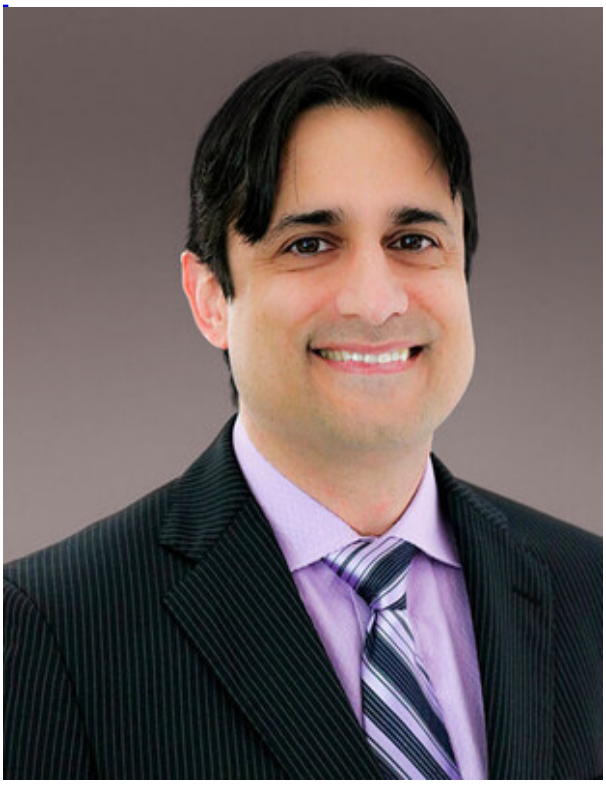
Biohaven Completes Enrollment in RISE 3 Pivotal Focal Epilepsy Study with Opakalim, a Selective Kv7.2/7.3 Activator

June 30, 2026

- *Enrollment complete in pivotal Phase 2/3 study evaluating opakalim in focal epilepsy (RISE3); top-line results on track for 2H 2026*
- *Emerging opakalim focal epilepsy and idiopathic generalized epilepsy data presented at recent R&D Day reinforce evidence of target engagement, potential for efficacy, and differentiated tolerability profile*
    - *In the ongoing focal epilepsy open-label extension (OLE) study, 54% of participants on opakalim 75 mg once-daily achieved a ≥50% reduction in seizure frequency compared to pre-randomization baseline, with a markedly lower incidence of nervous system adverse events compared to approved and investigational ASMs*
    - *High double-blind completion rates of ~95%, and high rollover rates into the OLE of ~95%, reflect favorable patient experience with opakalim*

NEW HAVEN, Conn., June 30, 2026 /PRNewswire/ -- Biohaven Ltd. (NYSE: BHVN), 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, today announced the completion of enrollment in RISE3, a pivotal Phase 2/3 randomized, double-blind, placebo-controlled studies evaluating its selective Kv7.2/7.3 channel activator, opakalim, for the treatment of refractory focal epilepsy. Top-line results from the study are expected in 2H 2026.



For the many people whose focal seizures remain uncontrolled despite available treatment, new options are urgently needed — and too often, the medicines meant to control seizures carry their own daily burden, from dizziness and drowsiness to fatigue and memory problems that can affect work, relationships, and independence. Opakalim is being developed to help control seizures without adding to that burden. Opakalim offers potential for easy-to-use, once-daily, orally administered treatment without the need for titration to control seizures, and without the burdensome central nervous system side effects frequently reported with approved and investigational antiseizure medicines (ASMs). Opakalim demonstrates selectivity for Kv7.2/7.3 heteromeric channels and lacks GABA receptor activity, distinguishing it from other investigational Kv7 activators.

RISE3 (NCT06309966) enrolled adult participants with refractory focal onset seizures who experienced at least four seizures per month and took one to three concurrent ASMs, consistent with criteria used in other recent focal epilepsy ASM trials. Following an 8-week observation phase to establish baseline seizure frequency, participants were randomized (1:1:1) to one of two doses of opakalim (75 mg and 50 mg) or placebo once daily, as adjunctive therapy on a stable background regimen of ASMs, for an 8-week double-blind treatment period. The primary endpoint measures the change from baseline in 28-day average seizure frequency during the treatment phase. RISE2 (NCT06132893) is ongoing and has identical entry criteria and endpoints with a 12-week double-blind treatment period and evaluates opakalim 25 mg and 50 mg once-daily in Part A and 75 mg once-daily in Part B.

In May 2026, at its R&D Day, Biohaven showcased evidence supporting the promise of opakalim to address the unmet need for a novel, effective, and well-tolerated antiseizure medicine. A recent analysis from the ongoing focal epilepsy OLE study demonstrated that 54% of participants on opakalim 75 mg once daily achieved a ≥50% reduction in seizure frequency over any consecutive six months of treatment compared to pre-randomization baseline (n>100), alongside a favorable tolerability profile and markedly lower incidence of nervous system adverse events (e.g., 5% dizziness, 4% fatigue) compared to approved and investigational ASMs. To date, ~95% of participants who reached the end of the double-blind treatment period in the pivotal Phase 2/3 studies (RISE2 and RISE3) completed it; and ~95% of those participants rolled over into the optional OLE study.

Jason Lerner, M.D., Medical Director, Research & Development and Epilepsy Development Lead at Biohaven, commented, "Completing enrollment in RISE3 marks an important milestone for the opakalim development program and brings us one step closer to offering people living with focal epilepsy a new treatment option that meaningfully controls seizures without compromising their quality of life. The high completion and rollover rates we continue to see reflect the favorable experience that patients and investigators have with opakalim's profile. We look forward to reporting top-line results in the second half of 2026, and we extend our deep gratitude to the patients who are participating in this study and to the sites whose dedication makes this possible."

About Opakalim

Opakalim (BHV-7000) represents a next-generation, selective Kv7.2/7.3 potassium channel activator targeting a clinically validated mechanism of action for the treatment of epilepsy. Opakalim is differentiated from both first- and second-generation Kv7 activators by its selectivity for the Kv7.2/7.3 heteromeric channels that are the predominant regulators of neuronal excitability, with substantially less activity at GABA receptors. This selectivity profile is hypothesized to underlie opakalim's favorable tolerability, including the low rates of somnolence, dizziness, and fatigue observed in clinical studies to date. Opakalim has been studied in more than 1,000 participants across multiple clinical trials, consistently demonstrating a favorable tolerability profile. Biohaven is currently conducting two pivotal Phase 2/3 randomized, double-blind, placebo-controlled studies (NCT06132893 and NCT06309966) comparing the efficacy of opakalim to placebo as an adjunctive therapy for refractory focal onset epilepsy, as well as an open-label extension study (NCT06443463) to evaluate its long-term efficacy and safety.

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; MoDE™ and TRAP™ extracellular protein degradation for immunological diseases; and myostatin inhibition for neuromuscular and metabolic diseases, including obesity. For more information, visit www.biohavenpharma.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 "expect," "on track," "potential," "will," "believe," "may," and similar expressions, is intended to identify forward-looking statements. Investors are cautioned that any forward-looking statements, including statements regarding the expected timing, conduct, and outcomes of Biohaven's ongoing and planned clinical trials of opakalim (including the RISE2 and RISE3 studies and the timing of top-line results), the potential therapeutic benefits, efficacy, safety, and tolerability of opakalim, and the timing of planned regulatory interactions and filings, 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. Additional important factors 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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