Biohaven's Clinical Data on BHV-1530, a Novel FGFR3-Directed ADC With a Proprietary Topoisomerase I (TopoIx) Payload, Selected for Oral Presentation at the EORTC-NCI-AACR Symposium 2026

September 28, 2026

- ***Oral presentation selected:*** *Phase 1 findings from the ongoing BHV1530-101 study will be featured in an oral presentation at the 38th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA 2026), a leading international forum for early-phase oncology drug development.*
- ***First-in-class FGFR3 ADC:*** *BHV-1530 is a first-in-class potential FGFR3-directed antibody-drug conjugate incorporating Biohaven's proprietary TopoIx payload, that has shown early clinical activity with a differentiated and tolerable safety profile.*
- ***Anti-PD-1 combination now enrolling:*** *Under its clinical supply agreement with Regeneron Pharmaceuticals, Inc., Biohaven has begun enrollment, evaluating BHV-1530 in combination with cemiplimab (Libtayo).*

NEW HAVEN, Conn., Sept. 28, 2026 /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, today announced that data on BHV-1530, its FGFR3-directed antibody-drug conjugate (ADC) using a novel topoisomerase I (TopoIx) payload, have been accepted for an oral presentation at the 38th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA 2026), to be held November 18-20, 2026, at the CCIB in Barcelona, Spain.

Selection for an oral presentation at the EORTC-NCI-AACR Symposium, one of the foremost venues for molecular-targeted and early-phase cancer therapeutics, underscores the scientific interest in FGFR3 as a therapeutic target and in Biohaven's TopoIx ADC platform. Early clinical activity has been observed, including confirmed partial responses in heavily pretreated patients, as previously disclosed. The data have shown a favorable and differentiated safety profile, with no dose-limiting toxicities and no FGFR inhibitor-class toxicities, such as hyperphosphatemia, nail disorders, stomatitis, or retinopathy, that commonly constrain dosing and duration of approved FGFR tyrosine kinase inhibitors.

Presentation Title: Phase 1 study of BHV-1530, a first-in-class FGFR3 ADC in Advanced Tumors

Abstract / Presentation Number: 2

Session: Plenary Session 3

Date and Time: 19Nov2026 at 10:00am

The oral presentation will provide an update from the ongoing BHV1530-101 study (NCT06874335), a Phase 1, first-in-human, open-label, multicenter, dose-escalation, dose-expansion and dose-confirmation study evaluating BHV-1530 as monotherapy and in combination with cemiplimab in adult participants with advanced or metastatic solid tumors.

BHV-1530 is designed to address FGFR3-driven cancers, including tumors with FGFR3 alterations and possibly, those with wild-type FGFR3 overexpression, a population not addressed by approved FGFR tyrosine kinase inhibitors. Further details, including the presentation title and session information, will be available in the ENA 2026 program.

Clinical Supply Agreement with Regeneron for BHV-1530 and Cemiplimab
Biohaven has entered into a clinical supply agreement with Regeneron Pharmaceuticals, Inc. to evaluate the combination of BHV-1530 and cemiplimab (Libtayo®) in patients with solid tumors, based upon previously disclosed emerging monotherapy clinical data and preclinical data demonstrating synergistic activity between BHV-1530 and Anti-PD-1 therapy. Enrollment into the combination cohort evaluating BHV-1530 with cemiplimab has begun. BHV-1530's TopoIx payload has been demonstrated to generate immunogenic cell death and stimulate an antitumor immune response, providing a compelling mechanistic rationale for combination with checkpoint inhibition. This agreement builds upon the existing clinical supply agreement between Biohaven and Regeneron for BHV-1510, a next-generation TROP2-directed ADC, further deepening the collaborative relationship between the two companies across Biohaven's oncology pipeline.

About BHV-1530
BHV-1530 is an antibody-drug conjugate directed against FGFR3, a validated but underexploited target in urothelial cancer and other FGFR3-driven cancers, and is a first-in-class potential FGFR3-directed ADC incorporating Biohaven's proprietary TopoIx payload. Unlike approved FGFR tyrosine kinase inhibitors, which are restricted to genomically selected patients and constrained by class-related toxicities, BHV-1530 is designed to target

FGFR3 independent of requiring pathway inhibition, with the potential to address both FGFR3-altered and wild-type overexpressing tumors. BHV-1530 is being studied in an ongoing Phase 1 dose-escalation trial in unselected patients with advanced urothelial cancer, head and neck squamous cell carcinoma, and non-small cell lung cancer who have failed standard-of-care therapy, as well as other tumor types harboring FGFR3 genomic alterations. Biohaven has initiated combination cohorts evaluating BHV-1530 with anti-PD-1 therapy, including the combination with cemiplimab (Libtayo), which is now enrolling.

About Biohaven
Biohaven Ltd. (NYSE: BHVN) 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.biohaven.com.

Forward-Looking Statements
This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the expected timing, conduct, and outcomes of Biohaven's ongoing and planned clinical trials of BHV-1530, including the combination with cemiplimab under the clinical supply agreement with Regeneron, the potential therapeutic benefits, efficacy, safety, and tolerability of BHV-1530, and the timing of planned regulatory interactions and filings. The use of certain words, including "continue," "plan," "will," "believe," "may," "expect," "anticipate," "on track," "potential," and similar expressions, is intended to identify forward-looking statements. Investors are cautioned that any forward-looking statements 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 and the expected timing thereof; the potential for Biohaven's product candidates to be successful 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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