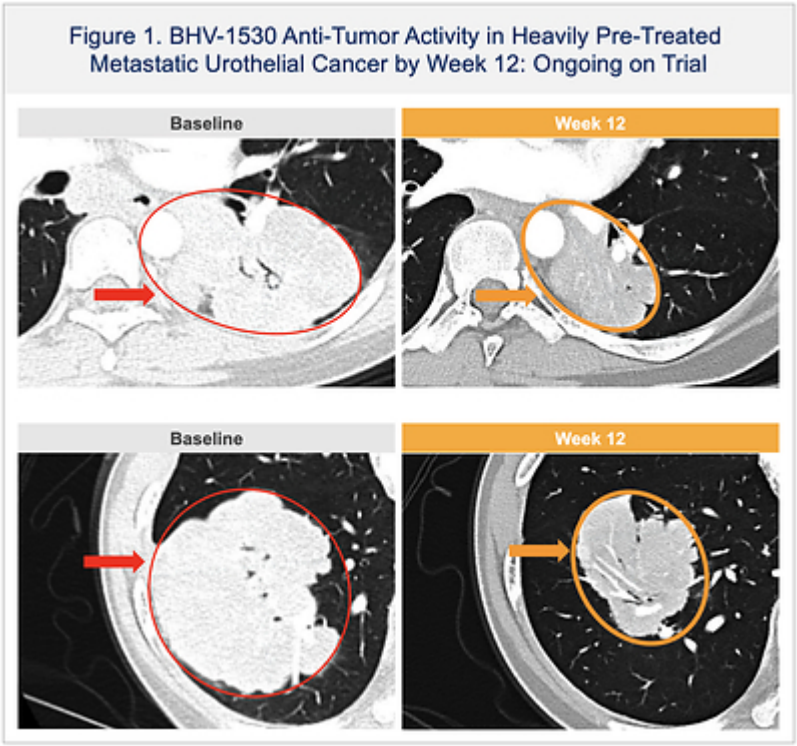
Biohaven to Present New Clinical Data at ESMO Congress on BHV-1530, a Novel FGFR3-Directed ADC With a Proprietary Topoisomerase I (TopoIx) Payload

July 20, 2026

Biohaven also announces new clinical supply agreement with Regeneron to evaluate BHV-1530 in combination with cemiplimab (Libtayo®)

- ***Early clinical activity observed:*** *Phase 1 dose-escalation data show early tumor reductions in patients with Fibroblast Growth Factor Receptor (FGFR)3-altered and wild-type overexpressing tumors. Signal activity including confirmed partial responses in heavily pretreated patients in multiple tumor types.*
- ***Differentiated safety profile:*** *No dose-limiting toxicities and no FGFR inhibitor-class toxicities observed, supporting a potentially broader therapeutic index than approved FGFR tyrosine kinase inhibitors (TKIs).*
- ***Potential to expand the addressable FGFR3 population:*** *Unlike FGFR TKIs, which are restricted to the ~15–20% of metastatic urothelial cancer patients with FGFR3 alterations, BHV-1530 is designed to target FGFR3 regardless of alteration status, including wild-type overexpression seen in approximately 50% of metastatic urothelial cancer cases as well as other tumor types that overexpress FGFR3.*
- ***Anti-PD-1 combination cohorts planned:*** *Biohaven has entered into a clinical supply agreement with Regeneron Pharmaceuticals, Inc. to evaluate BHV-1530 in combination with cemiplimab (Libtayo), building on preclinical data demonstrating synergistic activity between BHV-1530's TopoIx payload and immune checkpoint blockade.*

NEW HAVEN, Conn., July 20, 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 new data on BHV-1530, its FGFR3-directed antibody-drug conjugate (ADC) using a novel topoisomerase I (TopoIx) payload, will be presented at the European Society for Medical Oncology (ESMO) Congress 2026, to be held October 23-27 in Madrid, Spain.



1019P - Phase 1 study of BHV-1530, a first-in-class FGFR3 ADC in Advanced Tumors
October 23, 2026: 15:15 - 16:00

The new Phase 1 data planned for ESMO will provide a clinically meaningful update to the early Phase 1 data initially disclosed at Biohaven's R&D Day on May 27, 2026. The new data will include signals of clinical activity demonstrated in the ongoing Phase 1, open-label, dose-escalation study of BHV-1530 in patients with advanced solid tumors. The data from May 27 2026, showed early signs of antitumor activity in patients with both FGFR3-altered and wild-type overexpressing tumors, and across multiple tumor types. This included a heavily pretreated patient with FGFR3-TACC3 fusion–positive metastatic urothelial cancer who had progressed on four prior lines of therapy, including Padcev (a nectin-4-directed ADC), pembrolizumab, and two FGFR-targeting small molecules. This patient has tolerated BHV-1530 with no FGFR-related toxicity. The data has shown a favorable 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.

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 the emerging monotherapy clinical data and preclinical data demonstrating synergistic activity between BHV-1530 and immune therapy. 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. Of note, early clinical data from the BHV-1510 program demonstrate a signal consistent with this thesis, as responses have been observed in multiple patients with prior anti–PD-(L)1 therapy.

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 clinic 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 plans to initiate combination cohorts evaluating BHV-1530 with anti-PD-1 therapy, including the recently announced combination with cemiplimab (Libtayo), in the second half of 2026.

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 planned 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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