Biohaven Presents Oncology Program Updates and Preliminary Clinical Data Showcasing Innovative Trop2 and FGFR3 Antibody Drug Conjugates (ADCs) Incorporating Novel TopoIx Payload with Potential to Treat a Wide Variety of Tumors

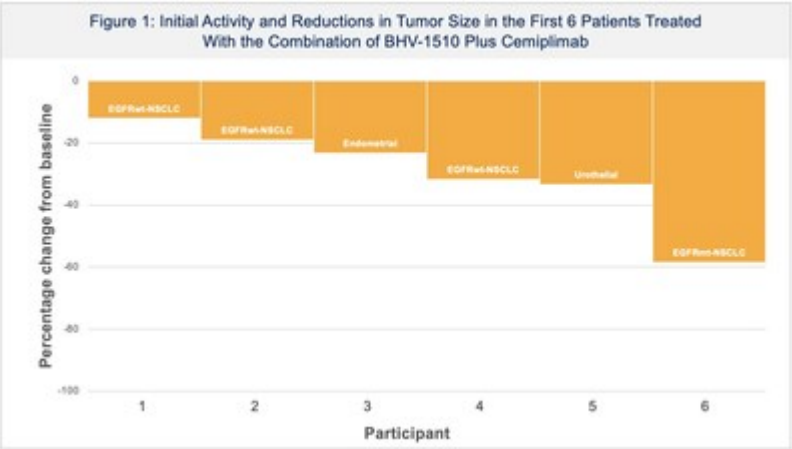
May 28, 2025

- BHV-1510, a highly differentiated Trop2 ADC incorporating the proprietary TopoIx payload, demonstrates early clinical activity and favorable safety profile in Phase 1 study as a monotherapy and in combination with Regeneron's anti-PD-1 cemiplimab.
    - Tumor reduction was observed in the first 6 out of 6 patients treated with BHV-1510 plus cemiplimab including confirmed partial responses
- First patient dosed with Biohaven's novel, first-in-class FGFR3 directed TopoIx ADC, BHV-1530
- Promising progress in the clinic demonstrates potential of Biohaven's innovative, next-generation ADC platform and TopoIx payload, with additional collaboration programs with Merus and GeneQuantum advancing preclinically.

NEW HAVEN, Conn., May 28, 2025 /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 provided an update and preliminary clinical data from its oncology development programs at Biohaven's 2025 R&D Day, held concurrently with the Yale Innovation Summit in New Haven, Connecticut. The presentation slides from Biohaven's R&D day for Oncology and its other platforms will be available on the **Events and Presentations page** of the Biohaven website just prior to their presentations.

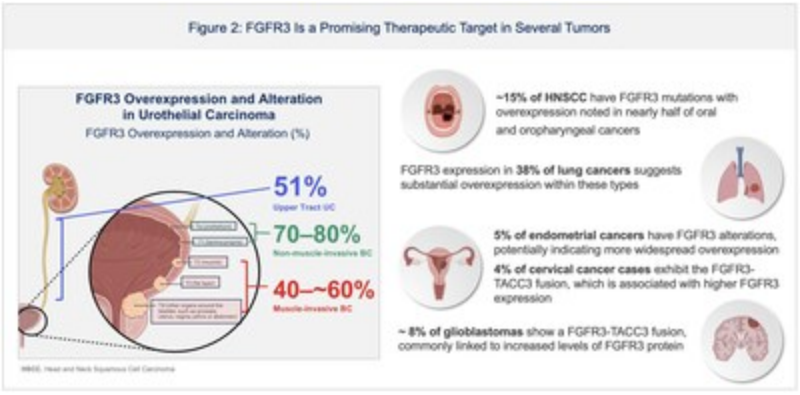
Biohaven reported that its novel next-generation trophoblast cell surface antigen 2 (Trop2) directed antibody drug conjugate (ADC), BHV-1510, demonstrated encouraging preliminary clinical activity both as a monotherapy and in combination with Regeneron's anti-PD-1 antibody cemiplimab. Early clinical data is consistent with BHV-1510's preclinical profile showing high ADC stability, differentiated safety and efficacy, immunogenic cell death, and anti-PD-1 synergism. Monotherapy tumor reductions including partial responses have been seen in patients failing standard of care therapies. The combination of BHV-1510 and cemiplimab in the ongoing Phase 1 study shows encouraging anti-tumor activity, with tumor shrinkage in the first 6 out of 6 patients treated, including confirmed partial responses and in patients with brain metastasis (Figure 1). The majority of patients treated with the combination had failed prior anti–PD-1/PD-L1 therapies. BHV-1510 showed a favorable pharmacokinetic (PK) profile, with very low levels of free payload. As monotherapy, the main toxicity observed thus far in the Phase 1 study has been stomatitis, an expected on-target Trop2 class toxicity that has been manageable. Importantly, there were no cases of payload-associated interstitial lung disease (ILD), and low rates of gastrointestinal (e.g., diarrhea) and hematologic toxicities observed. The combination with cemiplimab was well tolerated with no dose limiting toxicity to date in initial cohorts.

Figure 1: Initial Activity and Reductions in Tumor Size in the First 6 Patients Treated With the Combination of BHV-1510 Plus Cemiplimab



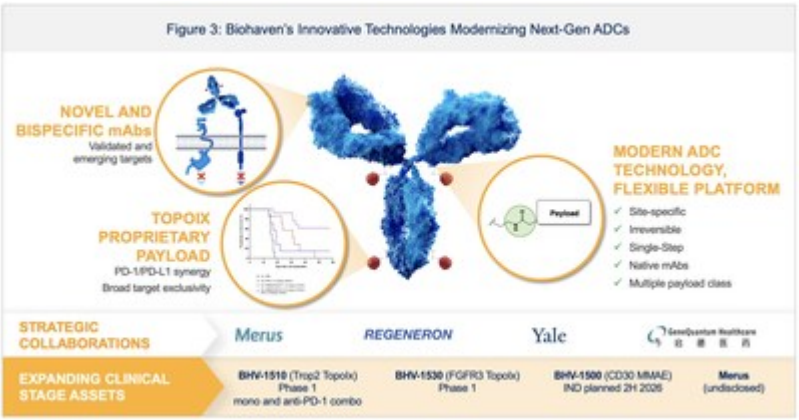
Nushmia Khokhar, M.D., Chief Medical Officer of Oncology at Biohaven, commented, "The early clinical data with BHV-1510 dosed in patients who failed standard of care treatment are highly encouraging, particularly the observed potential synergy with anti-PD-1 therapy. These findings, combined with the promising efficacy and tolerability profile of our novel TopoIx payload and stable linker technology, support the potential of BHV-1510 to advance into earlier lines of therapy for challenging tumor types."

Biohaven also announced the first patient has been dosed in the Phase 1 study of BHV-1530, a potential first-in-class fibroblast growth factor receptor 3 (FGFR3)-directed ADC which utilizes the proprietary TopoIx payload. BHV-1530 has potential in indications of cancers driven by FGFR3 alterations and/or upregulated FGFR3 protein expression, including urothelial cancers and other solid tumors (Figure 2). FGFR3 is a clinically validated target in oncology, with one small molecule inhibitor (erdafitinib) approved. There are no FGFR3 ADCs beyond BHV-1530 advanced in clinical testing.



Michael Song, M.D., Ph.D., Principal Investigator and leading medical oncologist and hematologist at NEXT Oncology with over 22 years of experience in cancer patient care and cancer research, stated, "We are excited to partner with Biohaven and dose the first patient on this important study. This is an exciting, validated target with potential to extend therapeutic benefit to several FGFR3 driven tumors."

Biohaven is also advancing a portfolio of innovative technologies to modernize next-generation ADCs through strategic collaborations with Merus and GeneQuantum (Figure 3). The preclinical programs leverage Biohaven's differentiated ADC platform directed against undisclosed novel validated and emerging high-value targets, and incorporating the TopoIx payload that preclinically demonstrated immunogenic cell death and synergistic efficacy with PD-1/PD-L1 checkpoint inhibitors.



Brian Lestini, M.D., Ph.D., President of Oncology at Biohaven, commented, 'We are excited to be in the clinic with two innovative ADCs and to share the early clinical experience with the first of our two programs, demonstrating the potential of our oncology portfolio to deliver a wide range of optimized, next-generation ADCs. The early clinical data from the Trop2 ADC, BHV-1510, shows the predicted profile and potential of the proprietary TopoIx payload as seen preclinically, and supports broad investigation of ADCs incorporating TopoIx and highly stable linker technologies. Similarly, initiation of the first-in-human study of BHV-1530, an FGFR3 directed ADC, demonstrates the versatility of our approach to generate novel drugs with the potential to address a wide variety of unmet needs in oncology. Together with our collaborations with Merus and GeneQuantum as well as licensed conjugation technology from Yale University, Biohaven's platform has the potential to generate multiple differentiated mono- and bispecific ADC therapies with greater potency and selectivity over currently available ADC approaches."

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; MoDE™ and TRAP™ 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; 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, including statements regarding the expected timing and amounts of funding under the NPA. 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, including the combination of BHV-1510 and cemiplimab in the ongoing Phase 1 study; 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, including the safety profile of BHV-1510. 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.

Investor Contact:
Jennifer Porcelli
Vice President, Investor Relations
jennifer.porcelli@biohavenpharma.com
+1 (201) 248-0741

Media Contact:
Mike Beyer
Sam Brown Inc.
mikebeyer@sambrown.com
+1 (312) 961-2502

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