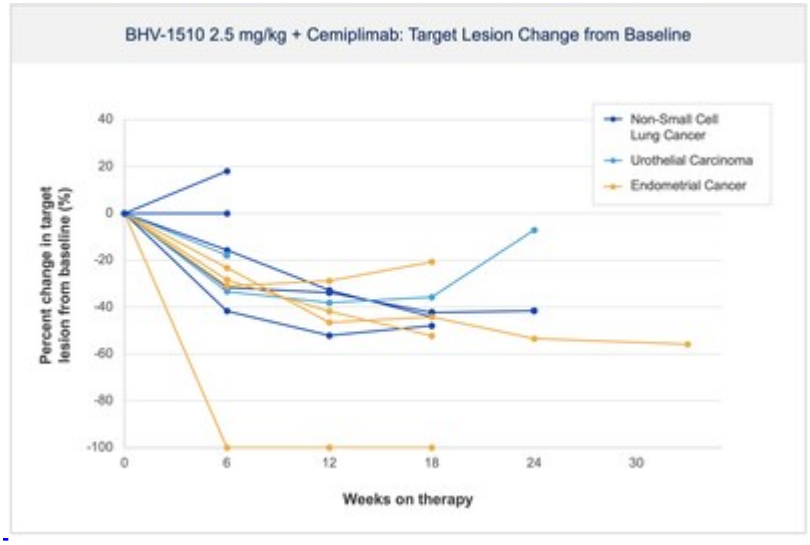
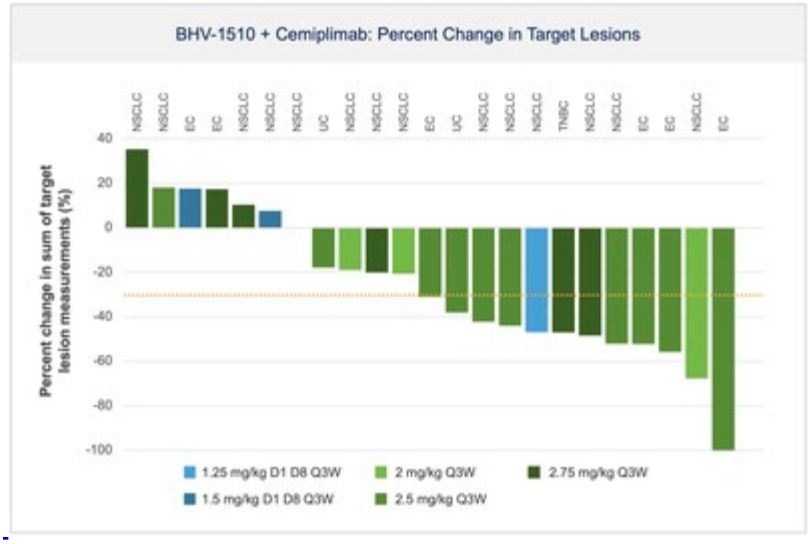
Biohaven Presents Clinical Safety and Efficacy Data for BHV-1510, a Next-Generation Trop2 Antibody Drug Conjugate in Combination with Cemiplimab at the 2025 European Society for Medical Oncology (ESMO) Immuno-Oncology Congress

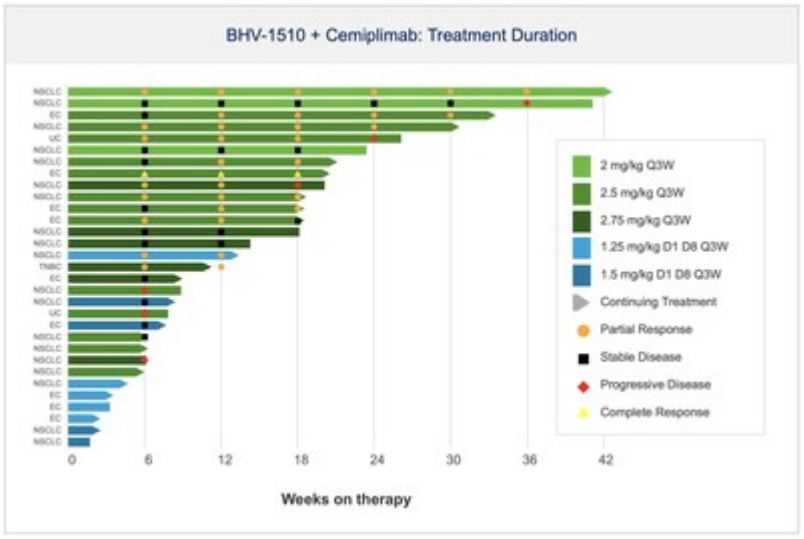
December 11, 2025

- In a pretreated population of participants with advanced/metastatic cancer and the majority with prior PD-(L)1 treatment, BHV-1510 2.5 mg/kg Q3W plus cemiplimab resulted in confirmed objective response rates 3/5 (60%) in NSCLC, 4/4 (100%) in endometrial cancer, and 1/2 (50%) in urothelial cancer
- There were low rates of adverse events attributed to unconjugated payload such as hematological toxicities and diarrhea, and there were no cases of interstitial lung disease, showing a differentiated safety profile of BHV-1510 from other Trop2 ADCs
- BHV-1510, a highly differentiated Trop2 ADC incorporating the proprietary TopoIx payload, demonstrates encouraging early clinical activity and favorable safety profile in a Phase 1 study in combination with the anti-PD-1 cemiplimab

LONDON and NEW HAVEN, Conn., Dec. 11, 2025 /PRNewswire/ -- Biohaven Ltd. (NYSE: BHVN) announced today that it presented clinical safety and efficacy data for BHV-1510 at the 2025 European Society for Medical Oncology (ESMO) Immuno-Oncology Congress, taking place from December 10-12, 2025, in London, United Kingdom. The presentation highlights Biohaven's novel next-generation trophoblast cell surface antigen 2 (Trop2) directed antibody drug conjugate (ADC), BHV-1510, in combination with Regeneron's anti-PD-1 cemiplimab demonstrating efficacy and manageable safety across several tumors.







At the BHV-1510 dose of 2.5 mg/kg Q3W in combination with cemiplimab, confirmed ORR was 72.7%. Confirmed responses were observed in 3/5 (60%) in NSCLC, 4/4 (100%) in endometrial cancer, which included a complete response, and 1/2 (50%) in urothelial cancer (Fig.1). In all 23 efficacy evaluable participants treated with BHV-1510 in combination with cemiplimab across dose levels, as of the clinical cutoff date (October 10, 2025) the confirmed objective response rate (ORR) was 52.2%, with confirmed objective responses in 6/14 (42.9%) in NSCLC, 4/6 (66.7%) in endometrial cancer, and 1/2 (50%) in urothelial cancer (Fig. 2). A confirmed response was reported in the participant with triple negative breast cancer.
The majority of participants had tumor reduction on their first scan, with a median time to response of 11.1 weeks. Participants remain on study at 6 months and beyond, 18 participants continue on the study treatment at time of the clinical cutoff date (Fig.3).

Ida Micaily, M.D., M.S., Principal Investigator and Assistant Professor at Sidney Kimmel Comprehensive Cancer Center at Jefferson stated, "We are excited by this emerging data and the potential synergy of BHV-1510 with cemiplimab. The early responses we are observing in these difficult-to-treat tumors—despite patients having received prior therapies, including other PD-1/PD-L1 agents—are particularly encouraging. We also have patients remaining on therapy beyond six months, suggesting the potential for durable disease control."

In the population studied, the median prior lines of therapy for advanced/metastatic disease were two and the majority (87.1%) had prior PD-(L)1 exposure with 16 participants (51.6%) receiving a PD-(L)1 as the most recent treatment prior to receiving study treatment. The maximum tolerated dose was not reached and only one participant had a dose limiting toxicity of stomatitis (Grade 3) at the 2.75 mg/kg Q3W dose. As of the clinical cutoff date, a total of 31 participants were treated with the combination of BHV-1510 and cemiplimab, with BHV-1510 doses ranging from 2-2.75 mg/kg Q3W and 1.25-1.5 mg/kg D1D8Q3W. Cemiplimab was given at 350 mg Q3W.

Across all doses BHV-1510, was generally well tolerated with a safety profile differentiated from other Trop-2 ADCs. The rate of neutrophil count decrease was low and manageable; all Grade (Grade ≥3), 12.9% (6.5%). Similarly, the rates of treatment emergent diarrhea and alopecia were low; all Grade (Grade ≥3), 6.5% (0) and 9.7% respectively. The most frequent toxicity observed was oral mucositis/stomatitis all Grade (Grade ≥3), 59.1% (22.7%) in the Q3W regimen and all Grade (Grade ≥3), 33.3% (11.1%) in the D1D8Q3W regimen. This is a well-known class effect which is manageable. Importantly, there were no cases of interstitial lung disease, and no participants discontinued treatment due to an adverse event. Treatment emergent SAEs were reported in 4 participants, none of which were related to the study treatment. The pharmacokinetic profile for BHV-1510 was favorable, the unconjugated payload concentration was low with a payload-to-ADC molar ratio < 1%, indicating that ADC was highly stable in the circulation.

Nushmia Khokhar, M.D., Chief Medical Officer of Oncology at Biohaven, commented, "Continued preliminary clinical data with BHV-1510 in patients

who have received and progressed on standard-of-care treatment, including prior anti-PD1/PDL1 therapy, are highly encouraging. These findings —together with the early promising efficacy, differentiated safety profile, lack of payload-related toxicity, enabled by our novel TopoIx payload and stable linker technology—underscores the potential for BHV-1510 to move into earlier lines of therapy, in particular with checkpoint inhibitor combinations, for these challenging tumor types."

Poster Presentation Information:

Poster 252P: Phase 1 clinical trial of BHV-1510, a next generation Trop2 ADC, in combination with the PD-1 monoclonal antibody, cemiplimab in patients with advanced solid tumors.
Date/Time: Wednesday, December 10, 2025, 5:15-6:30 pm GMT

The poster will be available on the **Posters and Presentations** page after the conference at **www.biohaven.com**.

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 key clinical and preclinical programs include Kv7 ion channel modulation for epilepsy and mood disorders; MoDE™ and TRAP™ extracellular protein degradation for immunological diseases; and myostatin-activin pathway targeting agent for neuromuscular and metabolic diseases, including SMA and 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. The use of certain words, including "continue", "plan", "will", "believe", "may", "expect", "potential first-in-class", "potentially", "groundbreaking" 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 studies of BHV-1510; the timing of planned interactions and filings with the FDA; the timing and outcome of expected regulatory filings; complying with applicable US regulatory requirements; the potential commercialization of Biohaven's product candidates; 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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