Biohaven Highlights Portfolio Progress, Positive Early Patient Data from Priority Degrader Programs and Anticipated Milestones at the 44th Annual J.P. Morgan Healthcare Conference

January 12, 2026

- **Reports positive early clinical experience from first and only clinically validated, extracellular protein degraders using Biohaven's proprietary MoDE™ and next-generation, highly selective TRAP™ degraders exclusively licensed from Yale University. Early clinical experience in patients demonstrates rapid removal of circulating disease-causing proteins, resulting in robust clinical improvement with a well-tolerated profile to date:**
  - **IgA Nephropathy (IgAN) Program:** First dosing of BHV-1400 TRAP degrader in IgAN patients achieved early observations of both biomarker and clinical responses including: selective lowering of only the disease-causing galactose-deficient IgA1 (Gd-IgA1) while sparing off-target effects on healthy antibodies (IgA, IgM, IgE, IgG), resolution of blood in the urine (hematuria), deep reductions in proteinuria, and improvement in fatigue and kidney function (eGFR) within weeks.
    - Completed 4Q25 FDA meeting to align on pivotal IgAN study design; study to initiate in early 2026
  - **Graves' Disease Program:** First-in-patient clinical experience with BHV-1300, an IgG MoDE degrader, resulted in a complete suppression of disease-causing TSH receptor-stimulating antibodies with accompanying normalization of previously elevated thyroid hormones within weeks after dosing a patient with Graves' disease. BHV-1300 has shown the potential for best-in-class reductions of IgG, with maximum reductions of up to an 87% decrease from baseline within weeks of dosing.
    - Biohaven is planning a pivotal study of BHV-1300 in Graves' disease in 2026.
  - **Advancement of Broad Degrader Portfolio:** With clinical proof-of-concept now established, Biohaven is positioned to advance multiple next-generation degraders targeting high value immune-mediated disease indications and explore strategic partnerships to advance the breadth of this platform technology.
- **Announces preliminary data with opakalim, a selective Kv7 channel activator, in an ongoing open-label extension (OLE) clinical study in focal epilepsy.**
  - Demonstrated clinically meaningful reductions in seizure frequency compared to pretreatment baseline. Specifically, the majority of participants treated with opakalim 75 mg once daily who completed at least 6 months of OLE treatment showed ≥50% reductions in seizure frequency compared to pretreatment baseline.
  - Well-tolerated in the OLE with a low incidence of central nervous system adverse events, representing a potential paradigm-shift for patients with a highly favorable and differentiated safety profile compared to other approved or investigational antiseizure medicines.
  - Pivotal results for opakalim in the treatment of focal epilepsy expected in 2026.
- **Announces initiation of obesity Phase 2 study with Biohaven's myostatin-activin inhibitor targeting high quality weight loss. Dosing began in 4Q 2025 with topline results expected in 2026**
  - Taldefgrobep alfa, an inhibitor of the myostatin-activin II receptor signaling pathways, directly targets: fat reduction, increased lean muscle mass and improves in bone density while avoiding intolerable adverse effects.
  - Taldefgrobep-myostatin complexes also result in the inhibition of Activin E - ALK7 in adipocytes, thereby having a direct effect on reducing adipose tissue.
  - Taldefgrobep has demonstrated a highly favorable safety and tolerability profile in >700 clinical trial participants studied to date.
- **Highlights clinical progress with Biohaven's next generation antibody drug conjugates (ADCs) in oncology**
  - Phase 1/2 study evaluating BHV-1510 (Trop2 ADC) as monotherapy and in combination with Regeneron's anti-PD-1 monoclonal antibody cemiplimab shows continued clinical activity with confirmed responses and a differentiated safety profile in the ongoing study.
  - Endometrial cancer expansion cohort has been initiated with the combination of BHV-1510 and cemiplimab.
  - Initiated novel subcutaneous dosing with BHV-1510, first and only Trop2 ADC in clinic with potential subcutaneous route of administration.
  - First-in-class FGFR3 directed ADC, BHV-1530, continues with dose escalation and no dose limiting toxicities to date.
- **Advancements across portfolio of early clinical and next-generation future programs, including:**
  - Pivotal clinical trial continues to advance enrollment with Biohaven's brain-penetrant TYK2/JAK1 inhibitor, BHV-8000 to treat early Parkinson's disease.
  - BHV-1955, a novel, long-acting intranasal formulation of oxytocin, for the central treatment of tinnitus.
  - BHV-8100, a brain-penetrant activator of the M2 isoform of pyruvate kinase (PKM2) for neurodegenerative

disorders and aging.

NEW HAVEN, Conn., Jan. 12, 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 highlighted its broad portfolio progress at the 44th Annual J.P. Morgan Healthcare Conference. A copy of the slide presentation is available on the Events and Presentations section of the Biohaven website.

Vlad Coric, M.D., Chairman and Chief Executive Officer of Biohaven, commented, "As we prioritize key programs across our portfolio that can efficiently deliver clear value for patients and investors, we are excited to highlight the first patient experiences using our proprietary MoDE™ and TRAP™ extracellular degraders at the annual J.P. Morgan Healthcare Conference. The early data continues to signal the important role that this transformative science can have in the treatment of immunological disease and the potential for our technology to provide differentiated treatments for patients suffering from immune-mediated conditions such as IgA nephropathy and Graves' disease. Our lead programs represent just the beginning of this platform; we aim to transform immunological disease therapy by selectively removing disease-causing proteins as they circulate in the blood and body, fulfilling the potential of true precision immunology to target the root cause of diseases without immunosuppression."

"We've dosed our first patient in our obesity program with taldefgrobep that introduces a dual-action therapy to not only reduce fat but also build lean muscle mass, addressing a critical unmet need in metabolic health," continued Dr. Coric "We expect topline data from this Phase 2 obesity proof-of-concept trial in 2026. In addition, we continue to advance a clinically validated approach for treating focal epilepsy that targets Kv7 ion channels with pivotal topline data expected in 2026. Our advancements and discovery expertise demonstrate our commitment to developing innovative treatments that address a wide range of patient needs."

Biohaven 2026 Portfolio Review and Anticipated Milestones

Biohaven is positioned to achieve significant milestones in 2026 across key programs targeting indications with high unmet need. Throughout its clinical-stage portfolio, combined with its innovative discovery engine, the company is advancing a broad range of innovative medicines that represent paradigm-shifting treatment options.

Novel Degrader Platforms: Biohaven Raises the Bar in Precision Immunology

Biohaven is pioneering scientific innovation in extracellular protein degradation, a transformational therapeutic approach for autoimmune diseases that focuses on the precise targeting and selective removal of disease-causing proteins. Based upon the groundbreaking work from the Spiegel Chemistry Lab at Yale University and exclusively licensed by Biohaven, the company's MoDE and TRAP degrader platform offers selectivity, speed, and patient-friendly self-administration to remove disease-causing extracellular proteins from the body to potentially treat a wide range of diseases.

As part of an initiative to further advance and accelerate next-generation degrader development, Biohaven also announced entering into an memorandum of understanding with the King Abdullah University of Science and Technology (KAUST) to collaborate on discovery efforts and leverage the University's technology capabilities including strengths in its Smart Health initiatives, generative AI, and supercomputing.

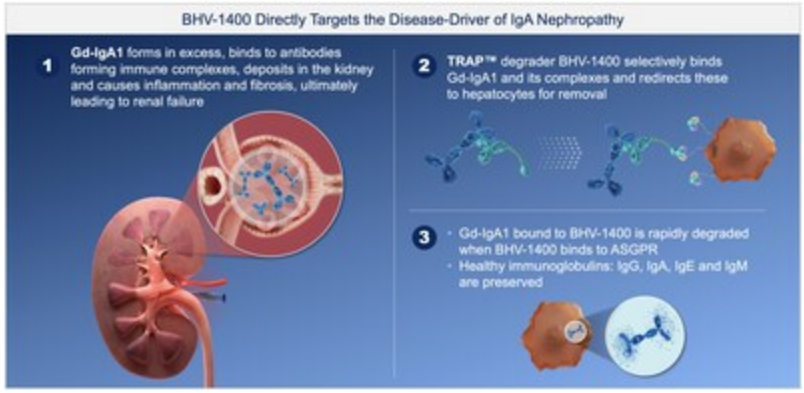
BHV-1400: Next-Generation TRAP Degrader for IgA Nephropathy (IgAN)

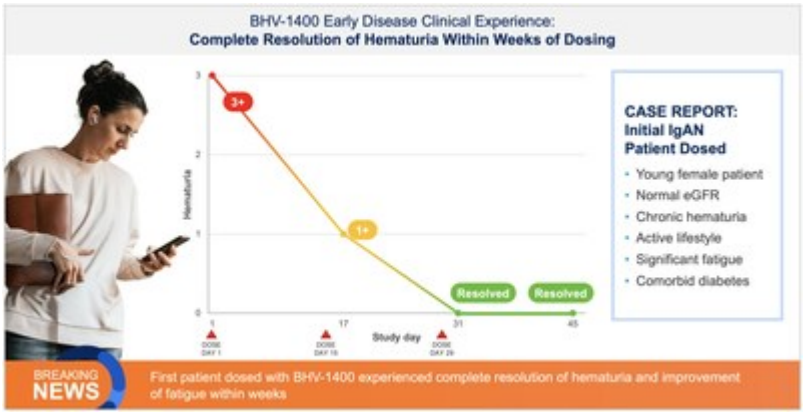
Biohaven's highly selective next-generation TRAP degraders target a specific disease-causing protein for degradation after removal from the circulation. The company's potential first-in-class TRAP degrader, BHV-1400, brings precision immunology to the treatment landscape of IgA nephropathy the most common primary glomerulonephritis worldwide. IgAN is caused by the excess production of galactose-deficient IgA1 (Gd-IgA1) which is bound by autoantibodies and forms complexes that deposit in the glomerular mesangium triggering a profibrotic and proinflammatory cascade, ultimately leading to renal failure.

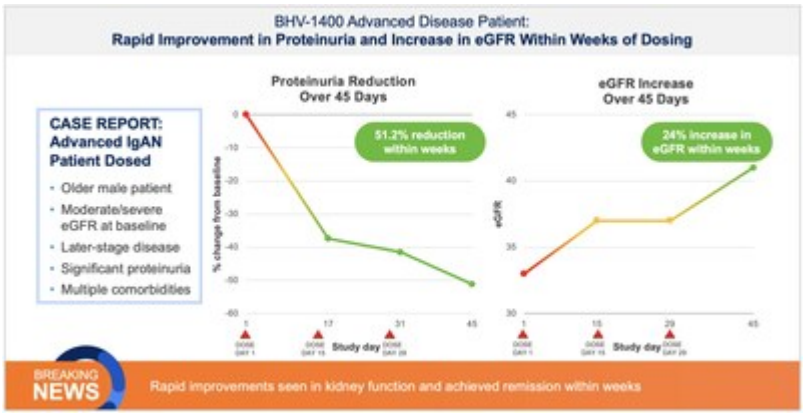
The first clinical experience with BHV-1400 underscores its paradigm-shifting potential to selectively remove only aberrant Gd-IgA1, the disease-causing species in IgA nephropathy, while sparing normal IgA. First-in-patient dosing with BHV-1400, a next-generation TRAP degrader, achieved selective lowering of Gd-1gA1 within hours, translating to hematuria resolution, deep reductions in proteinuria, and eGFR improvements within weeks of dosing.

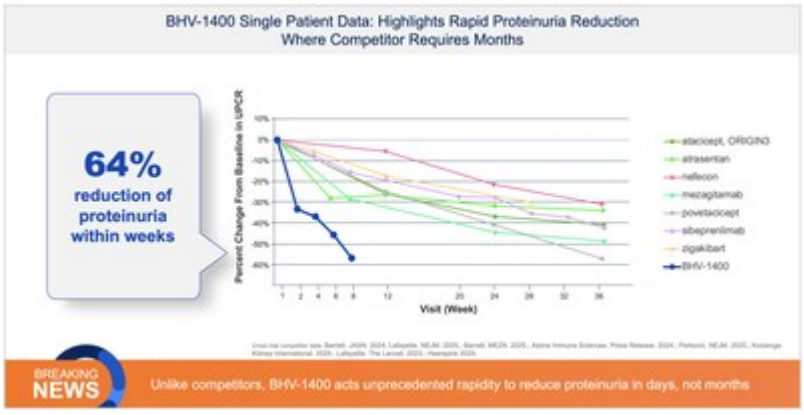
The first patient dosed, a young woman with early disease, normal baseline eGFR and chronic hematuria experienced rapid reductions in Gd-IgA1 associated with complete resolution of chronic hematuria and improvement in symptoms of fatigue within weeks of dosing. The second patient dosed, a man with late-moderate-to-severe loss of kidney function as evidenced by decreased baseline eGFR, experienced rapid reductions in Gd-IgA1 associated with robust reductions in proteinuria of greater than 60% and improvement in kidney function as measured by a 24% increase in GFR within weeks of dosing. Importantly, both patients showed no significant reductions in normal IgA, IgG, or IgM. Additional IgAN patients are being treated in the expansion cohort and plans are underway for initiating a pivotal trial of BHV-1400 in 2026.

In the ongoing Phase 1, BHV-1400 achieved rapid lowering of Gd-IgA1 with a mean reduction of >60% within hours. Maximum reduction exceeding 80% was observed following the first dose. This selective and rapid approach to immunoglobulin lowering represents a second-generation therapeutic approach to IgAN, potentially allowing for faster, meaningful disease control with less acute or long-term safety risks associated with complement inhibition or broad antibody suppression. As in healthy participants, BHV-1400 has been safe and well-tolerated in initial patients with IgAN. As of January 2026, there have been no drug-related adverse events in the Phase 1b expansion cohort.







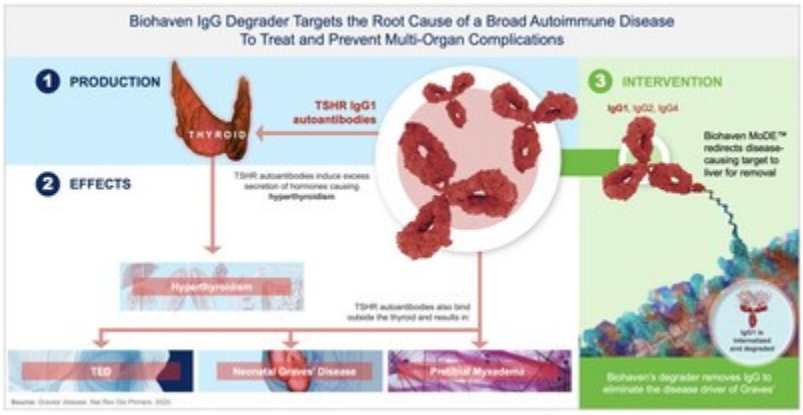


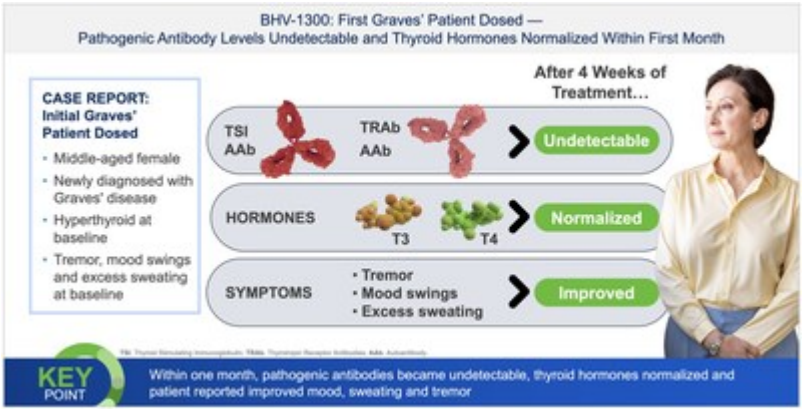
BHV 1300: MoDE Degrader with Potential to Transform Care Across Multiple IgG Mediated Diseases

BHV-1300, Biohaven's lead MoDE degrader, is currently in development for Graves' disease, an IgG1-mediated autoimmune disease caused by autoantibodies that hyperstimulate the TSH receptor, causing hyperthyroidism and requiring surgical removal or chemical ablation of the thyroid or the chronic administration of anti-thyroid drugs. BHV-1300 has shown the potential for best-in-class reductions of IgG, with maximum reductions up to an 87% decrease from baseline within weeks of dosing and has been safe and well-tolerated in Phase 1 clinical studies.

Results from the first-in patient clinical experience with BHV-1300 also showed that it induced complete suppression of pathogenic TSH receptor-

stimulating antibodies with normalization of previously elevated thyroid hormones within weeks after dosing. There were no clinically significant reductions in IgG3, IgA, IgE, IgM, or albumin, nor increases in cholesterol compared to baseline. Clinical findings to date position BHV-1300 for pivotal study initiation in Graves' disease in 2026, as well as additional follow-on studies in other autoimmune diseases where its therapeutic pan-IgG depletion capability is expected to have significant potential.





Biohaven Discovery Engine for Next-Generation Degraders

With proof-of-concept now established in patients for the first clinically validated extracellular protein degrader platform, Biohaven's discovery engine is prepared to advance next-generation MoDE and TRAP degraders as lead programs, including:

- BHV-1420, a PLA2R autoantibody specific TRAP degrader, for membranous nephropathy;
- BHV-1450, a IgG4 specific MODE degrader, for potential indications including pemphigus vulgaris and myasthenia gravis with anti-MuSK antibodies;
- BHV-1440, a TSHR autoantibody specific TRAP degrader, as the next-generation of immune therapy for Graves' disease and thyroid eye disease;
- BHV-6500, a proinsulin and insulin autoantibody TRAP degrader, for type 1 diabetes;
- BHV-1490, an IgM MoDE degrader for cryoglobulinemia, Waldenstrom's macroglobulinemia and IgM neuropathy;
- BHV-1310, a next generation IgG MoDE degrader, for management of rare IgG-mediated indications;
- BHV-1600, a beta-1 adrenergic receptor autoantibody degrader, for cardiomyopathy; and,
- Multiple undisclosed degrader targets in early discovery development.

Epilepsy Program: Revolutionizing the Treatment of Epilepsy with a Modern Kv7 Activator

Opakalim is a next-generation, selective Kv7 activator, targeting a clinically validated mechanism of action for the treatment of epilepsy. It is highly differentiated from ezogabine, a first-generation non-selective Kv7 activator previously approved for the treatment of focal seizures, and ezogabine analogs in development. Importantly, opakalim does not exhibit the GABA receptor activity seen with ezogabine and other antiseizure medicines (ASMs), which contribute to central nervous system (CNS) adverse effects and their poor tolerability in the clinic. Opakalim is being developed to address the significant unmet medical need that exists for novel ASMs having a favorable tolerability profile, especially those with mechanisms of action that are complementary to currently available ASMs.

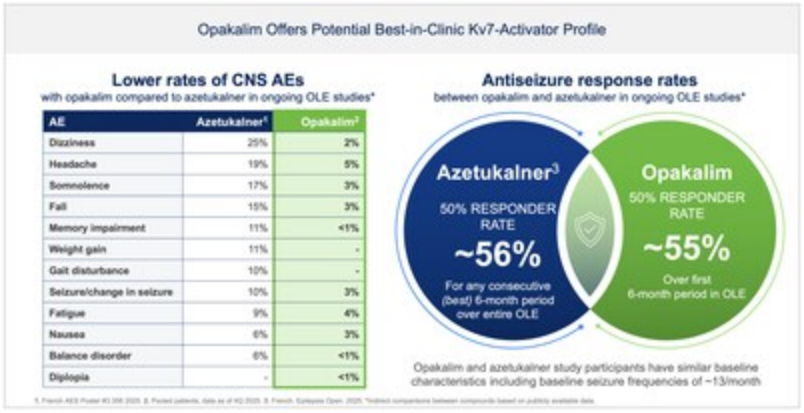
Biohaven is currently conducting two Phase 2/3 randomized, double-blind, placebo-controlled studies (NCT06132893 and NCT06309966) comparing the efficacy of opakalim to placebo as an adjunctive therapy for refractory focal onset epilepsy, as well as an open-label extension (OLE) study (NCT06443463) to evaluate the long-term efficacy and safety of opakalim in participants who completed either parent study.

Review of data from the ongoing open-label clinical trial experience with opakalim in focal epilepsy support the potential for opakalim to achieve compelling efficacy and to deliver a highly favorable and differentiated safety profile. Open-label treatment with opakalim demonstrated clinically meaningful reductions in seizure frequency compared to the pretreatment baseline observation period prior to randomization. Specifically, 55% of participants showed ≥50% reductions in seizure frequency (≥50% responder rate), for those who completed at least 6 months of treatment with opakalim 75 mg once daily in the open-label study; and this result is comparable to the ≥50% responder rate published for other investigational agents

in the class such azetukalner (which has reported 56% of patients with a ≥50% responder rate over any consecutive best 6-month period from its Phase 2b OLE data). Notably, the antiseizure effects of opakalim were correlated with plasma concentrations, based on a preliminary exposure-response analysis. Opakalim was well-tolerated in the open-label study with a low incidence of CNS adverse events, consistent with prior studies with opakalim.

These preliminary observations support the paradigm-shifting potential of opakalim to achieve antiseizure efficacy with a highly favorable and differentiated tolerability profile compared to other approved ASMs and those in development.

- Pivotal topline results for opakalim in the treatment of focal epilepsy are expected in 2026.



Obesity Program: Targeting High Quality Weight Loss

Taldefgrobep alfa is Biohaven's novel inhibitor of the myostatin-activin signaling pathway with the potential to achieve high quality weight loss in people living with obesity.

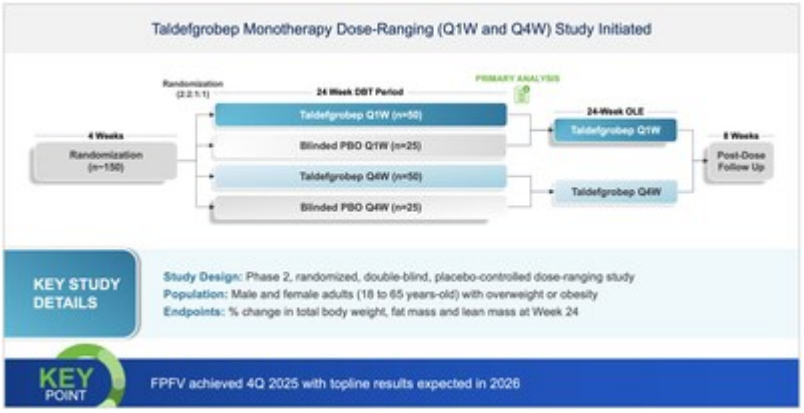
Biohaven initiated a taldefgrobep Phase 2 proof-of-concept study in obesity during the fourth quarter of 2025 (NCT07281495). This randomized, double-blind, placebo-controlled, 24-week, dose-ranging study is evaluating the efficacy and tolerability of once-weekly and once-monthly taldefgrobep as monotherapy, via self-administered autoinjector, in adults living with overweight and obesity. Approximately 150 participants will be enrolled. The primary outcome measure is percent change in total body weight from baseline to Week 24.

Taldefgrobep's differentiated mode of action targets fat reduction, builds muscle, and increases bone density.

In the clinic, taldefgrobep has demonstrated beneficial changes in fat mass and lean mass in non-obese populations, including healthy adult participants in a Phase 1 study. Participants who received taldefgrobep once-weekly realized significant reductions in total body fat mass (>6%) and increases in lean muscle mass (up to 4%) after one month of dosing. Notably, these body composition parameters continued to demonstrate additional improvements after cessation of dosing associated with the persistence of the pharmacologically active taldefgrobep-myostatin complex and suggesting the drug may support extended dosing intervals. Recent nonclinical data demonstrates that this complex cam also potently inhibit the Activin E-ALK7 signaling axis within adipocytes, further underpinning the complementary mechanistic advantages of taldefgrobep in both growing muscle and reducing fat.

Taldefgrobep has an established safety profile that is well-suited for an indication in overweight and obesity. It has been previously evaluated in >700 clinical trial participants across 5 completed studies and an ongoing Phase 3 trial in spinal muscular atrophy. Throughout its clinical development, taldefgrobep has been well tolerated, with rates of muscle and gastrointestinal adverse events comparable to placebo.

- Phase 2 topline results for taldefgrobep in the treatment of obesity are expected in 2026.



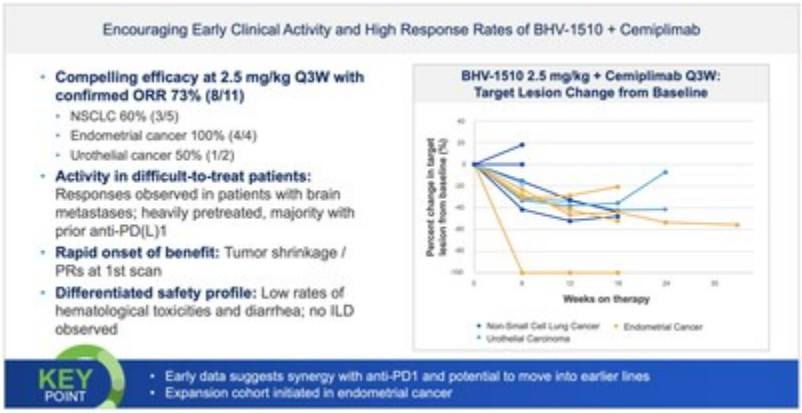
Advancement of Key Next Generation ADC Oncology Programs

BHV-1510 (Trop2 ADC): Preliminary Phase 1 results for BHV-1510 showed encouraging clinical activity with confirmed responses and a differentiated safety profile demonstrating clinical proof of principle with Biohaven's novel topoisomerase 1 (TopoIx) payload. In a pretreated population of participants with advanced/metastatic cancer, the majority with prior PD-(L)1 treatment, BHV-1510 2.5 mg/kg IV Q3W plus cemiplimab resulted in a

confirmed objective response rate of 72.7% (8/11), including 3/5 (60%) in NSCLC, 4/4 (100%) in endometrial cancer, and 1/2 (50%) in urothelial cancer. BHV-1510 demonstrated low rates of adverse events consistent with very low levels of unconjugated payload (such as hematological toxicities and diarrhea), and there were no cases of interstitial lung disease, thus indicating a differentiated safety profile of BHV-1510 from other Trop2 ADCs. The most frequent toxicity was oral mucositis/stomatitis, a known class effect that is manageable with supportive care. Based on these data, an expansion cohort has initiated in endometrial cancer for the combination of BHV-1510 plus cemiplimab.

Biohaven also announced the successful initiation of subcutaneous administration with BHV-1510, as the first and only Trop2 ADC in clinic with the potential for subcutaneous delivery. In the first patients, early data showed bioavailability in the predicted range with tumor shrinkage in first patient dosed. Subcutaneous delivery may offer several advantages over intravenous infusion, including a more patient-friendly experience and rapid administration (minutes vs hours). In addition, subcutaneous dosing may provide an optimized pharmacokinetic profile with lower Cmax and more stable exposure, which may support improved safety and efficacy.

BHV-1530 (FGFR3 ADC): Biohaven also provides an update of the ongoing first-in-human clinical trial of BHV-1530, a potential first-in-class FGFR3-directed ADC that also leverages the proprietary TopoIx payload. In the initial cohorts, no dose-limiting toxicities were observed, and no safety signals have emerged. Early tumor reduction was seen in a patient with an FGFR3 mutation as dosing enters the predicted efficacious range. The pharmacokinetic profile indicates a highly stable ADC, consistent with Biohaven's next-generation platform technology. FGFR3 is a promising therapeutic target in patients with genetic alterations or overexpression including urothelial cancer and may also be relevant across other solid tumors with high unmet need.



Progress across portfolio of clinical and next-generation discovery programs:

Patient enrollment continues in pivotal Phase 2/3 clinical trial in early Parkinson's disease with brain-penetrant **TYK2/JAK1 inhibitor,** BHV 8000.

Biohaven Discovery Engine: Next wave of innovative, therapeutics primed to advance forward at an intentional cadence.

- Discovery has advanced multiple novel development candidates for future clinical development. Beyond the degrader platform, these include:
  - BHV-1955 targeting the oxytocin receptor centrally for the treatment of tinnitus;
  - BHV-2120, oral small molecule TRPM3 inhibitor for epilepsy
  - BHV-8555, a brain penetrant, oral small molecule preventing a-synuclein aggregation in Parkinson's disease; and
  - BHV-8100, a brain-penetrant, oral small molecule activating the M2 isoform of pyruvate kinase (PKM2) for neurodegenerative disorders and aging.

About Biohaven
Biohaven is a biopharmaceutical company focused on the discovery, development and commercialization of life-changing treatments in key therapeutic areas, including immunology, obesity, 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 MoDE™ and TRAP™ extracellular protein degraders for immunological diseases; myostatin-activin pathway targeting agents for neuromuscular and metabolic diseases, including SMA and obesity; and Kv7 ion channel modulation for epilepsy. 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", "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; 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; the potential for Biohaven's product candidates to be best-in-class or first-in-class; 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.

MoDE and TRAP are trademarks of Biohaven Therapeutics Ltd.

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

Media Contact:
Christy Curran
Sam Brown Inc.
christycurran@sambrown.com
615-414-8668

View original content to download multimedia:https://www.prnewswire.com/news-releases/biohaven-highlights-portfolio-progress-positive-early-patient-data-from-priority-degrader-programs-and-anticipated-milestones-at-the-44th-annual-jp-morgan-healthcare-conference-302658655.html

SOURCE Biohaven Ltd.