# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, DC 20549**

# FORM 8-K
**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of**
**The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): January 13, 2025

## Biohaven Ltd.
(Exact name of registrant as specified in its charter)

| **British Virgin Islands** | **001-41477** | **Not applicable** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**c/o Biohaven Pharmaceuticals, Inc.**
**215 Church Street**
**New Haven, Connecticut 06510**
(Address of principal executive offices, including zip code)
**(203) 404-0410**
(Registrant's telephone number, including area code)
**Not applicable**
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading symbol | Name of each exchange on which registered |
|---|---|---|
| Common Shares, no par value | BHVN | New York Stock Exchange |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure**

On January 13, 2025, Biohaven Ltd. will be making an investor presentation (the "Presentation"). A copy of the Presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit Number | Exhibit Description |
|---|---|
| 99.1 | Investor Presentation, dated January 2025. |
| 104 | The cover page of this Current Report on Form 8-K formatted as Inline XBRL. |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 13, 2025

**Biohaven Ltd.**

By: /s/ Matthew Buten
Matthew Buten
Chief Financial Officer

biohaven®

# DAYS MATTER™

## 43rd Annual J.P. Morgan Healthcare Conference

January 13, 2025

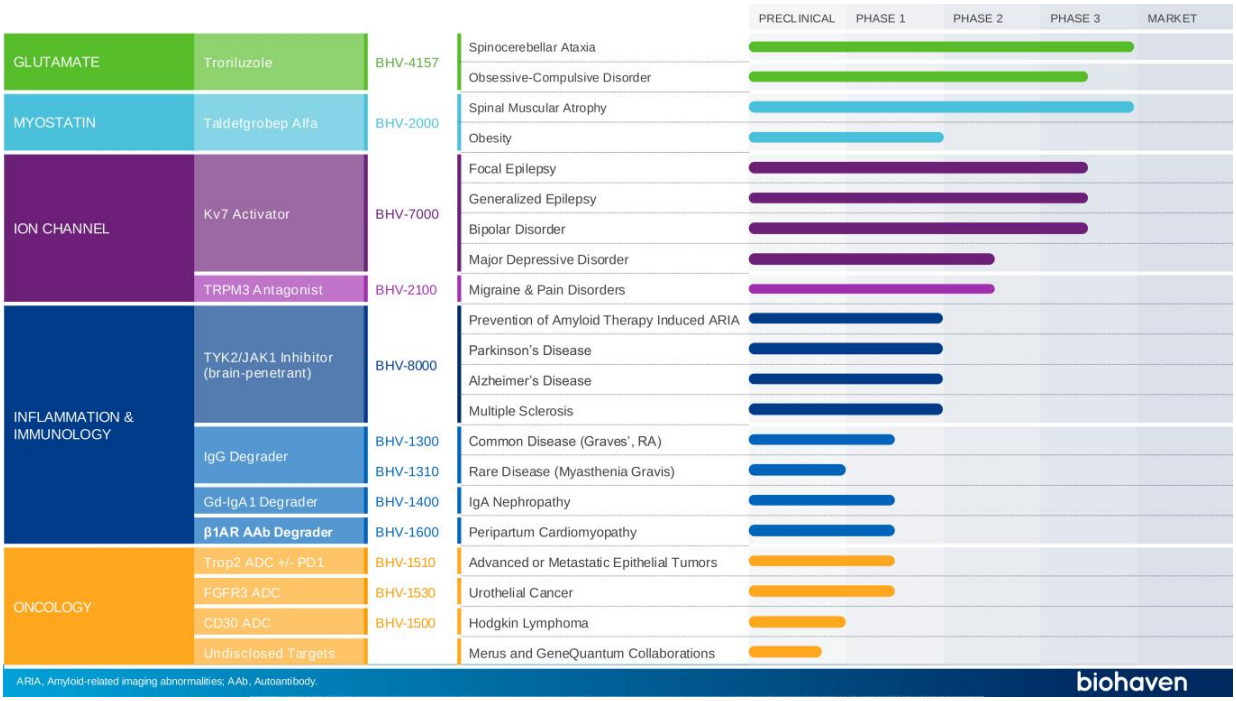
Vlad Coric, M.D.
Chairman and Chief Executive Officer



# Forward-Looking Statement

This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about Biohaven Ltd. (the “Company”) and our planned and ongoing clinical trials for our taldefgrobep alfa, troriluzole, BHV-2100, BHV-7000, BHV-8000, BHV-1300, BHV-1310, BHV-1510 and BHV-1530 development programs, the timing of and the availability of data from our clinical trials, the timing and our decisions to proceed with our planned regulatory filings, the timing of and our ability to obtain regulatory approvals for our product candidates, the clinical potential utility of our product candidates, alone and as compared to other existing potential treatment options, and the potential advancement of our early phase programs including BHV-1400, BHV-1500, and BHV-1600. 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 our 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 Food and Drug Administration; 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 first-in-class or best-in-class therapies; and the effectiveness and safety of Biohaven's product candidates. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Additional important factors to be considered in connection with forward-looking statements are described in the Company’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”. This presentation also contains market data and other information based on industry publications, reports by market research firms or published independent sources. Some market data and information is also based on the Company’s good faith estimates, which are derived from management’s knowledge of its industry and such independent sources referred to above.


DIVERSIFIED
into top areas of
INNOVATION
IMMUNOLOGY & INFLAMMATION
NEUROLOGY
OBESITY
ONCOLOGY
CARDIOVASCULAR
RENAL
RARE DISEASE
Focused on Days Matter™
COMMERCIALIZATION
OF NOVEL TXs
INCREASED
MARKET CAP
10X
POSITIONED FOR
FUTURE
VALUE
CREATION
ADVANCING
CANCER
TREATMENTS
with strategic partnerships
TWO YEARS
SINCE SPIN-OFF
biohaven®
PIONEERING
therapies for
rare diseases
including
SMA &
SCA
CLINICALLY
VALIDATED
NEXT-GEN TRAP™
DEGRADERS
Targeted removal of
aberrant proteins
Integrated
DISCOVERY
ENGINE


PRECLINICAL
PHASE 1
PHASE 2
PHASE 3
MARKET
GLUTAMATE
Troriluzole
BHV-4157
Spinocerebellar Ataxia
Obsessive-Compulsive Disorder
MYOSTATIN
Taldefgrobep Alfa
BHV-2000
Spinal Muscular Atrophy
Obesity
ION CHANNEL
Kv7 Activator
BHV-7000
Focal Epilepsy
Generalized Epilepsy
Bipolar Disorder
Major Depressive Disorder
TRPM3 Antagonist
BHV-2100
Migraine & Pain Disorders
INFLAMMATION & IMMUNOLOGY
TYK2/JAK1 Inhibitor (brain-penetrant)
BHV-8000
Prevention of Amyloid Therapy Induced ARIA
Parkinson's Disease
Alzheimer's Disease
Multiple Sclerosis
IgG Degrader
BHV-1300
Common Disease (Graves', RA)
BHV-1310
Rare Disease (Myasthenia Gravis)
Gd-IgA1 Degrader
BHV-1400
IgA Nephropathy
β1AR AAb Degrader
BHV-1600
Peripartum Cardiomyopathy
ONCOLOGY
Trop2 ADC +/- PD1
BHV-1510
Advanced or Metastatic Epithelial Tumors
FGFR3 ADC
BHV-1530
Urothelial Cancer
CD30 ADC
BHV-1500
Hodgkin Lymphoma
Undisclosed Targets
Merus and GeneQuantum Collaborations
ARIA, Amyloid-related imaging abnormalities; AAb, Autoantibody.
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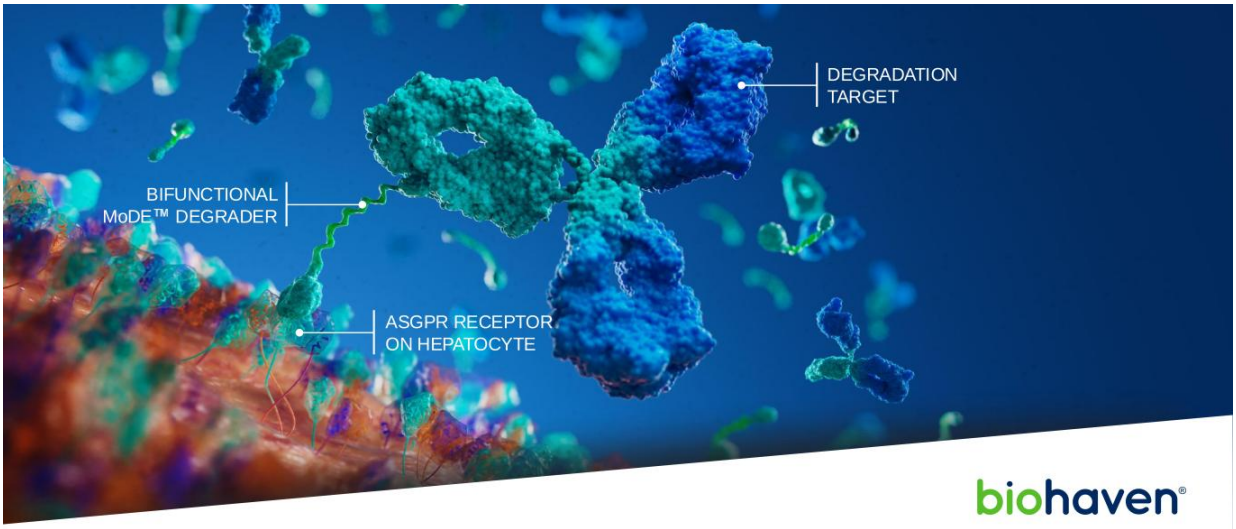



# EXTRACELLULAR DEGRADERS

## RAPID AND SELECTIVE REMOVAL OF DISEASE-CAUSING PROTEINS

## MoDE™ Platform: Degraders Designed for Real-life and to Preserve Healthy Immune Functioning

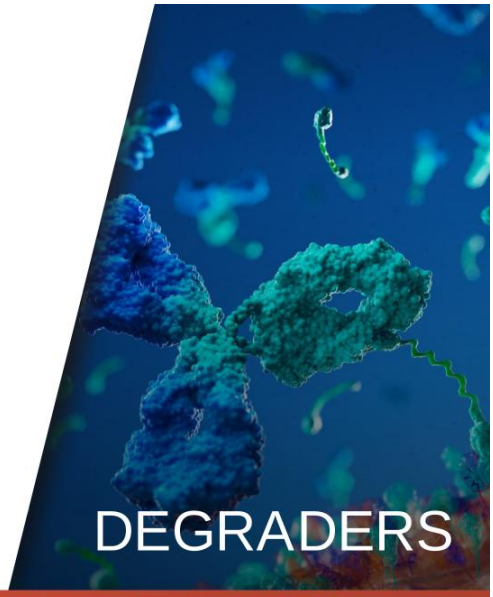
- Maximizes selectivity to treat disease while minimizing side effects
- Short half-life enables concomitant administration with Fc-biologics
- Allows for subcutaneous and autoinjector formulations

## Advancing Next-Generation TRAP™ (Targeted Removal of Aberrant Proteins) Degraders:

- Only degrades specific disease-causing targets while leaving healthy immune system completely intact
- New Phase 1 clinical trial data demonstrates deep, rapid, and selective lowering of very specific targeted species

## 3 Exciting New Indications

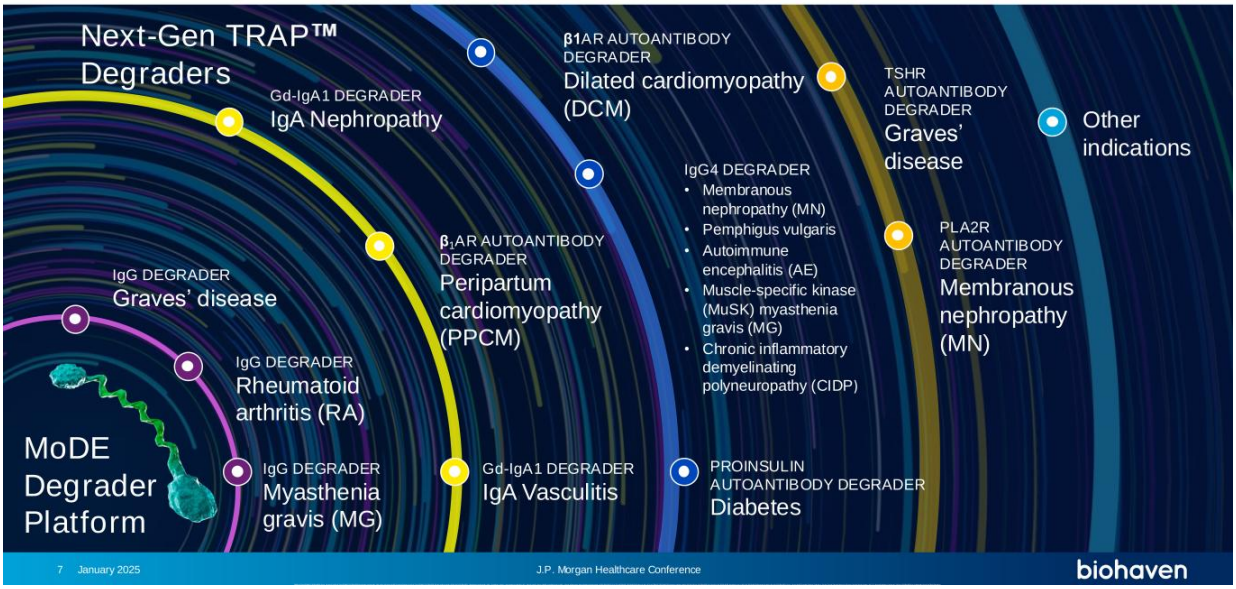
IgA Nephropathy | Peripartum Cardiomyopathy | Graves' Disease



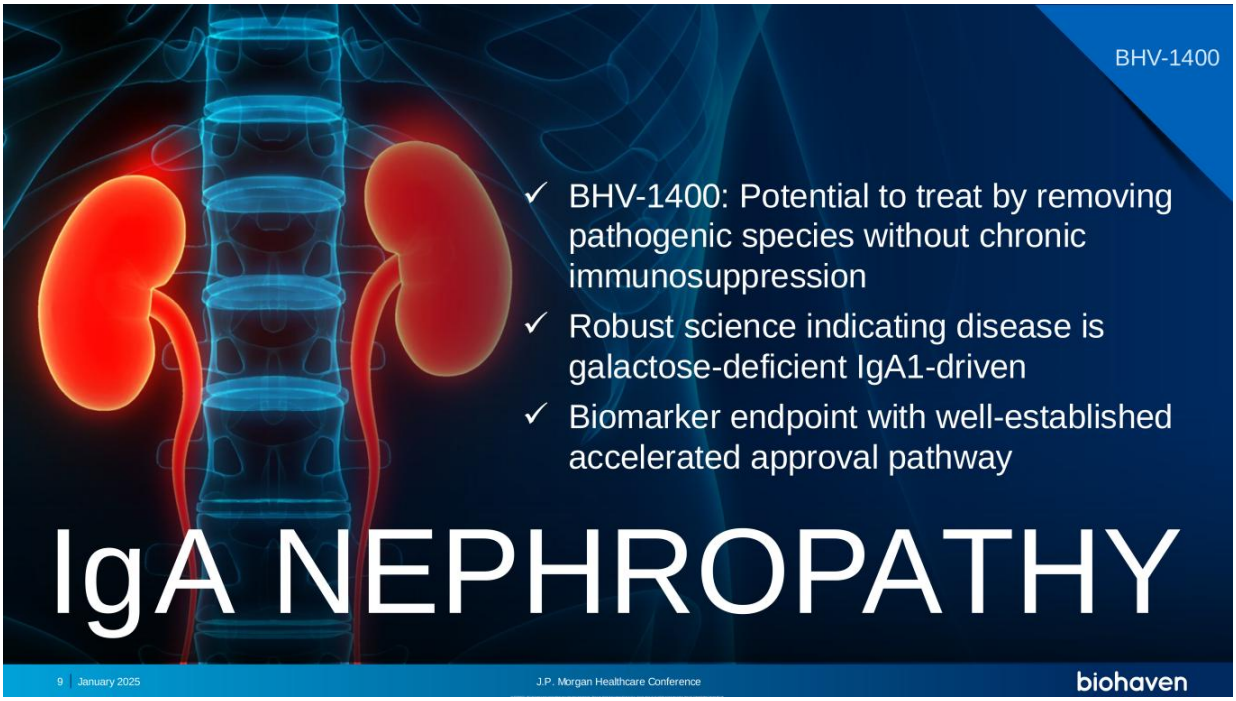

BREAKING NEWS

Emerging clinical data with BHV-1400 shows rapid, deep, and selective removal of only galactose-deficient IgA1 while preserving healthy immune function

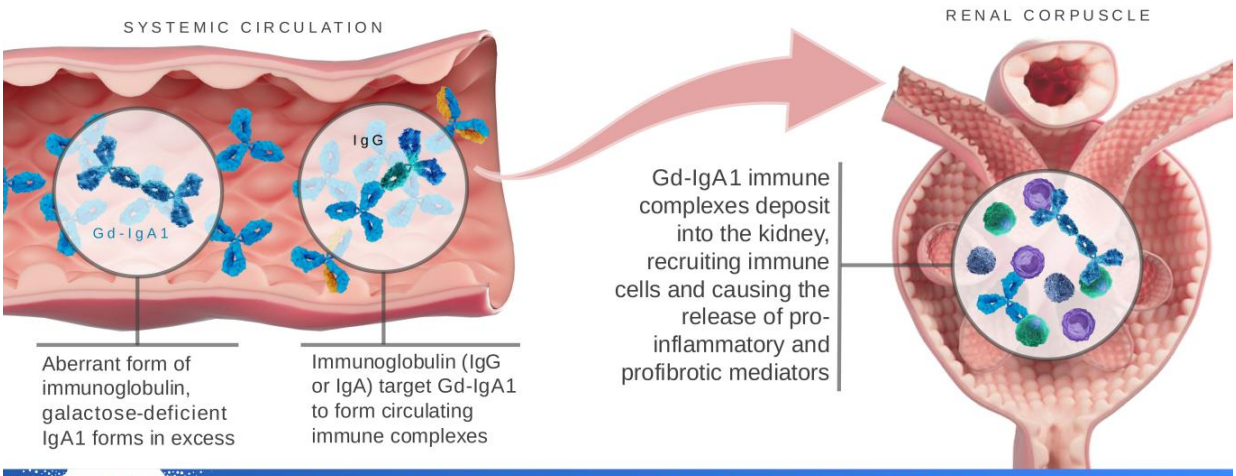
# MoDE™ Degrader Platform Technology: Driving Toward Targeted Removal of Disease-Causing Proteins




Degrader Platform Technology
FAST AND DEEP
Removes disease-causing proteins within hours
EASY-TO-USE
• Easy-to-use autoinjector for self-administration
• Allows for concomitant use of biologics
PATIENT CENTRIC
LIFE ALTERING
biohaven
SELECTIVE
Designed to target specific pathogenic species for maximal efficacy and minimal side effects
TUNABLE
• Level of degradation carefully modulated by dose level and frequency
• Employs body's natural mechanism for removal of senescent proteins
biohaven


BHV-1400
✓ BHV-1400: Potential to treat by removing pathogenic species without chronic immunosuppression
✓ Robust science indicating disease is galactose-deficient IgA1-driven
✓ Biomarker endpoint with well-established accelerated approval pathway
IgA NEPHROPATHY
9 | January 2025
J.P. Morgan Healthcare Conference
biohaven

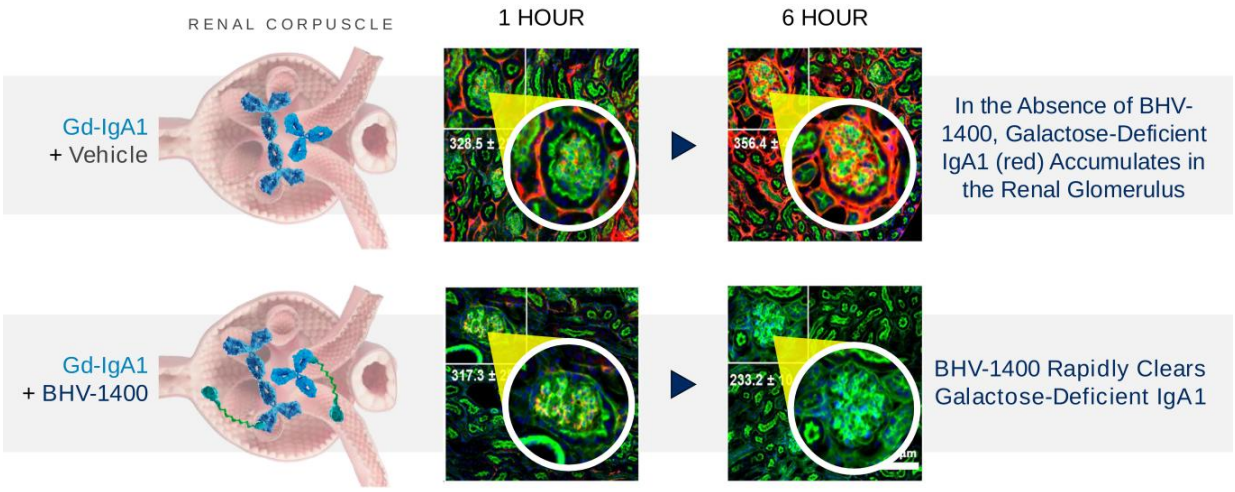
# IgA Nephropathy Is Caused by Excess Production of Galactose-Deficient IgA1 (Gd-IgA1)



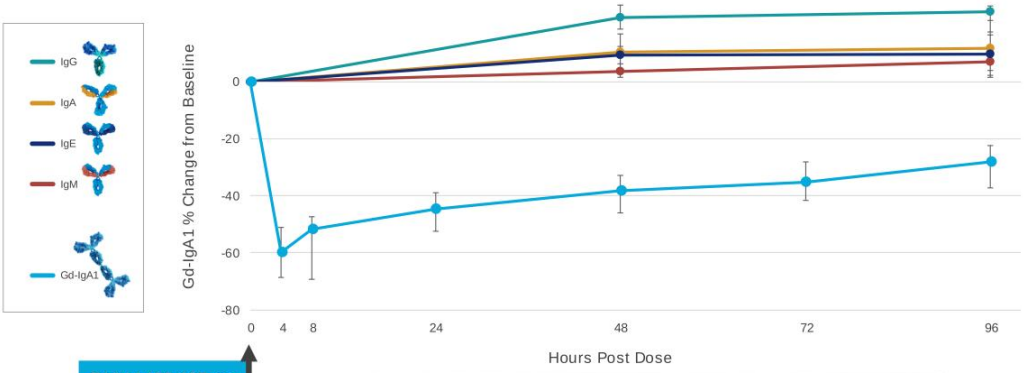

KEY POINT

No therapy selectively targets the pathogenic nidus of disease, Gd-IgA1... UNTIL NOW

# BHV-1400 Rapidly Removes Galactose-Deficient IgA1 from Circulation and from the Renal Glomerular Mesangium in vivo in Pre-Clinical Studies



# Preliminary Phase 1:
# Selective and Deep Removal of Gd-IgA1 Within Hours



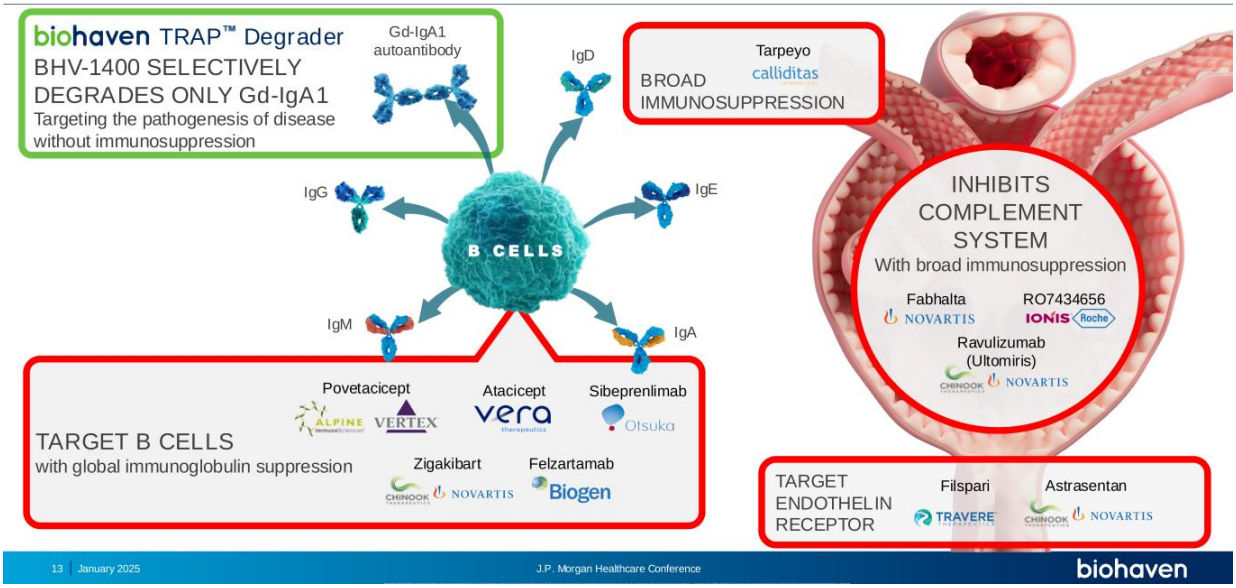

BHV-1400 125 mg
Single dose

> 60% Gd-IgA1 LOWERING within 4 hours

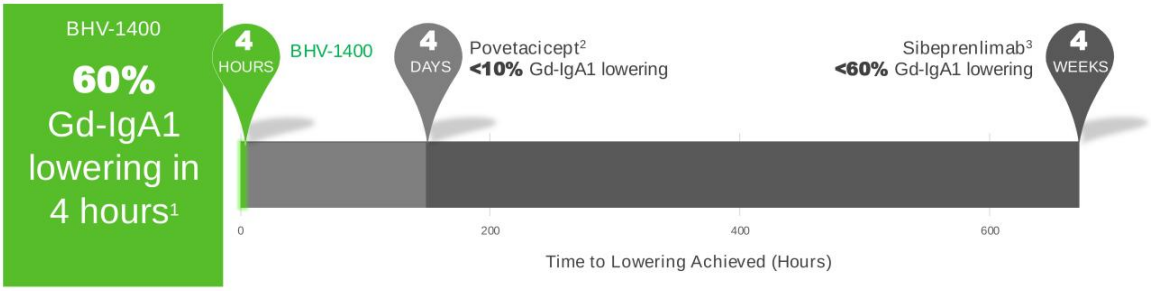
BREAKING NEWS

BHV-1400 at the lowest SAD cohort rapidly and selectively removes 60% of Gd-IgA1 while preserving normal immunoglobulins (IgG, IgE, IgA, IgM)

# BHV-1400: Selective Removal of Disease-Causing Gd-IgA1 without Immunosuppression Compared to Market Competitors



# BHV-1400 Degrades Gd-IgA1 Rapidly: Timeline of Earliest Reported Gd-IgA1 Lowering Across Key Market Competition

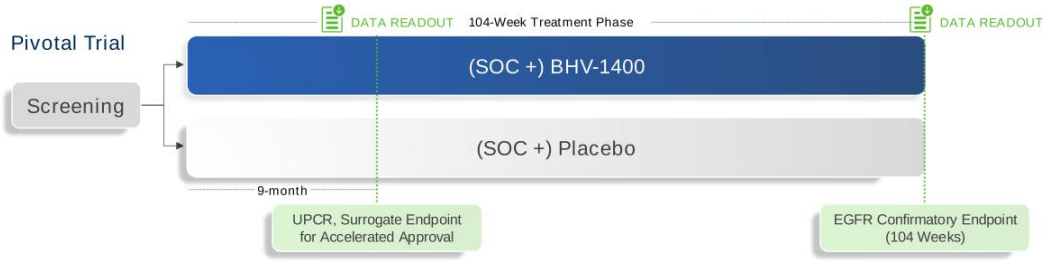



1. Lowering numbers reported for the median from the first and lowest BHV-1400 SAD cohort and for mean lowering for the highest dose SAD cohorts for Sibeprenlimab (12.0 mg/Kg) and Povetacicept (960 mg) 2. Davies et al. A first-in-human, randomized study of the safety, pharmacokinetics and pharmacodynamics of povetacicept, an enhanced dual BAFF/APRIL antagonist, in healthy adults. Clin Transl Sci. 2024 Nov;17(11):e70055. doi: 10.1111/cts.70055. PMID: 39494621; PMCID: PMC11532938. 3. Mathur et al. Safety, tolerability, pharmacokinetics, and pharmacodynamics of VIS649 (sibeprenlimab), an APRIL-neutralizing IgG2 monoclonal antibody, in healthy volunteers. Kidney Int Rep. 2022 Feb 8; 7(5): 993-1003. doi: 10.1016/j.ekir.2022.01.1073. PMID: 35570983; PMCID: PMC9091613.

**KEY POINT**

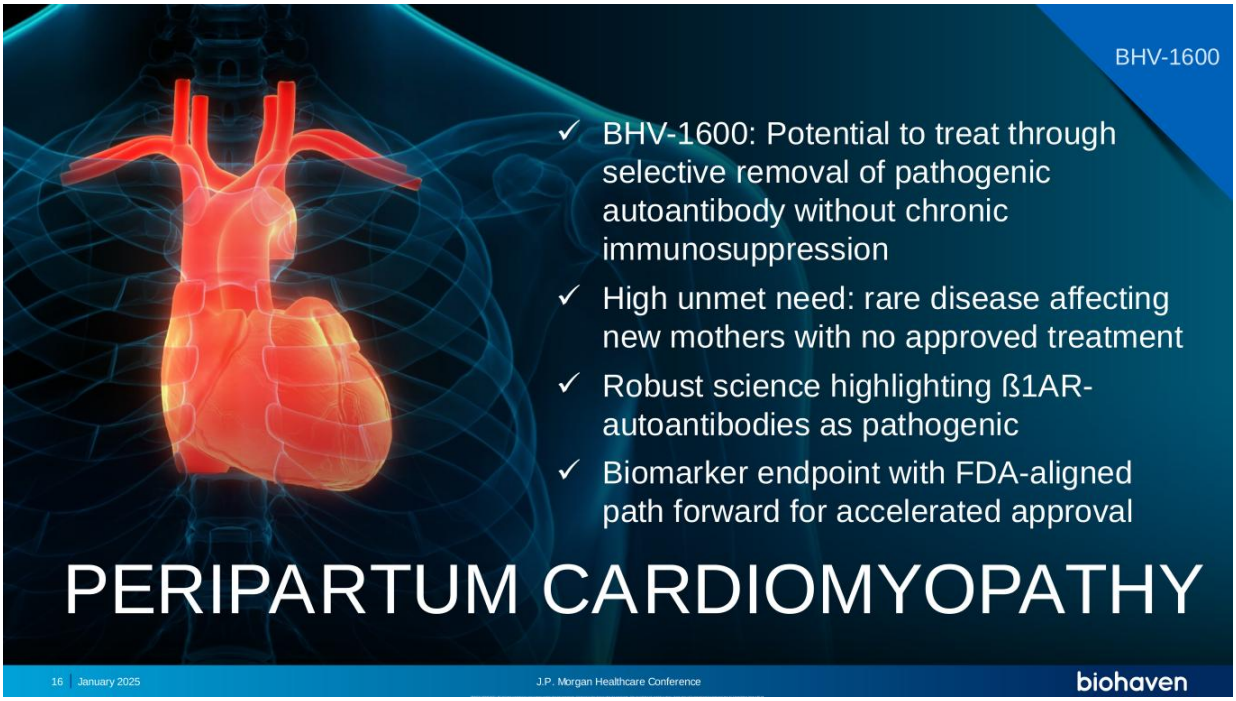
Lowest dose of BHV-1400 tested shows deep reductions of Gd-IgA1 within hours

# Harnessing Efficient Trial Design to Address a High Unmet Need
# BHV-1400 Phase 2/3 Study Concept

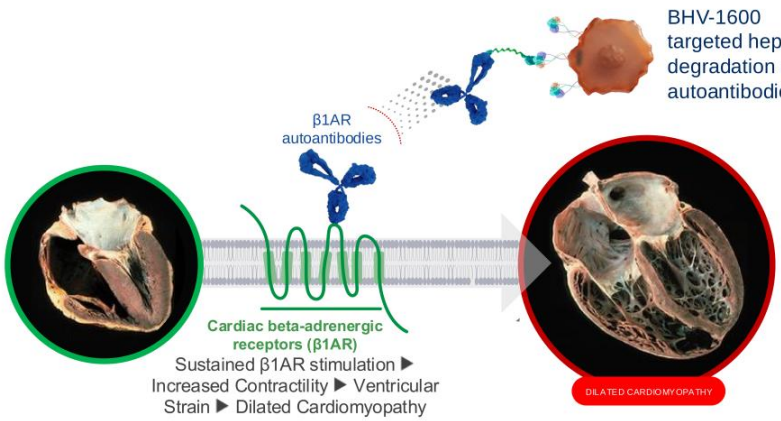



KEY POINT

Accelerated approval pathway to bring a selective, disease-specific therapeutic to treat IgAN


BHV-1600
✓ BHV-1600: Potential to treat through selective removal of pathogenic autoantibody without chronic immunosuppression
✓ High unmet need: rare disease affecting new mothers with no approved treatment
✓ Robust science highlighting ß1AR-autoantibodies as pathogenic
✓ Biomarker endpoint with FDA-aligned path forward for accelerated approval
PERIPARTUM CARDIOMYOPATHY
16 | January 2025
J.P. Morgan Healthcare Conference
biohaven

# BHV-1600, a Novel Investigational Treatment for Peripartum Cardiomyopathy




PERIPARTUM CARDIOMYOPATHY:

- A rare disease with high unmet need
- Maternal mortality highest since 1965 and primary contributor is PPCM with mortality rates reported up to 20%
- 10% go on to require mechanical support (LVAD or heart transplant)
- BHV-1600 degrades ß1AR autoantibodies to potentially prevent irreversible heart failure

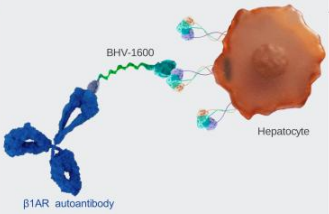
**KEY POINT**

BHV-1600 degrades ß1AR autoantibodies to potentially prevent permanent heart failure in previously healthy mothers

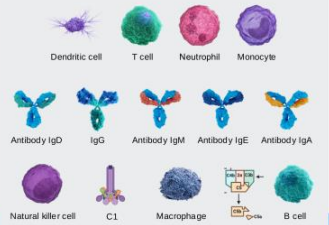
# Ongoing Phase 1 Preliminary Clinical Data

- First-in-human dosing with BHV-1600 has been safe and well-tolerated to date with two cohorts dosed
- All AEs have been mild, with no SAEs
- Laboratory data demonstrate optimal safety profile:
  - No clinically relevant changes in white blood cells or immunoglobulins IgG, IgA, IgE, and IgM
  - No clinically significant reductions in albumin, liver function test abnormalities, or increases in cholesterol compared to baseline
- Study ongoing 1H 2025

BHV-1600, designed to selectively degrade ß1AR autoantibodies to treat PPCM



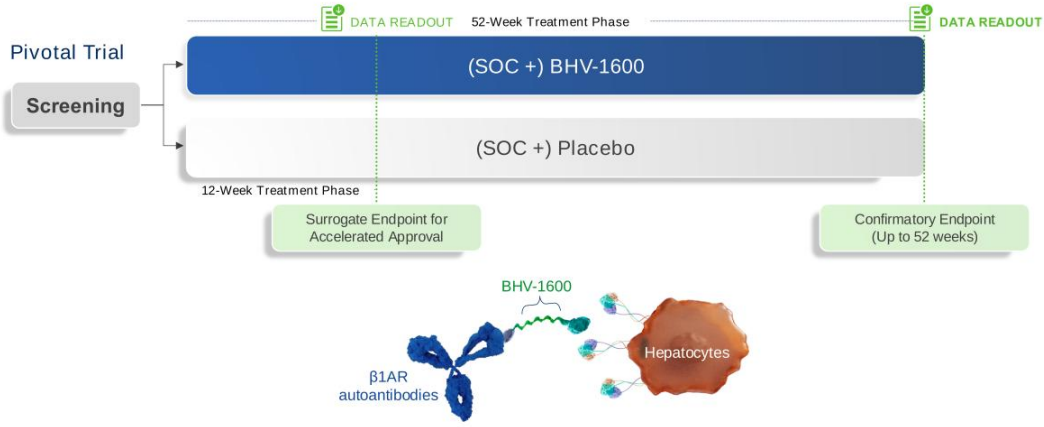

While Preserving Immunity




KEY POINT

BHV-1600 selectively targets ß1AR autoantibodies to treat PPCM with Optimal Safety Profile

# Harnessing Efficient Trial Design to Address a High Unmet Need

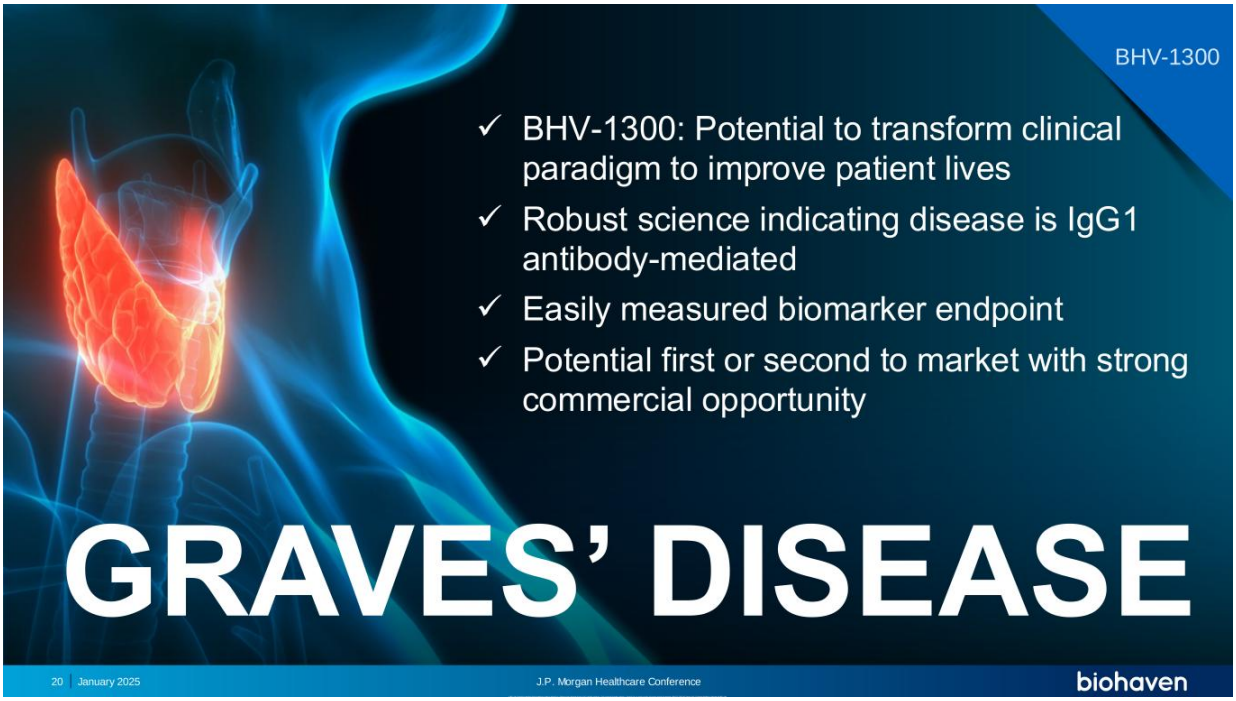




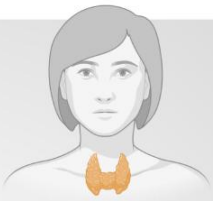


**KEY POINT**

Completed INTERACT meeting with FDA regarding accelerated approval pathway to bring a much-needed therapeutic to women with PPCM efficiently


BHV-1300
✓ BHV-1300: Potential to transform clinical paradigm to improve patient lives
✓ Robust science indicating disease is IgG1 antibody-mediated
✓ Easily measured biomarker endpoint
✓ Potential first or second to market with strong commercial opportunity
GRAVES' DISEASE
20 | January 2025
J.P. Morgan Healthcare Conference
biohaven

# Seventy Years of Research Demonstrate the Pathogenicity of TSH Receptor Autoantibodies in Graves' Disease (GD)

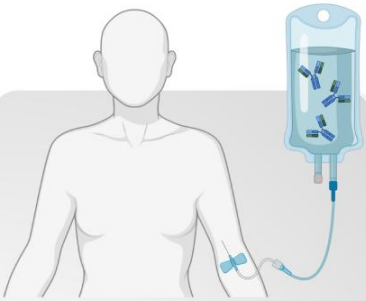


**1950s**

"Long-Acting Thyroid Stimulator," (TSH receptor autoantibody) identified in the serum of GD patients

**1960s**

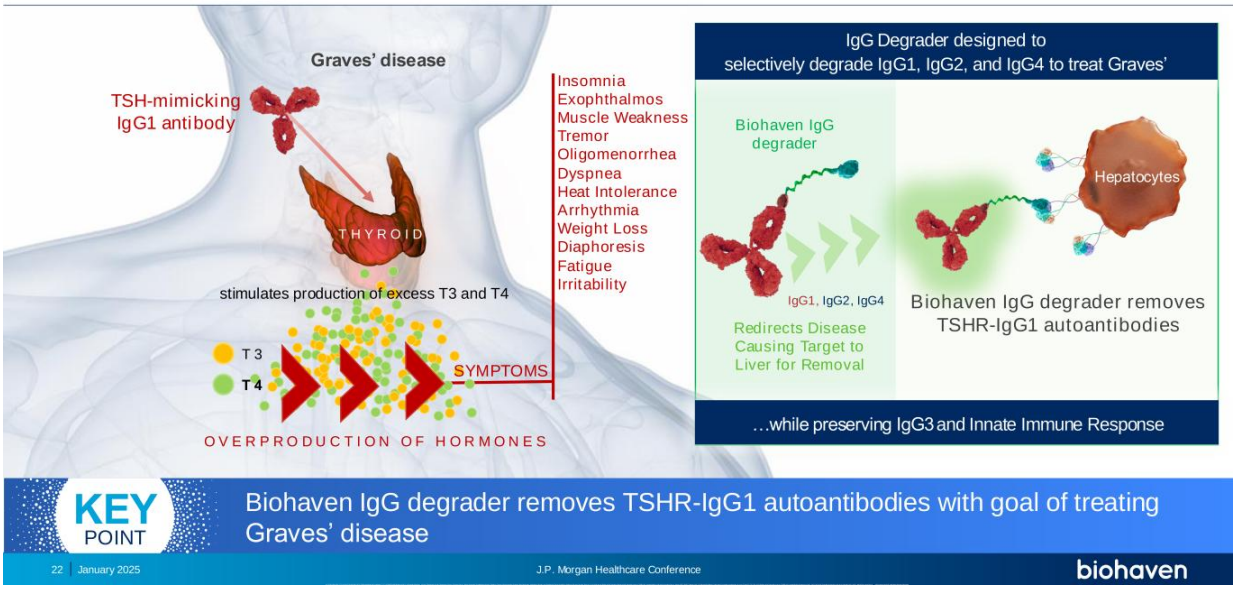
TSH receptor autoantibodies are detected in serum of neonates with hyperthyroid mothers with GD



**1970s**

Passive transfer of TSH receptor autoantibodies into healthies prove definitively to stimulate the thyroid

# Biohaven IgG1,2,4 Degrader Platform:
# A Novel Therapeutic for the Treatment of Graves' Disease




**KEY POINT** Biohaven IgG degrader removes TSHR-IgG1 autoantibodies with goal of treating Graves' disease

# Redefining Possibilities in Graves' Disease Treatment: Treat the Mechanism of Disease, Spare Patients their Thyroid

"Why lose my thyroid?"

"Why expose myself to radiation?"

"Why trade HYPERthyroidism for HYPOthyroidism?"

"A drug that causes fatal agranulocytosis and liver failure is probably not one I want to take."

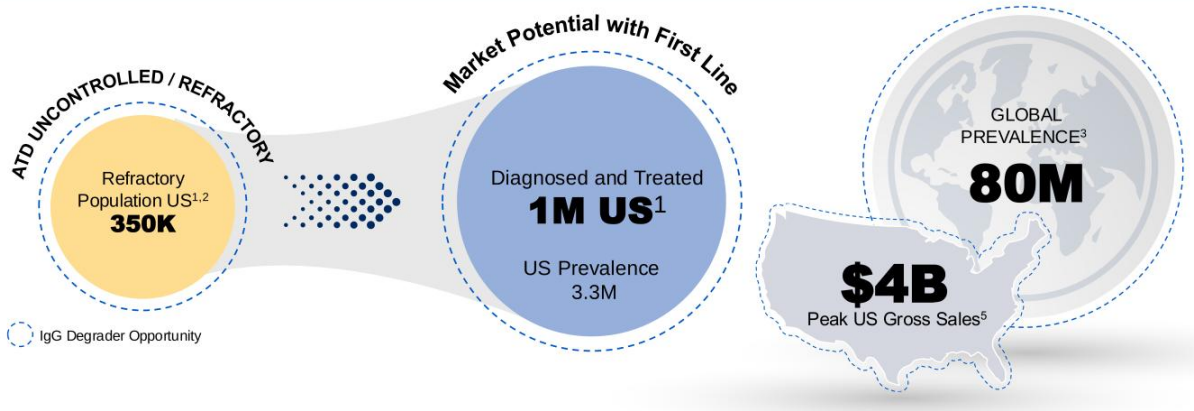
## LIMITATIONS OF ANTI-THYROID THERAPY (ATD)

- Does not treat the underlying autoimmune disease
- Are associated with birth defects
- Side effects include liver toxicity, agranulocytosis, hypothyroidism, allergic reactions, etc.
- Other treatment options like ablation or surgery invasive and causes permanent hypothyroidism resulting in life-long need for thyroid hormone replacement

**KEY POINT**

BHV-1300 targets the underlying autoimmune pathology of Graves' disease to potentially improve disease control and avoid the undesirable adverse effects of ATD's and surgery

# Broad Market Strategy to Modify Graves' Disease

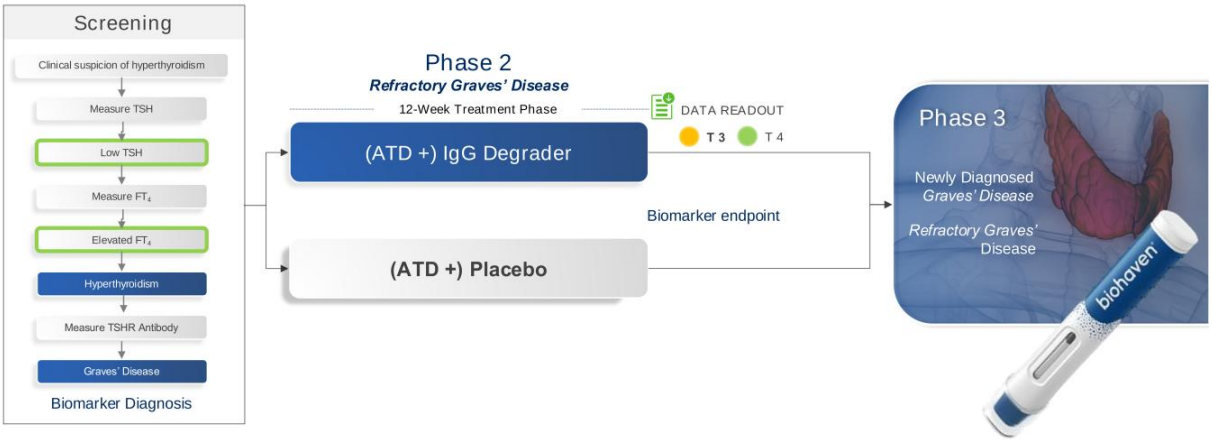



1. Forian Insurance Claims Data Base Analysis Jun 2016-September 2024; 2. Percent of ATD patients refractory or uncontrolled:Sundaresh V, Brito JP, Thapa P, Bahn RS, Stan MN. Comparative Effectiveness of Treatment Choices for Graves' Hyperthyroidism: A Historical Cohort Study. Thyroid. 2017 Apr;27(4):497-505. doi: 10.1089/thy.2016.0343. Epub 2017 Feb 6. PMID: 28049375; PMCID: PMC5385429; 3. NBK448195/NIDDKD. Graves disease. Accessed September 11, 2024. https://www.niddk.nih.gov/health-information/endocrine-diseases/graves-disease; 4. US prevalence and Incidence: Pokrel B, Bhusal K. Graves Disease. [Updated 2023 Jun 20]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/; 5. Biohaven Internal Analysis: Peak US Gross Sales

**KEY POINT**

Degraders redefine care, targeting the autoimmune pathogenesis of disease with the potential to treat across the course of disease

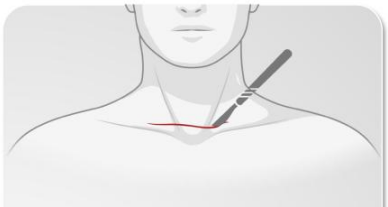
# Graves' Disease Mid-2025 with Biomarker Endpoint




KEY POINT

Biomarker-driven diagnosis and endpoints facilitate efficient trial design in Graves' disease patients

# Biohaven's Goal Is to Change the Treatment Paradigm in Graves' Disease

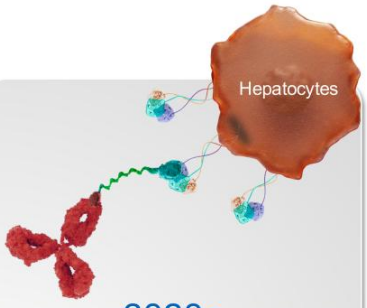


**1790s**

DeSault performs first successful partial thyroidectomy

**1940s**

Antithyroid drugs and radioactive iodine (RAI) used as alternative to surgery, chronic thyroid replacement

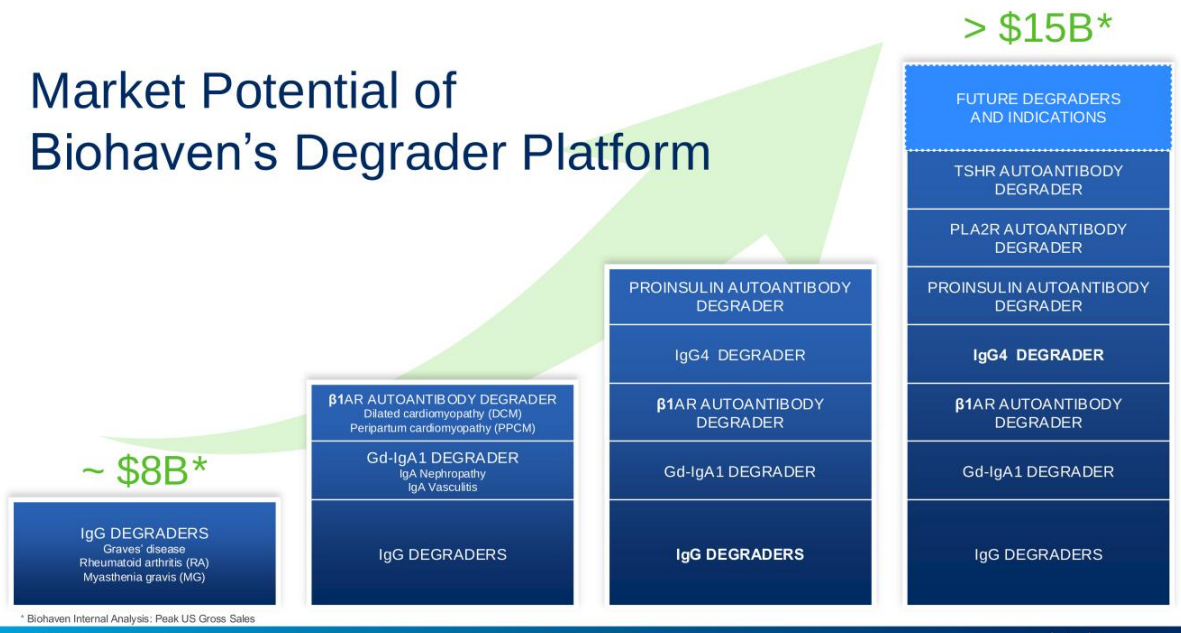



**2020s**

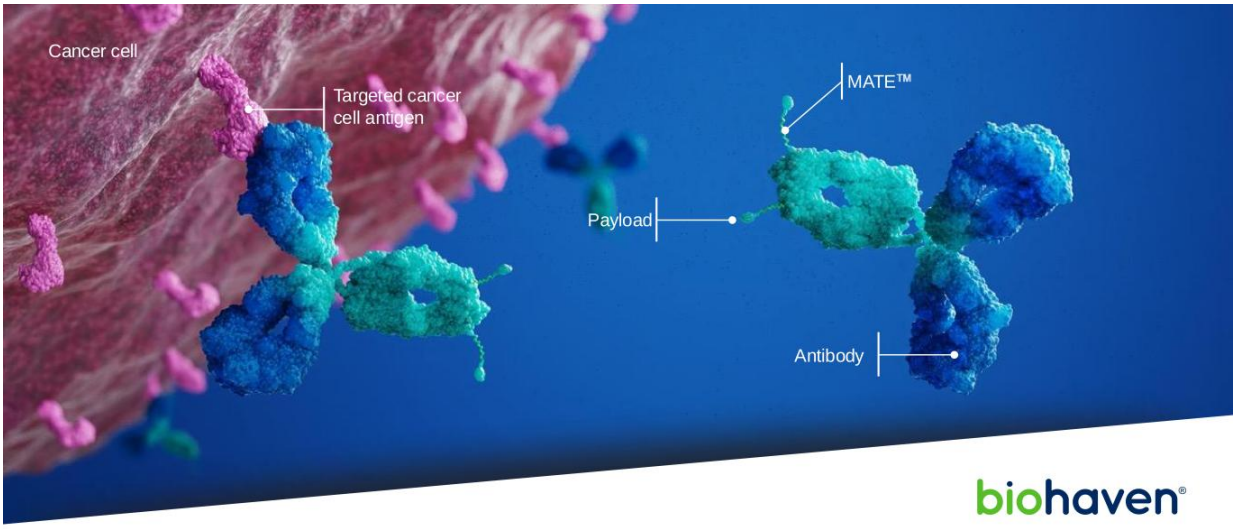
Biohaven technology redirects TSH receptor autoantibodies to the liver for removal, treating the underlying cause of Graves' disease

TRAb, TSH Receptor Autoantibodies

# Market Potential of Biohaven's Degrader Platform




* Biohaven Internal Analysis: Peak US Gross Sales




# Oncology: Next-Generation ADCs

# Biohaven's Novel ADC Conjugation Technology and Strategic Collaborations Driving Next-Generation Cancer Therapies

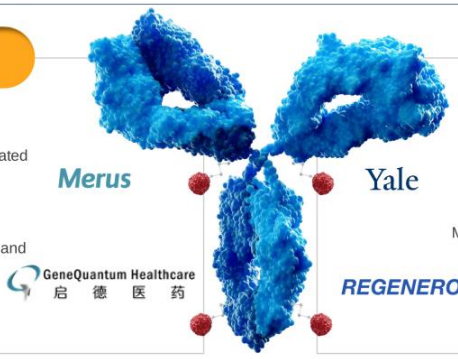
**Collaborate to generate highly differentiated ADCs**

Novel mAbs

- Validated and emerging targets
- Merus collaboration leverages differentiated dual-targeting antibody platform

Exclusivity to TopoIx payload

- Superior preclinical anti-PD/L1 synergy and immunogenic cell death
- GeneQuantum collaboration provides broad target exclusivity to the payload for 18 oncology targets




**Broad and flexible platform applicability**

Single-step chemistry, native mAbs

Modular, efficient, and scalable MATE® technology developed from Yale University Spiegel Lab

Irreversible, Site-Specific Conjugation

Minimize payload-associated tox, DAR homogeneity

Combination I/O Therapies

Supply agreement: BHV-1510 with Libtayo®

BHV-1510 (Trop2 TopoIx) in Phase 1 (mono and anti-PD1 combination)

BHV-1530 (FGFR3 TopoIx) in Phase 1 startup — FPI early 2025

BHV-1500 (CD30 MMAE) IND planned 2025

**Novel ADCs and De-Risked Fast-Followers in Clinic**

STRATEGIC COLLABORATIONS AND CLINICAL SUPPLY AGREEMENTS

MULTIPLE DC/INDs planned 2025–2026

## BHV-1510 is a Highly Differentiated Trop2 ADC

- Ideally positioned for fast-to-market strategy with anti-PD-1 combo

## Novel TopoIx Payload Synergy with Anti-PD-1 In Vivo

- Induces immunogenic cell death and complete tumor regressions
- Superior to datopotamab deruxtecan (DS-1062) plus anti-PD-1

## Fully Optimized Next-generation ADC

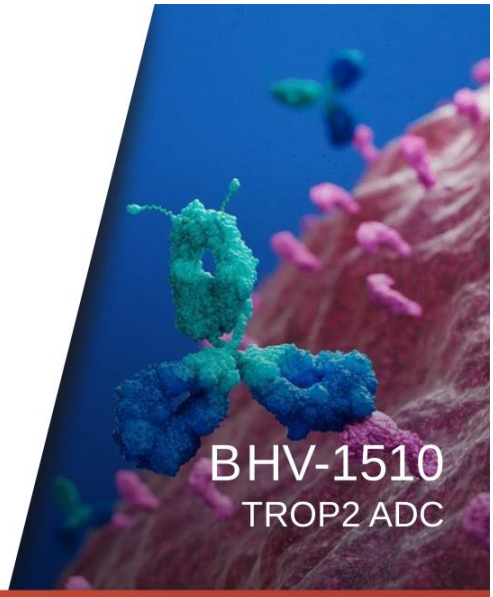
- Novel and highly stable linker-payload (DAR4)

## Differentiated Pre-clinical Safety Profile

- Datopotamab deruxtecan (DS-1062): interstitial lung disease (ILD)
- Sacituzumab tirumotecan (MK2870/SKB264): hematological toxicities
- TRODELVY®: neutropenia, diarrhea

## Milestones Achieved

- First-in-human trial initiated April 2024
- Anti-PD-1 combo cohorts with Libtayo® initiated 4Q 2024



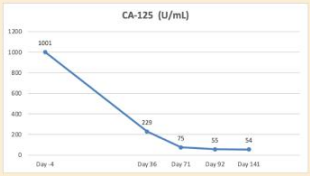

BREAKING NEWS

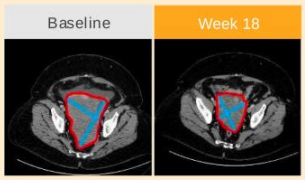
- Clinical activity and no ILD with TopoIx observed in early cohorts
- Target exclusivity expanded for up to 18 ADC targets incorporating TopoIx payload

# BHV-1510 (Trop2 ADC with TopoIx) with Early Clinical Activity in Phase 1

- Clinical activity across doses starting at the lowest dose (2 mg/kg, Q3W)
  - Tumor reduction observed in tumor types including ovarian, SCLC, NSCLC
- Favorable preliminary safety and PK profile
  - No payload-associated ILD, diarrhea, or significant hematological toxicity
  - Main toxicity observed is on-target Trop2 ADC class mucositis; an expected and manageable effect
  - Very low free payload in serum, demonstrates high ADC stability
- Dose escalation (mono and Libtayo® combo) and dose/schedule optimization ongoing

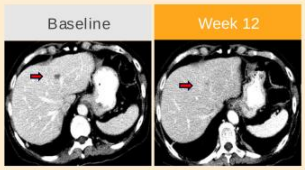
Case 1: 71 y/o, Platinum-resistant ovarian cancer, 2 mg/kg, Q3W
25% tumor reduction at week 18 with dramatic drop in CA-125




Case 2: 70 y/o, SCLC post carboplatin+durvalumab and lurbinectedin, 4 mg/kg Q3W

PR (~60% reduction) at week 12




**KEY POINT**

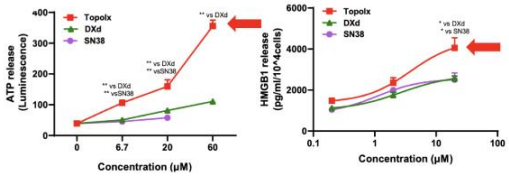
Observed clinical activity and safety supports broad investigation of ADCs incorporating novel TopoIx payload and highly stable linker

# TopoIx Payload Is a Novel Topoisomerase 1 Inhibitor With a Superior Pre-clinical Profile Compared to DXd and SN-38

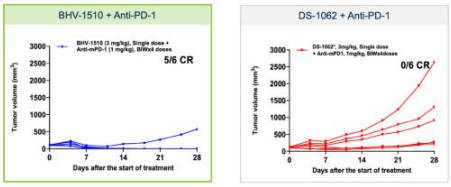
## Superior Pre-clinical Profile

| | SN-38 | DXd | TopoIx |
|---|---|---|---|
| In vitro cytotoxicity | ++ | ++ | +++ |
| ICD* | + | + | ++ |
| Transported by ABCG2 | n/a | Y | N |
| Bystander killing | n/a | ++ | +++ |
| In vivo efficacy | + | ++ | +++ |

## Superior Immunogenic Cell Death




## Synergy with anti-PD1 Combination




KEY POINT

Biohaven retains broad target exclusivity with GeneQuantum for up to 18 ADC targets incorporating TopoIx to leverage unique profile as monotherapy and in anti-PD1-based combinations

## Advancing TopoIx Payload in Next-Gen ADC to Target Urothelial Cancer and Other Solid Tumors

- Novel and proprietary FGFR3 mAb
- Enzymatic, site-specific conjugation
- Favorable nonclinical tox profile

## Validated target with limited competition

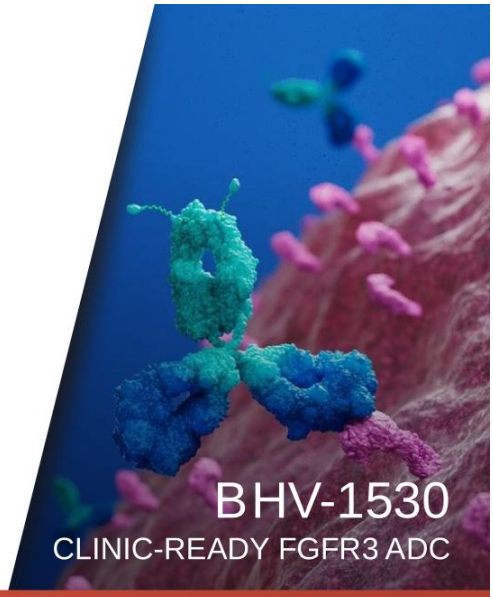
- No ADCs approved or in advanced development
- Core opportunity in FGFR3-altered metastatic urothelial cancer (mUC) – only 1 Tyrosine Kinase Inhibitor approved
- Potential extension into other FGFR3-driven solid tumors
- ~$400M to > ~$1B peak US gross sales potential

## Synergistic Efficacy With Checkpoint Inhibitors In Vivo

- BHV-1530/anti-PDL1 combination showed synergy similar to BHV-1510
- PD1 synergy with PADCEV® (Nectin-4 ADC with MMAE payload) showed dramatically improved survival in mUC

## Milestones Achieved

- US FDA IND May Proceed Letter granted

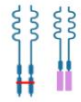



BREAKING NEWS

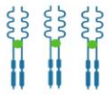
First-in-Human study planned to initiate in 1H 2025

# BHV-1530: Potential to Address Unmet Need in Metastatic Urothelial Cancer (mUC) and other FGFR3-driven Tumors

## FGFR3 overexpression, mutation, or fusion leads to excessive pathway activation and increased tumorigenicity



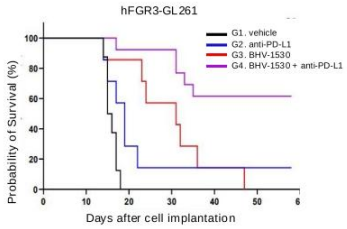
FGFR3 mutation/fusion in ~20% mUC



FGFR3 overexpression ~35% mUC

- 62K new mUC cases, 14K deaths / year in US (2023)
- Multiple opportunities for BHV-1530 across therapy lines
  - Synergistic CPI combinations in FGFR3+ biomarker-selected 1L
  - Limited efficacy of current 2L options
- Several tumor types beyond mUC also driven by FGFR3

## BHV-1530 shows synergistic activity in vivo with anti-PD-L1 combination



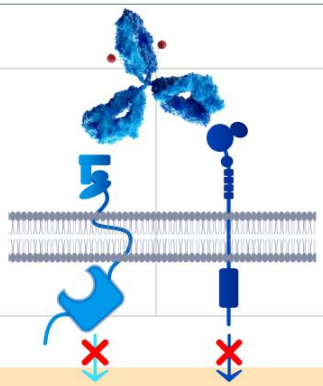

| Group | % Increased Life Span (ILS) | Median Survival (days) |
|---|---|---|
| G1 | - | 15 |
| G2 | 27% | 19 |
| G3 | 107% | 31 |
| G4 | >300% | >63 |

# Biohaven-Merus Collaboration Represents a Leading-Edge Approach to Developing Highly Optimized Bispecific ADCs

**Merus**

A leader in developing differentiated bispecific mAbs for oncology

- Clinically validated platform
- Lead program (Zenocutuzumab) granted US FDA accelerated approval in December 2024



**biohaven**

Next-generation ADC conjugation and payload platform technologies

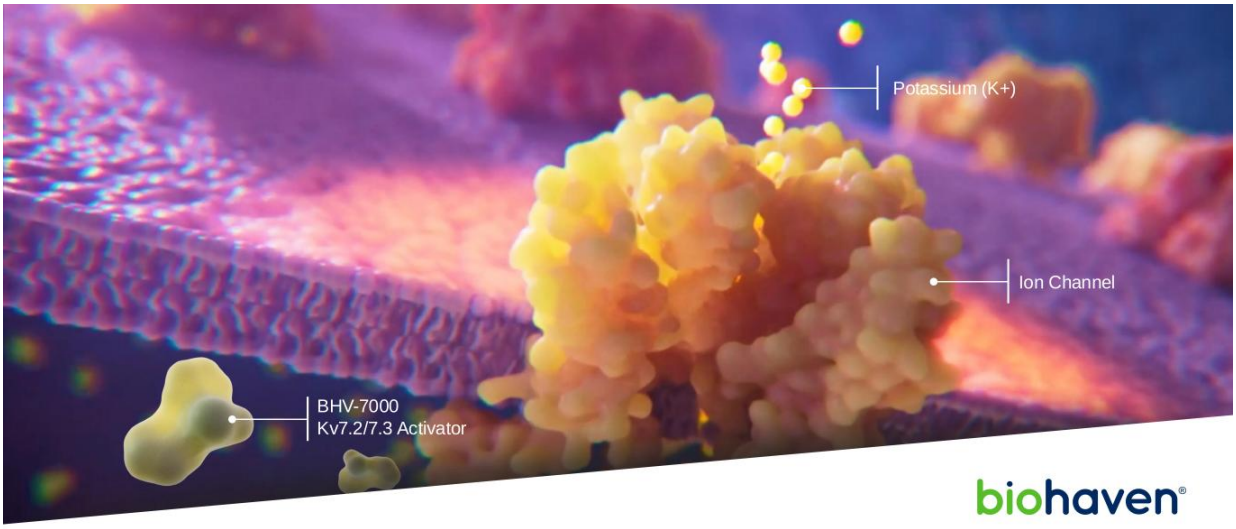
- Potential for superior specificity and benefit/risk profile vs. single target ADCs
- Co-development maximizes expertise and efficiencies

**Potential advantages of dual-target bispecific ADCs**

- Preferential binding
- Improved internalization
- Optimal tumor penetration
- Multiple MOA of tumor cell killing

BREAKING NEWS

Multi-target collaboration, leveraging each company's innovative tech for ADC co-development




# Ion Channel Platforms

# BHV-7000, Potential Best-in-Clinic Selective Kv7 Activator, Nears Completion of Pivotal Trials with Blockbuster Potential

## Bipolar Disorder
## 7M Patients

- Novel MOA for bipolar disorder
- Differentiated profile vs. antipsychotics, lithium, and ASMs

Acute bipolar mania topline results expected in 1H 2025

## Major Depressive Disorder
## 21M Patients

- Clinically validated MOA for MDD
- Differentiated profile vs. SSRIs

Topline results expected in 2H 2025

## Epilepsy
## 3.5M Patients

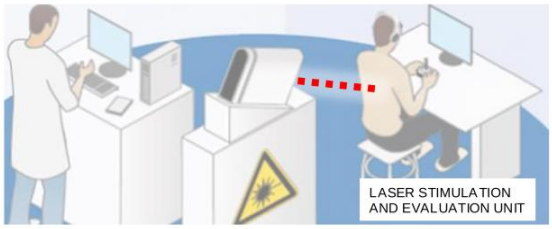
- Clinically validated MOA for epilepsy
- Global Phase 2/3 program ongoing in focal epilepsy (2 trials) and idiopathic generalized epilepsy (1 trial)

1st focal epilepsy study topline results expected in 1H 2026

BREAKING NEWS

Pivotal topline results for BHV-7000 development program expected within the next year

# BHV-2100: Proof of Concept Pain Study Demonstrates Anti-Nociceptive and Anti-Hyperalgesic Effects

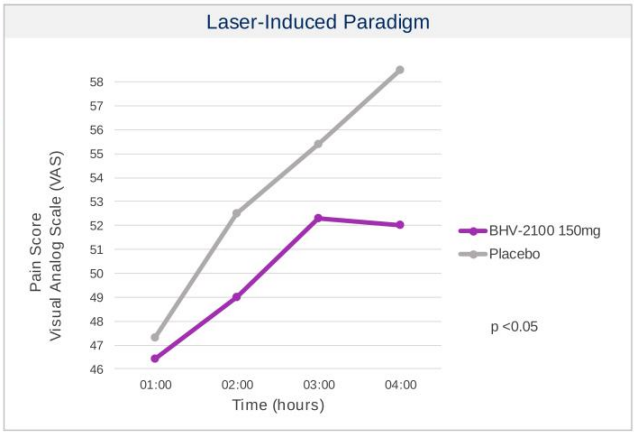



Efficacy

- Lowering in self-reported VAS pain rating scale
- Clinically meaningful reductions in laser-evoked potentials in normal and UVB-inflamed skin

Safety

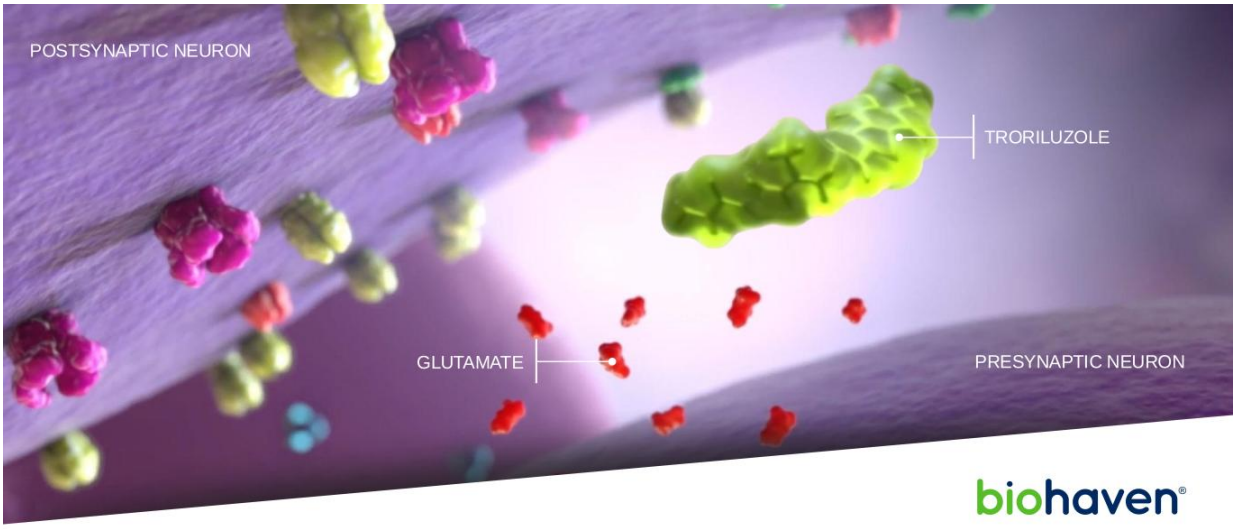
- Well-tolerated
- No effects observed on core temperature
- No change on heat pain threshold




Preliminary Data up to Tmax; p-value out to 8 hour test period

KEY POINT

First indication of potential clinical efficacy in pain with the novel TRPM3 mechanism




# Troriluzole — SCA

## Troriluzole Is First Treatment to Slow SCA Disease Progression

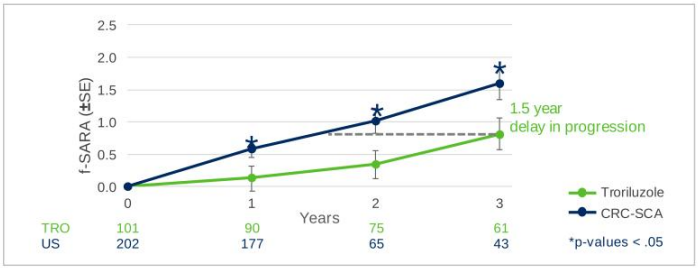
- Long-term RWE study confirmed benefit over 3 years in all SCA genotypes

## SCA Represents Significant Commercial Opportunity

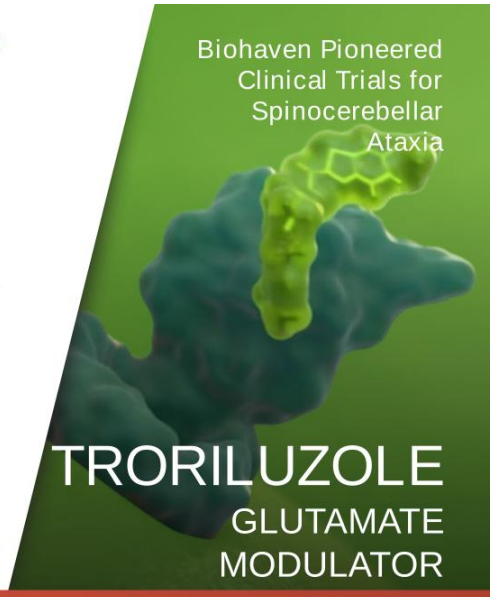
- Est. 15,000 patients in the US and 24,000 in UK and EU
- No currently approved SCA treatments

## Milestones Achieved

- Submitted NDA after pre-NDA meeting in 4Q 2024 (potential Priority Review)
- EMA MAA for all SCA genotypes under review

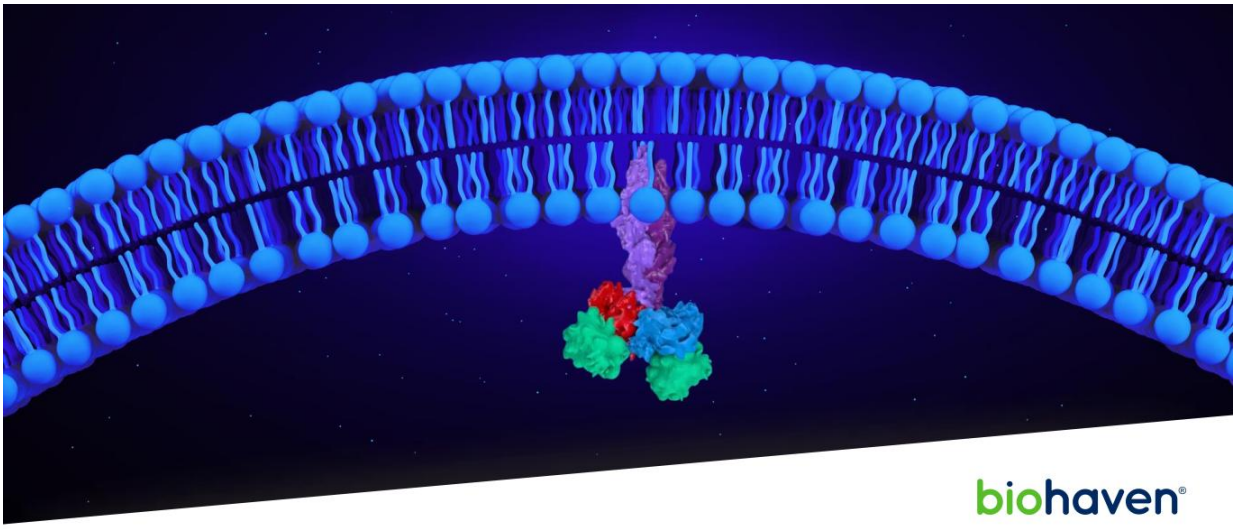



CRC-SCA, Clinical Research Consortium for SCA; EUROSCA, European registry of SCA; f-SARA, Functional Scale for the Assessment and Rating of Ataxia; LSM, least squares mean; PSM, Propensity Score Matching




BREAKING NEWS

- Submitted NDA for treatment of all SCA genotypes (potential Priority Review)
- Preparing for commercial launch in 2025



biohaven®

BHV-8000

### First-in-Clinic, Oral, Selective, Brain-Penetrant TYK2/JAK1 Inhibitor

- Uniquely potent, TYK2/JAK1 selective, brain-penetrant inhibitor
- Selectivity profile avoids class risks associated with JAK2/3 inhibition

### Breaks the Cycle of Neuroinflammation

- Reduces inflammatory impacts of microglia, astrocytes and infiltrating T-lymphocytes

### Potential to Treat Multiple Neuroinflammatory Disorders

- Supported by a broad range of clinical, translational, and epidemiological evidence
- Indications include Parkinson's disease, anti-amyloid therapy induced ARIA, Alzheimer's disease, and multiple sclerosis

### Encouraging Results from Completed Phase 1 Trial

- Safe and well-tolerated
- Evidence of target engagement
- Robust brain penetration

### Milestone Achieved

FDA meetings successfully completed enabling registrational programs for Parkinson's disease and prevention of ARIA


ARIA, Amyloid-related imaging abnormalities; SAD, single ascending dose; MAD, multiple ascending dose; TYK, tyrosine kinase; JAK, Janus kinase.

BREAKING NEWS

Pivotal study in Parkinson's disease planned to initiate in 1H 2025

# Real-World Analytics of Large Healthcare Database Show Parkinson's Disease Risk Reduction With TNF/IL-17 Targeting Therapies


- Biohaven conducted analysis using Komodo Health database (over 320 million patients since 2012) examining treatment with anti-TNF or anti-IL17 and incidence of PD
- Millions of patients over 8+ years of dosing captured key epidemiologic confirmation of the neuroinflammatory hypothesis
- Results support rationale for the effectiveness of BHV-8000 in treating PD

| Treatment | PD Events | Person-years | Rate (per 100 person-years) | Adjusted IRR (95% CI) | P-value |
|---|---|---|---|---|---|
| Anti-TNF or Anti-IL-17 exposure | 2,957 | 393,114 | 0.66 | 0.77 (0.74 – 0.80) | <0.0001 |
| No Treatment | 50,562 | 5,328,307 | 0.95 | | |
| Anti-TNF exposure | 2,471 | 371,867 | 0.66 | 0.64 (0.52 – 0.80) | <0.0001 |
| No Treatment | 50,562 | 5,328,307 | 0.95 | | |
| Anti-IL-17 exposure | 81 | 15,598 | 0.52 | 0.77 (0.78 – 0.81) | <0.0001 |
| No Treatment | 50,562 | 5,328,307 | 0.95 | | |

IRR, incidence rate ratio; TNF, tumor necrosis factor.

# BHV-8000 Demonstrates a Promising Phase 1 Profile

## STUDY COMPLETED: 3 SAD cohorts and 3 MAD cohorts

- SAD dose cohorts (10, 20 and 30 mg); MAD dose cohorts (6, 10 and 20 mg)
- 8 healthy subjects per cohort (6 active: 2 placebo)

## SAFETY PROFILE: Safe and well-tolerated to date

- No SAEs or severe AEs; only mild AEs observed that resolved spontaneously
- No adverse laboratory trends related to study drug

## PHARMACODYNAMIC EFFECTS

hs-CRP, IFN-beta, and IP-10 showed drug-related changes in plasma

## PHARMACOKINETICS

Approximately 50% CNS penetration in humans

AE, adverse event; hs-CRP, high-sensitivity C-reactive protein; IFN-beta, Interferon beta; MAD, multiple ascending dose; SAD, single ascending dose; SAE, serious adverse event.

KEY POINT

BHV-8000 is safe and well-tolerated at doses showing evidence of CSF penetration and target engagement

# BHV-8000: Unique Phase 2/3 Study Design for Parkinson's Disease

## Novel Primary Efficacy Endpoint

Time-to-**event (≥ 2**-point worsening on MDS-UPDRS-Part II)

- Addresses FDA requirement for a functional endpoint in PD trials
  - MDS-UPDRS-Part II recommended, but declines very slowly in early PD
- 300 fewer patients per trial versus a mean change on MDS-UPDRS-Part II
- Based on comprehensive analyses of PPMI and placebo-arm clinical trial data (C-Path)

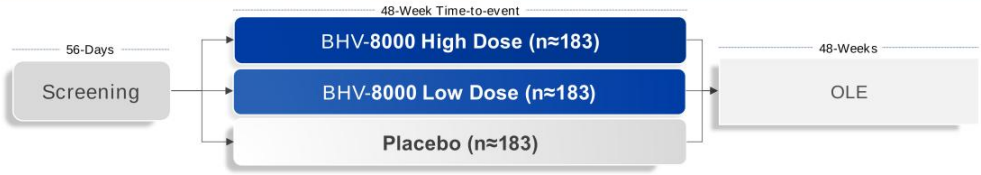
Provides a meaningful efficacy endpoint with a smaller sample size

## Novel Composite Endpoint

**Parkinson's Disease Composite Score (PARCOMS)**

- Based on established methodology (i.e., Alzheimer's Disease Composite Score [ADCOMS])
- Leverages PPMI and placebo-arm clinical trial data (C-Path)
- Comprises the most responsive items from common endpoints in early PD trials

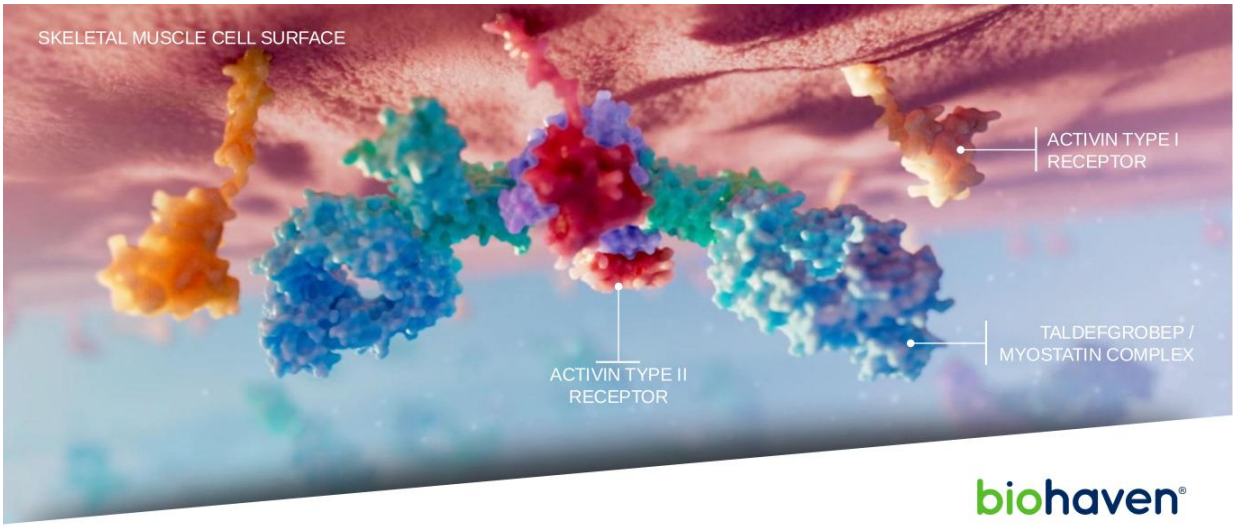
Provides a highly-sensitive supportive secondary efficacy endpoint




PPMI, Parkinson's Progression Markers Initiative; MDS-UPDRS, Movement Disorder Society – Unified Parkinson's Disease Rating Scale.

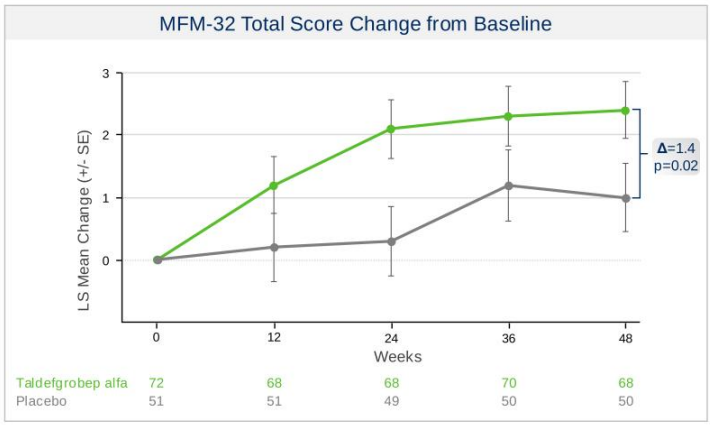
BREAKING NEWS

Pivotal study planned to initiate in 1H 2025




# Myostatin — SMA and Obesity

# Efficacy Results: Clinically Meaningful Improvements Enhanced In Myostatin-Positive Caucasian Participants




L.S. least squares; MFM-32, 32-Item Motor Function Measure; SE, standard error
* response defined as ≥ 3-point change from baseline improvement on MFM-32 at Week 48 **Preliminary data

## ADDITIONAL SUPPORTIVE DATA

- Responder Analysis*
  50% of taldefgrobep-treated participants responded vs. 30% on placebo
- Open-label Extension**
  Motor function continues to improve

### Taldefgrobep Significantly Reduced Fat Mass Gain in SMA Participants While Increasing Lean Muscle Mass and Bone Density (vs. Placebo)

DXA prespecified outcome measures in overall study population at Week 48 demonstrated:

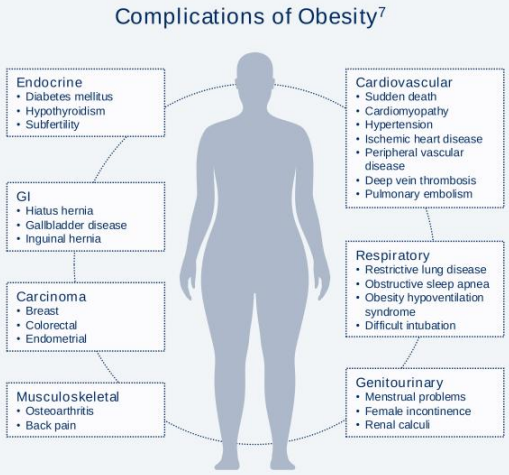
- Greater reduction in percent change in total body fat mass (p=0.008)
- Numerically larger increases in lean muscle mass
- Numerically larger increases in bone density

**KEY POINT**

Placebo adjusted difference similar to what was seen with other SMA therapy (risdiplam) in registrational SUNFISH trial; magnitude of effect appears addictive since added to SOC

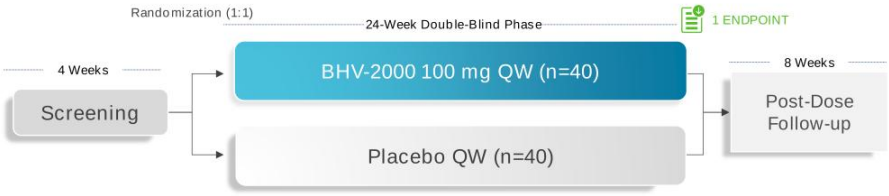
# Optimal Management of Obesity Remains a Critical Unmet Medical Need

- By 2030, 1 billion people worldwide will be living with obesity, including 50% of American adults[1]
- Obesity is a disease of excess and/or abnormal adipose tissue, not excess mass
- Incretin mimetics have revolutionized management of obesity, but present liabilities
  - Up to 40% of total body weight loss is lean mass[2]
  - Gastrointestinal side effects[3]
  - Reduced bone mass[4]
  - Two-thirds stop GLP-1 therapy within 1 year[5]
  - Two-thirds of lost body weight returns within 1 year of stopping GLP-1 therapy[5,6]




1 https://www.worldobesity.org/resources/resource-library/world-obesity-atlas-2022; Accessed 9-JAN-2025. 2. Wilding JPH et al, N Engl J Med. 2021;384(11):989-1002. 3. Wilding, et. al., Diabetes Obes Metab. 2022; 24(8):1553-64. doi: 10.1111/dom.14725 4. Hansen MS, et al., eClinicalMedicine. 2024;72:102624 5. Scientific American. What happens when you quit Ozempic or Wegovy? APR 2024. https://www.scientificamerican.com/article/you-quit-ozempic-or-wegovy-what-happens-next/ Accessed 9-JAN-2025. 6. Sikirica MV. Et al., Diabetes Metab Syndr Obes. 2017;10:403-12. 7. UpToDate. Overweight and obesity in adults: health consequences. https://www.uptodate.com/contents/overweight-and-obesity-in-adults-health-consequences. Accessed 9-JAN-2025.

# Taldefgrobep Phase 2 Study in Obesity




| | |
|---|---|
| DESIGN | Randomized, double-blind, placebo-controlled trial |
| POPULATION | Male and female adults living with overweight or obesity (BMI 27 - 40) without comorbid diabetes mellitus |
| SAMPLE SIZE | 80 participants randomized 1:1 (Sex [M/F] and BMI [<35, ≥35-40]) |
| TREATMENT | Taldefgrobep 100 mg SC QW via autoinjector vs. Placebo SC QW |
| TREATMENT DURATION | 24-week treatment period, 8-week post-dose follow-up |
| KEY ENDPOINTS | Change in lean mass, fat mass, bone density, total body weight, and insulin sensitivity; PK/PD; safety/tolerability |

KEY POINT

Phase 2 study planned to initiate in 1H 2025

# Company Capitalization Updates

## POTENTIAL ROYALTIES

Pfizer will make royalty payments in low- to mid-teens% in respect of annual US net sales of rimegepant and zavegepant >$5.25B, subject to annual cap ($400M/year)[1]

CGRP

SHARES OUTSTANDING

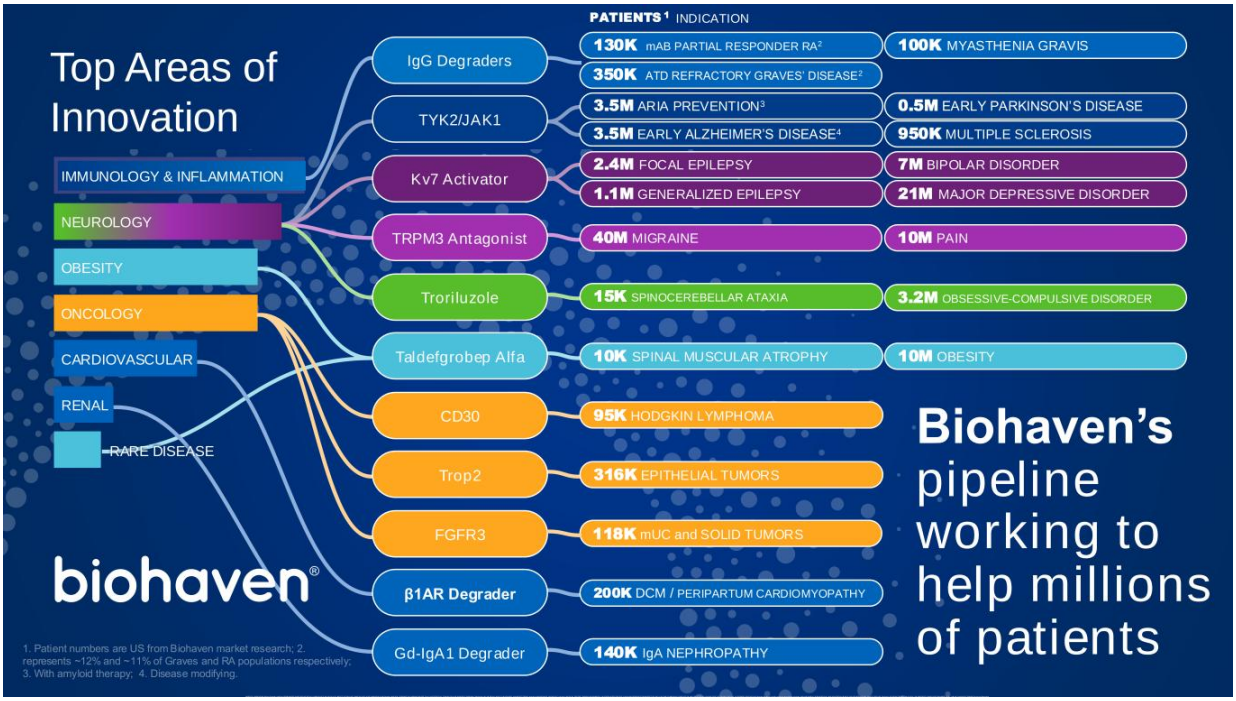
101.1M[2]

DAYS MATTER™

CASH

~$642M[3]

1. Cap reached if aggregate annual U.S. net sales of rimegepant and zavegepant amount to $8.15B. Royalty payments would be in respect of years ended on or before 12/31/40. 2. As of November 8, 2024; excludes outstanding options. 3. As of October 2, 2024; includes proceeds raised from underwritten public offering


Top Areas of Innovation
IMMUNOLOGY & INFLAMMATION
NEUROLOGY
OBESITY
ONCOLOGY
CARDIOVASCULAR
RENAL
RARE DISEASE
biohaven®
PATIENTS[1] INDICATION
IgG Degraders
130K mAB PARTIAL RESPONDER RA[2]
350K ATD REFRACTORY GRAVES' DISEASE[2]
100K MYASTHENIA GRAVIS
TYK2/JAK1
3.5M ARIA PREVENTION[3]
3.5M EARLY ALZHEIMER'S DISEASE[4]
0.5M EARLY PARKINSON'S DISEASE
950K MULTIPLE SCLEROSIS
Kv7 Activator
2.4M FOCAL EPILEPSY
1.1M GENERALIZED EPILEPSY
7M BIPOLAR DISORDER
21M MAJOR DEPRESSIVE DISORDER
TRPM3 Antagonist
40M MIGRAINE
10M PAIN
Troriluzole
15K SPINOCEREBELLAR ATAXIA
3.2M OBSESSIVE-COMPULSIVE DISORDER
Taldefgrobep Alfa
10K SPINAL MUSCULAR ATROPHY
10M OBESITY
CD30
95K HODGKIN LYMPHOMA
Trop2
316K EPITHELIAL TUMORS
FGFR3
118K mUC and SOLID TUMORS
β1AR Degrader
200K DCM / PERIPARTUM CARDIOMYOPATHY
Gd-IgA1 Degrader
140K IgA NEPHROPATHY
Biohaven's pipeline working to help millions of patients
1. Patient numbers are US from Biohaven market research; 2. represents ~12% and ~11% of Graves and RA populations respectively; 3. With amyloid therapy; 4. Disease modifying.


DAYS
MATTER™
biohaven®
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