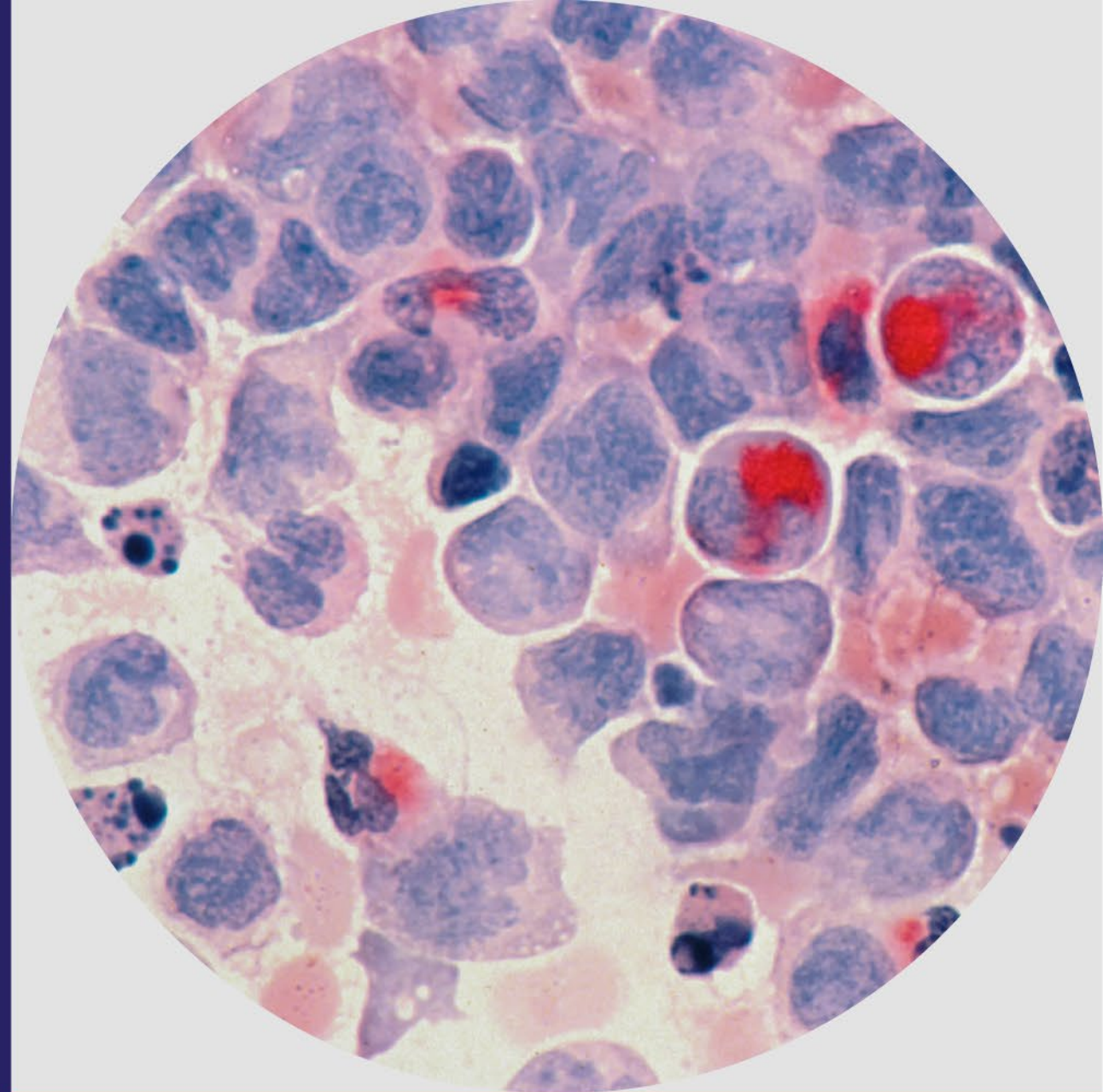


# Roivant Overview

December 2024

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# Forward-Looking Statements

This presentation includes forward-looking statements that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, potential uses of cash and capital allocation, research and development plans, profitability, the anticipated timing, costs, design, conduct and results of our ongoing and planned preclinical studies and clinical trials for our products and product candidates, and any commercial potential of our products and product candidates are forward-looking statements.

These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this presentation and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements.

These forward-looking statements may be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the sections captioned “Risk Factors” and “Forward-Looking Statements” of our filings with the U.S. Securities and Exchange Commission, available at [www.sec.gov](http://www.sec.gov) and [investor.roivant.com](http://investor.roivant.com). We operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this presentation, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

This presentation includes data for each of brepocitinib and mosliciguat as compared to certain other potential competitor products generated from separate, independent studies and that do not come from head-to-head analyses. Differences exist between study or trial

designs and subject characteristics and caution should be exercised when comparing data across studies. Data regarding other products is based on publicly available information.

## Disclaimer

This presentation is intended for the investor community only; it is not intended to promote the product candidates referenced herein or otherwise influence healthcare prescribing decisions.

# Focusing on Clinical Trial Execution to Drive Significant Potential Value

## Executing Clinical Trials in First-in- and Best-in-Class Opportunities

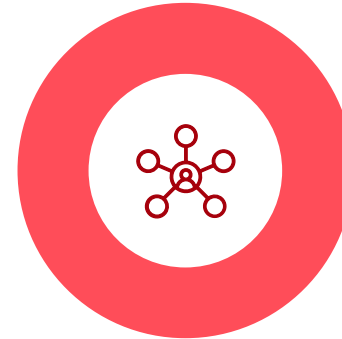
## Delivering Near-Term Clinical Trial Readouts



# Continuing to Evolve the Business for Next Era of Growth Through Multiple Value Creating Events

## Dermavant Deal Closed

- Allows us to focus on clinical execution of existing pipeline while maintaining a large share in potential VTAMA upside<sup>1</sup>
- Deal generates meaningful additional capital for Roivant with potential for additional shareholder return



## Ongoing Capital Return

- Cash, cash equivalents, restricted cash and marketable securities of \$5.4BN as of Sep. 30, 2024
- Aggregate \$754M share repurchases under \$1.5BN authorization, including \$106M in quarter ended Sep. 30, 2024
- Ongoing commitment to be prudent and thoughtful deploying capital for shareholders

## LNP Litigation Progress

- Pfizer/BioNTech Markman hearing in December 2024
- Moderna trial in September 2025
















## Ongoing Business Development

- Multiple ongoing negotiations for potential in-licensing of new programs

# Our Next Chapter is Anchored by Our Robust Late-Stage Pipeline

Exciting late-stage pipeline with 7 ongoing registrational trials in multi-billion dollar markets and 4-5 potentially registrational programs with IMVT-1402 expected by March 31, 2025

	Modality	Phase 1	Proof of Concept	Registrational
 <b>IMVT-1402</b> Graves' Disease   <i>Immunovant</i>	Biologic			★
 <b>IMVT-1402</b> Difficult-to-Treat Rheumatoid Arthritis   <i>Immunovant</i>	Biologic			★
 <b>IMVT-1402</b> Myasthenia Gravis   <i>Immunovant</i>	Biologic			★
 <b>IMVT-1402</b> Chronic Inflammatory Demyelinating Polyneuropathy   <i>Immunovant</i>	Biologic			★
 <b>IMVT-1402</b> Indication 5   <i>Immunovant</i>	Biologic			★
 <b>BATOCLIMAB</b> Myasthenia Gravis   <i>Immunovant</i>	Biologic			★
 <b>BATOCLIMAB</b> Thyroid Eye Disease   <i>Immunovant</i>	Biologic			★
 <b>BATOCLIMAB</b> Chronic Inflammatory Demyelinating Polyneuropathy   <i>Immunovant</i>	Biologic			★
 <b>BREPOCITINIB</b> Dermatomyositis   <i>Priovant</i>	Small Molecule			★
 <b>BREPOCITINIB</b> Non-Infectious Uveitis   <i>Priovant</i>	Small Molecule			★
 <b>BREPOCITINIB</b> Other Indications   <i>Priovant</i>	Small Molecule		▶	
 <b>MOSLICIGUAT</b> Pulmonary Hypertension associated with Interstitial Lung Disease   <i>Pulmovant</i>	Inhaled		▶	
 <b>ONGOING BD</b> Pipeline Expansion Opportunities   <i>Roivant</i>				

# Charting a Path to a \$10BN+ Portfolio Spanning Multiple Therapeutic Areas

Continuing to focus on patients suffering from diseases with high mortality, low quality of life and limited treatment options

**2024-2026**

**Multiple new approvals, 6+ Phase 2 or 3 data readouts including multiple late-stage data sets each year, and pipeline additions**

**2026-2030**

**Wave of potential additional approvals across large established I&I and untapped high-value growth markets, and continued pipeline expansion**

**2030+**

**Multiple blockbuster products with \$10BN+ aggregate peak revenue potential across I&I, PH and potential additional therapeutic areas**

# Pipeline Expansion Enabled By Roivant's Track Record and Balance Sheet

Our partners come from all over the pharmaceutical landscape












We build win-win deals for us and our partners

- 10-Year track record of finding, securing and developing high-conviction promising drug candidates
- Creative deal structures have led to win-win outcomes for our partners and Roivant
- Shared financial successes with partners has increased collaboration interest with Roivant
- Our balance sheet and execution capabilities make us a uniquely valuable partner

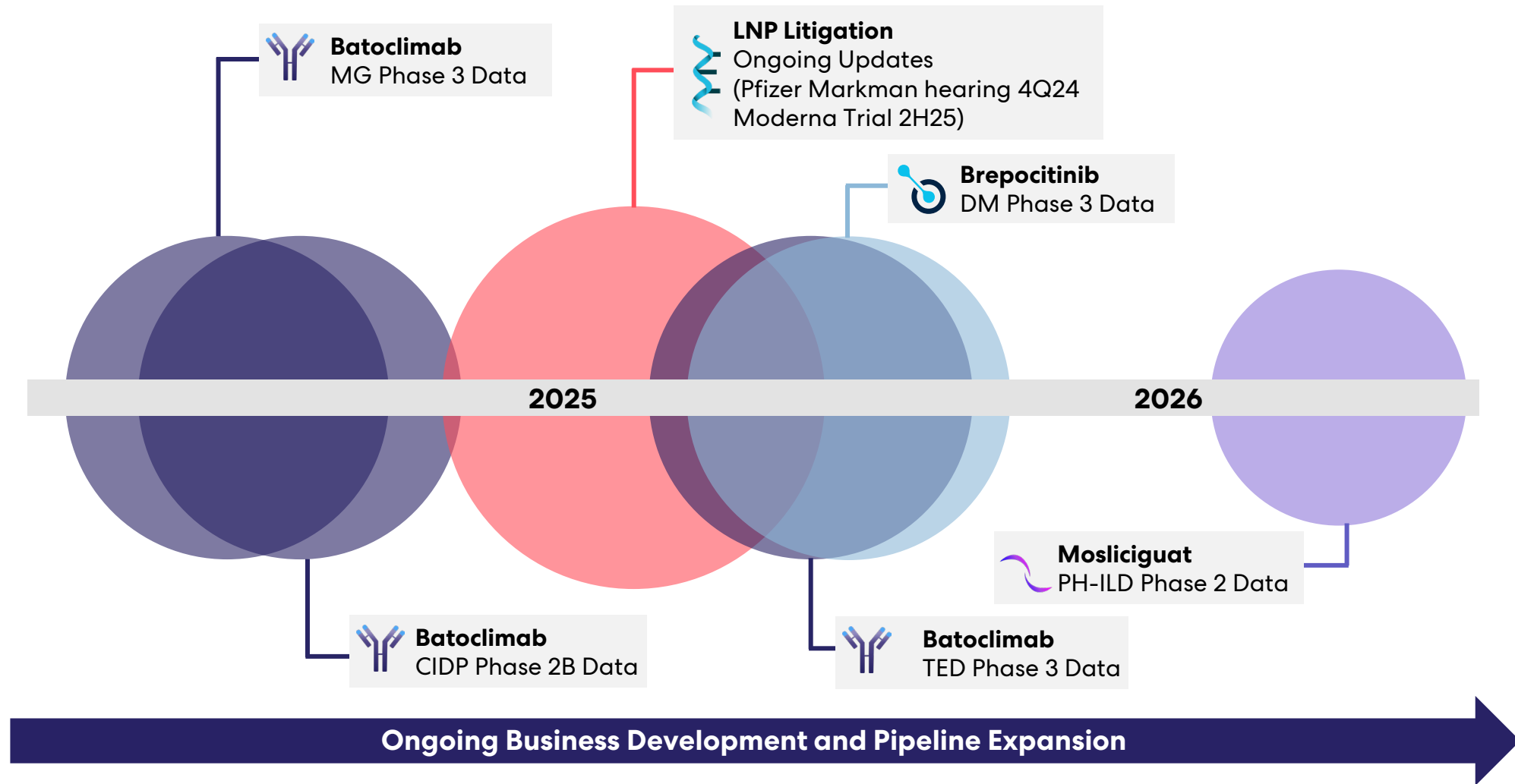


# Rich Catalyst Calendar

Program	Vant	Catalyst	Expected Timing
Roivant pipeline growth		New mid/late-stage in-licensing announcements	Ongoing
LNP platform		Markman hearing in Pfizer/BioNTech case	4Q 2024
Batoclimab		Topline data from Phase 3 trial in myasthenia gravis	By FY End
Batoclimab		Initial data from period 1 of Phase 2B trial in chronic inflammatory demyelinating polyneuropathy	By FY End
LNP platform		Summary judgment phase in Moderna case	2Q-3Q 2025
LNP platform		Trial in Moderna case	2H 2025
Batoclimab		Topline data from Phase 3 trials in thyroid eye disease	2H 2025
Brepocitinib		Topline data from Phase 3 trial in dermatomyositis	2H 2025
Mosliciguat		Topline data from Phase 2 trial in pulmonary hypertension associated with interstitial lung disease	2H 2026



# Multi-Billion \$ Value Creation Opportunities Over the Next 2 Years

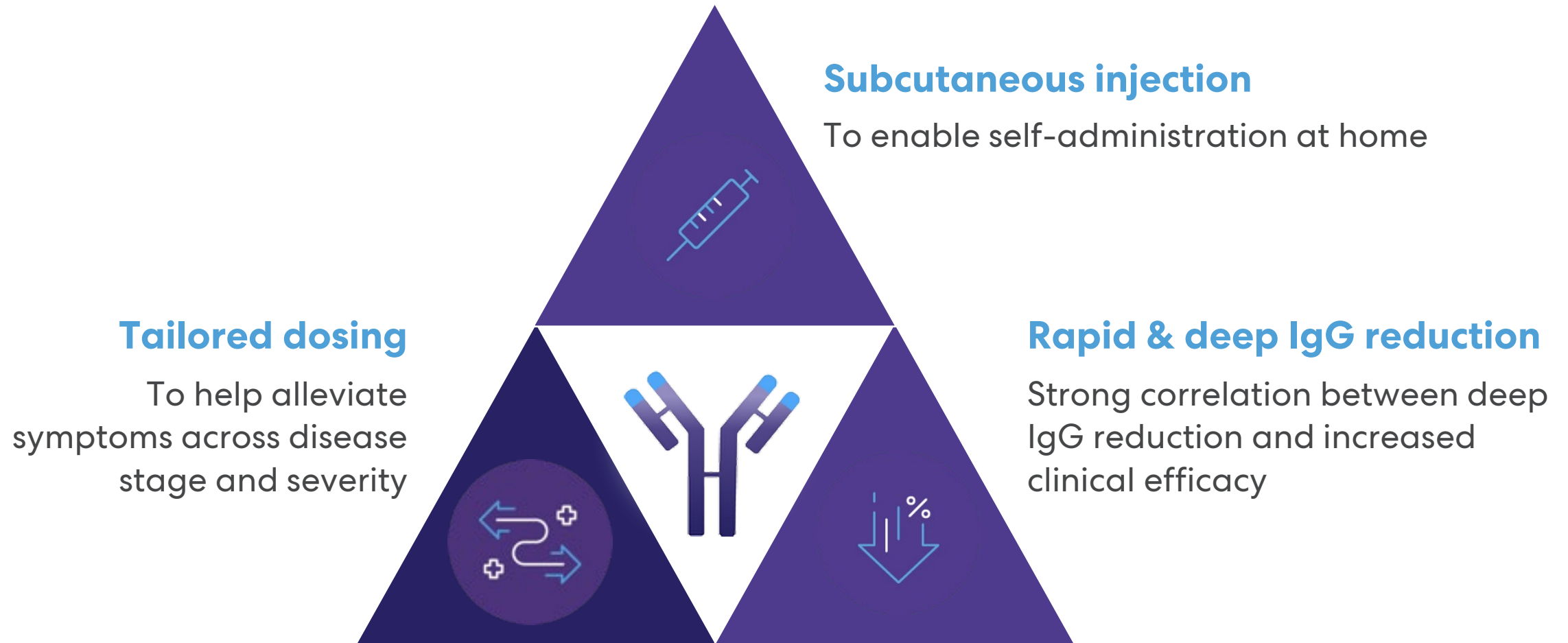


# Anti-FcRn Franchise: IMVT-1402 and Batoclimab

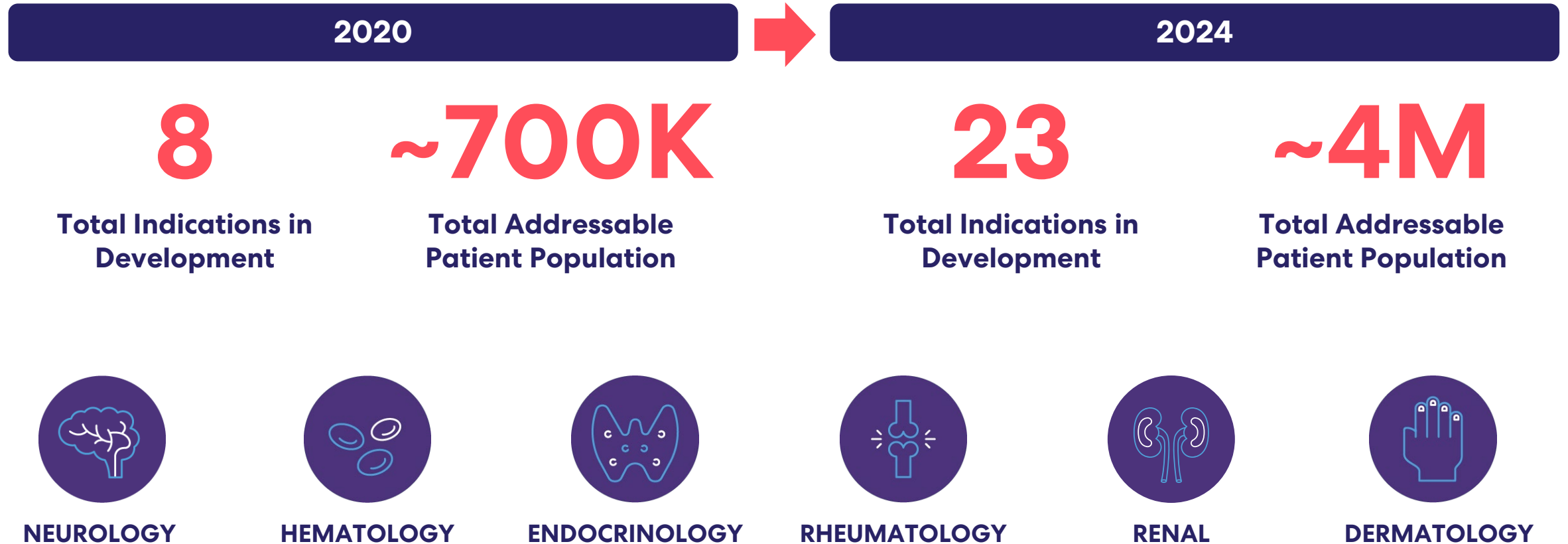
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# FcRn Franchise Offers Three Potentially Unique Attributes to Address Unmet Patient Needs



# Anti-FcRn Antibody Development has Seen Explosive Growth from 2020 to 2024



# Substantial Increase in Clinical Validation of FcRn Antibody Biology: Now with ~2,000 Patients Studied in 22 Positive Late-stage Trials

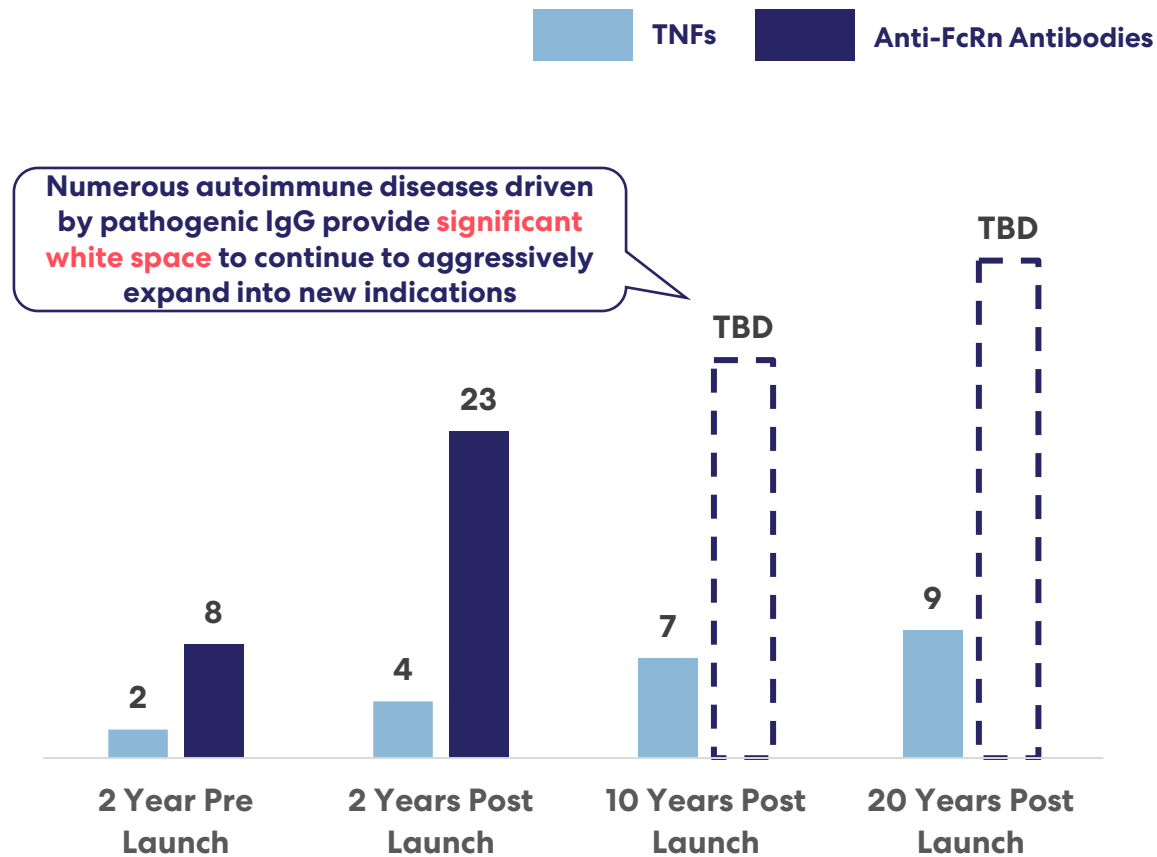
4 compounds across 9 indications have demonstrated success in 7 Phase 3 (N = ~1,300) and 15 Phase 2 (N = ~700) trials, with only 3 failed trials

Indication	FcRn	Phase	N
Myasthenia Gravis	Efgartigimod (SC)	Phase 3	110
	Efgartigimod (IV)	Phase 3	167
	Efgartigimod (IV)	Phase 2	24
	Rozanolixizumab (SC Infusion)	Phase 3	200
	Rozanolixizumab (SC Infusion)	Phase 2	43
	Nipocalimab (IV)	Phase 3	199
	Nipocalimab (IV)	Phase 2	68
	Batoclimab (SC) – Immunovant	Phase 2	17
	Batoclimab (SC) – Harbour	Phase 3	132
Batoclimab (SC) – Harbour	Phase 2	30	
Primary Immune Thrombocytopenia	Efgartigimod (IV)	Phase 3	131
	Efgartigimod (IV)	Phase 2	38
	Rozanolixizumab (SC Infusion)	Phase 2	66
Sjogren's Syndrome	Efgartigimod (IV)	Phase 2	31
	Nipocalimab (IV)	Phase 2	163
Thyroid Eye Disease	Batoclimab (SC)	Phase 2b	65
	Batoclimab (SC)	Phase 2a	7
Pemphigus Vulgaris / Pemphigus Foliaceus	Efgartigimod (IV)	Phase 2	34
Chronic Inflammatory Demyelinating Polyneuropathy	Efgartigimod (SC)	Phase 2/3	322
Graves' Disease	Batoclimab (SC)	Phase 2a	25
Hemolytic Disease of the Fetus and Newborn	Nipocalimab (IV)	Phase 2	13
Rheumatoid Arthritis	Nipocalimab (IV)	Phase 2	53
<b>Total Indications = 9</b>	<b>Total Compounds = 4</b>	<b>Total Trials = 22</b>	<b>Total N = ~2,000</b>

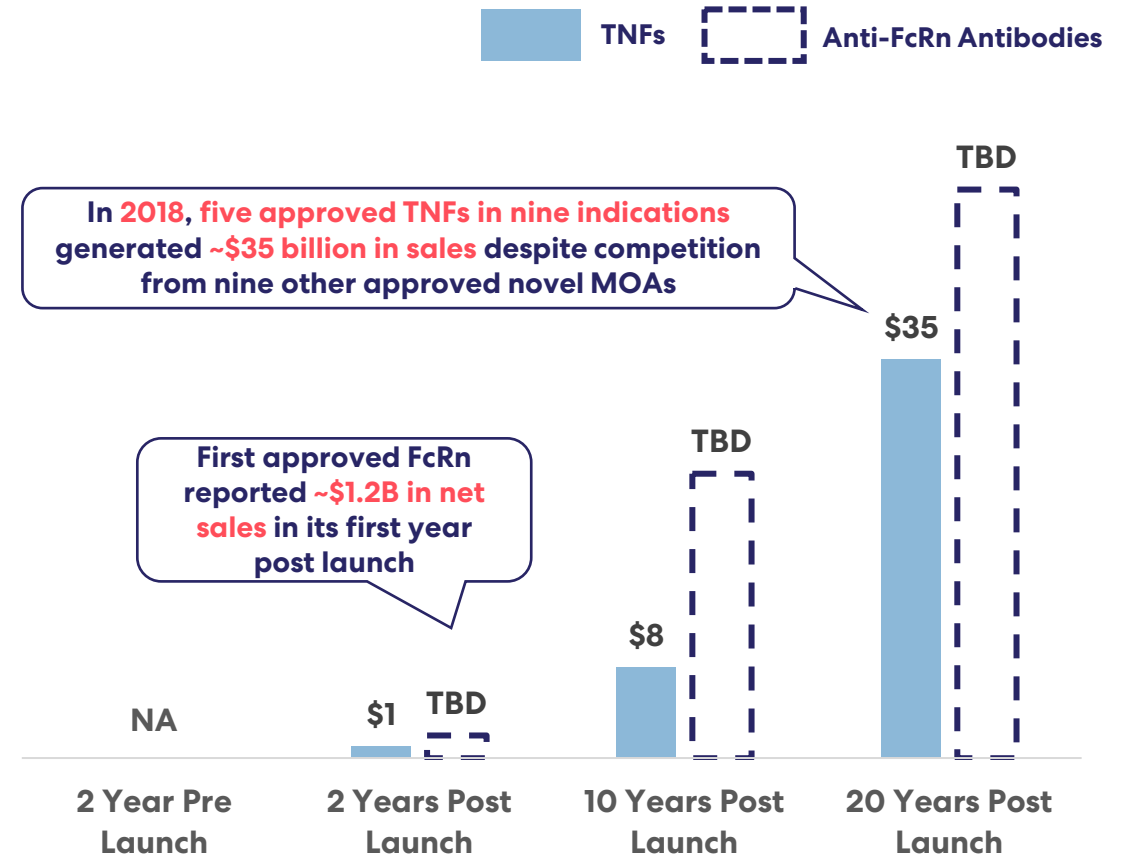
# Evolution of the Anti-FcRn Antibody Class is Analogous to the TNF Class

Anti-FcRn antibodies, at the beginning of their development cycle, are already outpacing indication expansion timeline of TNF agents at a similar timepoint

## Indications Approved/In Development

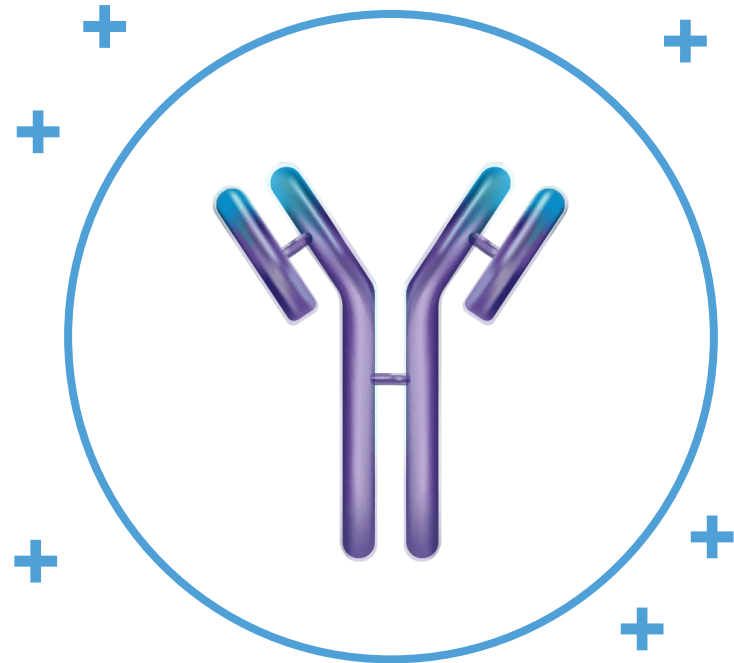


## Sales (\$ in Billions)



# IMVT-1402 Has a Combination of Potentially Best-In-Class Attributes Not Seen with Other Anti-FcRns

## IMVT-1402



Novel, fully human, monoclonal antibody inhibiting FcRn-mediated recycling of IgG



**Deep IgG Lowering** Initial Phase 1 data suggests deep dose-dependent IgG lowering



**Favorable Analyte Profile** Initial Phase 1 data supports a favorable analyte profile with no or minimal effect on albumin and LDL



**Convenient Administration** Formulated for simple subcutaneous injection that may enable self-administration at home



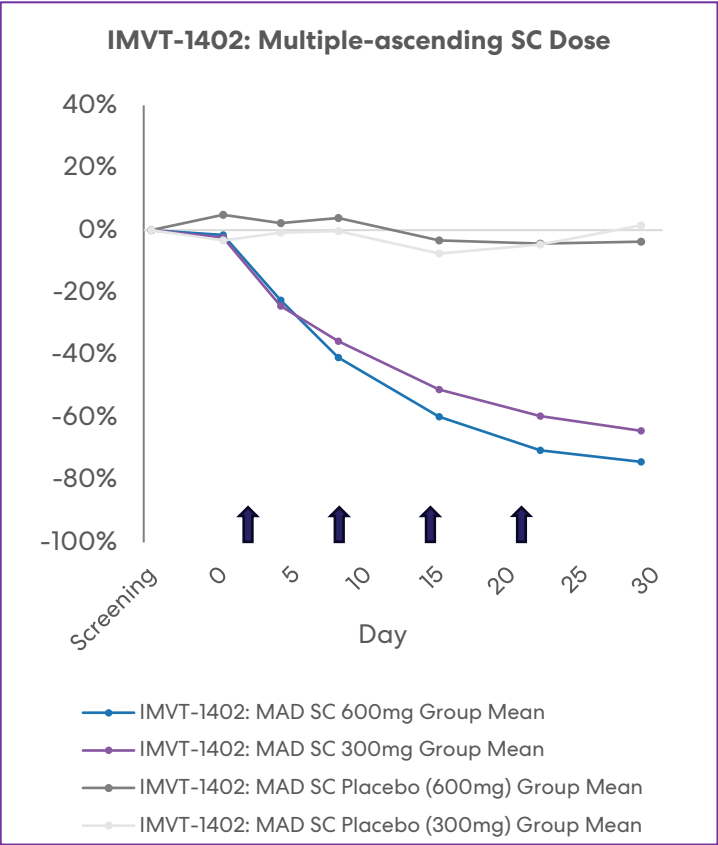
**Compelling Patent Protection** Issued patent covers composition of matter, method of use and methods for manufacturing to 2043\*



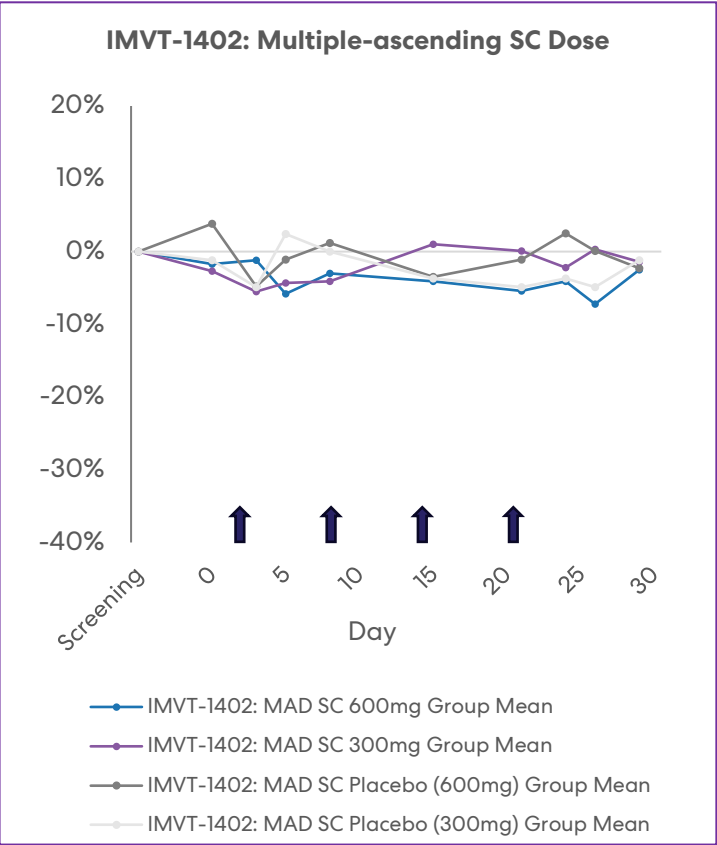
# IMVT-1402 Demonstrated Potentially Best-in-Class Profile in Initial Phase 1 Clinical Trial Data in Healthy Adults

Deep IgG reduction with minimal to no impact on albumin and LDL

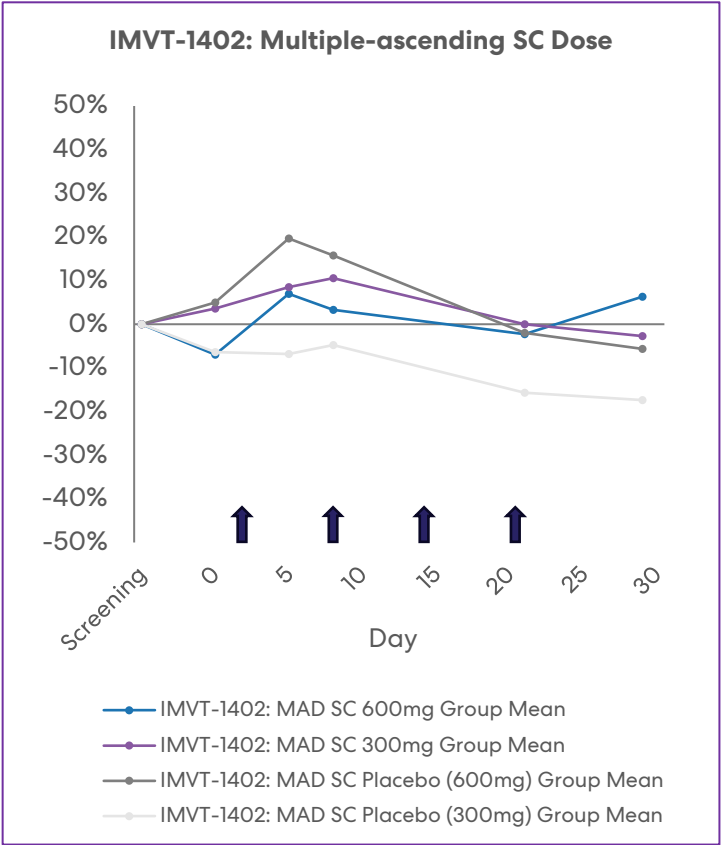
IgG % change over time









Albumin % change over time



LDL % change over time



# Consistent Evidence Across Programs and Indications that Greater IgG Reduction Leads to Greater Efficacy\*

	Company	Evidence of Greater IgG Reductions Translating to Clinical Benefit
MG	 	Patient-level scatter plot showed that greater IgG declines → greater MG-ADL improvements
TED		Greater IgG reduction across arms → higher rates of anti-TSHR antibody reduction and greater clinical response rates
GD		Greater IgG reduction across treatment cohorts → higher rates of anti-TSHR autoantibody reduction and numerically higher responses for ATD dose tapering and ATD discontinuation observed
ITP		Greater IgG reduction across arms → greater platelet responses
RA		In those patients with greater IgG reduction → correlation with greater autoAb reduction → correlation with greater clinical response

# Potential Best-in-Class Product Profile Opens Broad Range of Indication Opportunities for IMVT-1402

## First-in-Class

- Assuming differentiated benefit/risk and simple SC delivery, opportunity to leverage potency of 1402 to further expand applicable patient types for anti-FcRn development
- Example – Graves' Disease

**High unmet need, biologic plausibility**

## Best-in-Class

- IgG autoantibodies part of disease pathophysiology
- Insights from later-stage anti-FcRn programs may be leveraged together with 1402 potency to optimize development approach for IMVT-1402
- Example – Myasthenia Gravis

**Classic autoAb, class data positive**

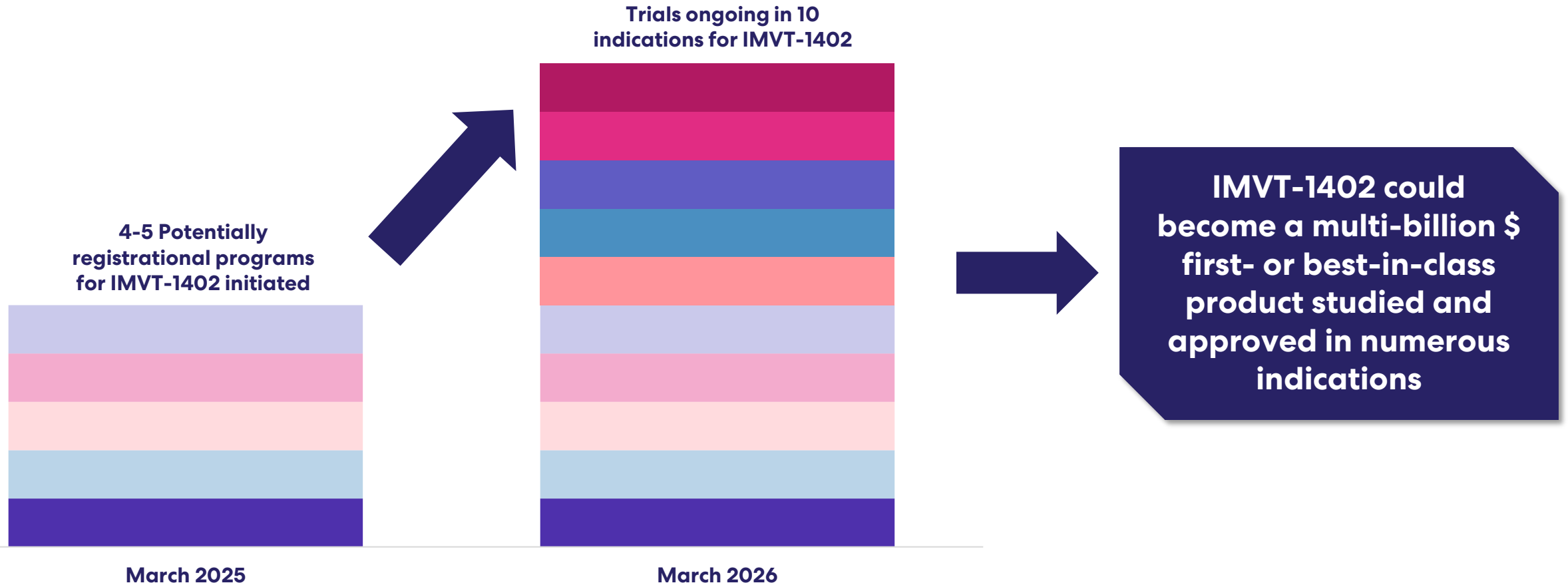
## Best-in-Class

- Other underserved patient populations
- Potential to enhance PTS via focus on subset of patients with autoantibodies of interest and leverage 1402 potency
- Example – ACPA+ Difficult-to-Treat Rheumatoid Arthritis

**Other auto-immune, class data suggestive**

# Immunovant is Aggressively Developing IMVT-1402 with Plans to Initiate Trials in a Total of 10 Indications by March 31, 2026

5 INDs cleared for IMVT-1402 across a range of therapeutic areas and FDA divisions



# Two Indications Announced Out of Five Active INDs for IMVT-1402 to Potentially Transform the Treatment Paradigm for Patients with Unmet Need

	Graves' Disease First-in-Class Potential	Rheumatoid Arthritis Best-in-Class Potential
<b>01</b> Meaningful unmet need for subset of patients	Patients not well controlled on ATDs	Patients with D2T RA, multiple therapies failed
<b>02</b> Underlying pathology driven by IgG Ab	FcRn inhibition observed to lower TRAb	FcRn inhibition observed to lower ACPA
<b>03</b> In-class proof-of-concept data	Higher response rate across multiple measures with $\geq 70\%$ IgG reduction <sup>1</sup>	Response rate higher for patients with high baseline ACPA & deep IgG reduction <sup>2</sup>
<b>04</b> IMVT-1402 trial design	600mg dose for deep IgG reduction; Primary endpoint includes off-ATD	600mg dose for deep IgG reduction; Open-label lead-in

1. Data on file at Immunovant

2. Pharmacodynamic effects of nipocalimab in patients with moderate to severe active rheumatoid arthritis (RA): Results from the multicenter, randomized, double-blinded, placebo-controlled Phase 2A IRIS-RA study  
Janssen Research & Development, ACR poster, November 2023

# Anti-FcRn Indications

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# Graves' Disease

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# Graves' Disease: a Systemic Disease that Impacts Multiple Organ Systems Leaving Many Patients with Substantial Symptoms

Graves' Disease is an immune disorder characterized by hyperthyroidism and has an incidence of ~65K<sup>1</sup> cases per year and prevalence of ~880K<sup>2</sup> patients in the US

## Clinical Presentation and Unmet Need

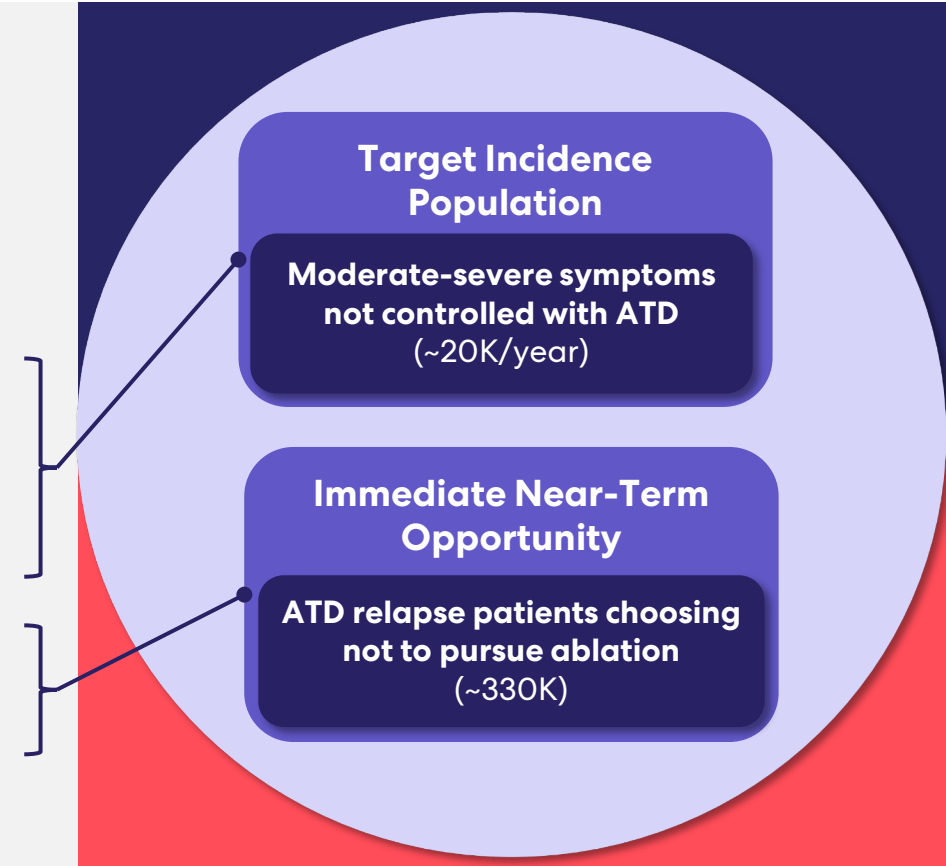
Caused by anti-TSHr autoantibodies which overstimulate the thyroid gland and cause hyperthyroidism; FcRn inhibition could foster degradation of those autoantibodies

Because thyroid hormones affect many body systems, Graves' Disease can impact many organ systems with variable symptoms per patient<sup>3-9</sup>

- Heart, skeletal muscle, skin, bones, eyes, liver, brain, reproductive and GI systems may be affected

Many patients with Graves' Disease remain symptomatic despite maximally tolerated anti-thyroid medications; others would avoid ablation if possible

- 25-30% of the ~65K<sup>1</sup> US incident Graves' patients are difficult to control with ATD and remain symptomatic
- Additional upside as alternative to ablative therapies
- 35-40% of the ~880K<sup>2</sup> US prevalent population are ATD relapse patients choosing not to pursue ablation



# Minimal Innovation in Graves' Disease Treatment Options over the Past 70+ Years

No existing pharmacologic therapy addresses underlying disease pathology

## Standard-of-Care Treatments

### Anti-Thyroid Drugs (ATDs)

- ~25-30% of patients are relapsed, uncontrolled or intolerant to ATDs<sup>1</sup>
- Potential for serious adverse events, including hepatotoxicity (liver injury ~3%) and agranulocytosis (loss of white blood cells ~0.3%)<sup>2,3</sup>

### Radioactive Iodine

- TED development and/or exacerbation in 15-33% of patients<sup>4</sup>
- Dose dependent, long-term increased risk of death (5-12% increased risk per 100-mGy dose) from solid cancers<sup>5</sup>
- Necessitates life-long thyroid replacement therapy

### Thyroidectomy

- Recurrent laryngeal nerve damage risk in 1-4% of patients leading to dysphonia<sup>3</sup>
- Permanent hypoparathyroidism observed in 2.6% of patients<sup>4</sup>
- Necessitates life-long thyroid replacement therapy

## Associated Challenges

# Multiple Market-Sizing Analyses Confirm High Unmet Need in Graves' Disease with at Least 25-30% of Patients Relapsed, Uncontrolled, or Intolerant to ATDs

**1**

Conservative Inovalon claims analysis yields ~880K prevalent Graves' Disease patients

**2**

Conservative Inovalon claims analysis yields ~65K incident Graves' Disease patients

**3**

Deep dive endocrinologist survey of 140 healthcare providers treating Graves' Disease patients indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

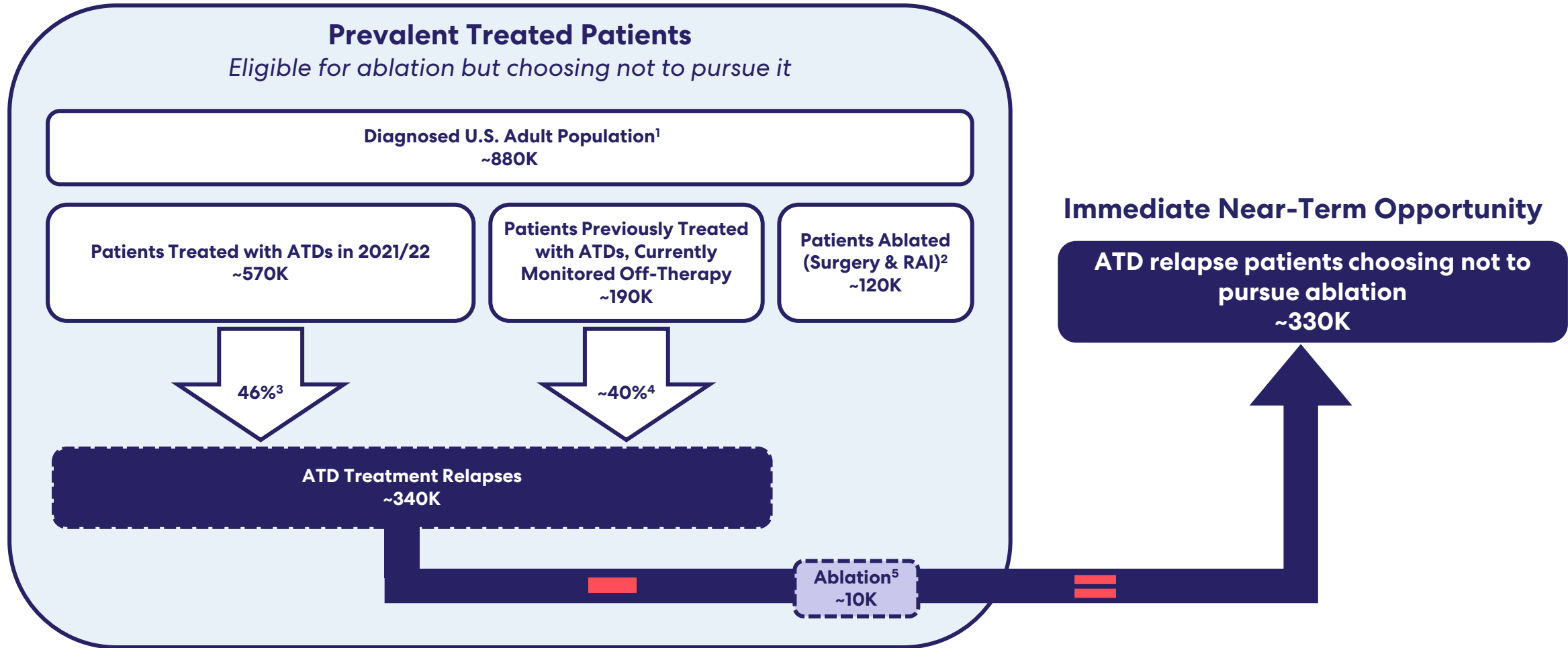
**4**

Real-world chart audit of 1,120 Graves' Disease patients treated by surveyed endocrinologists indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

**5**

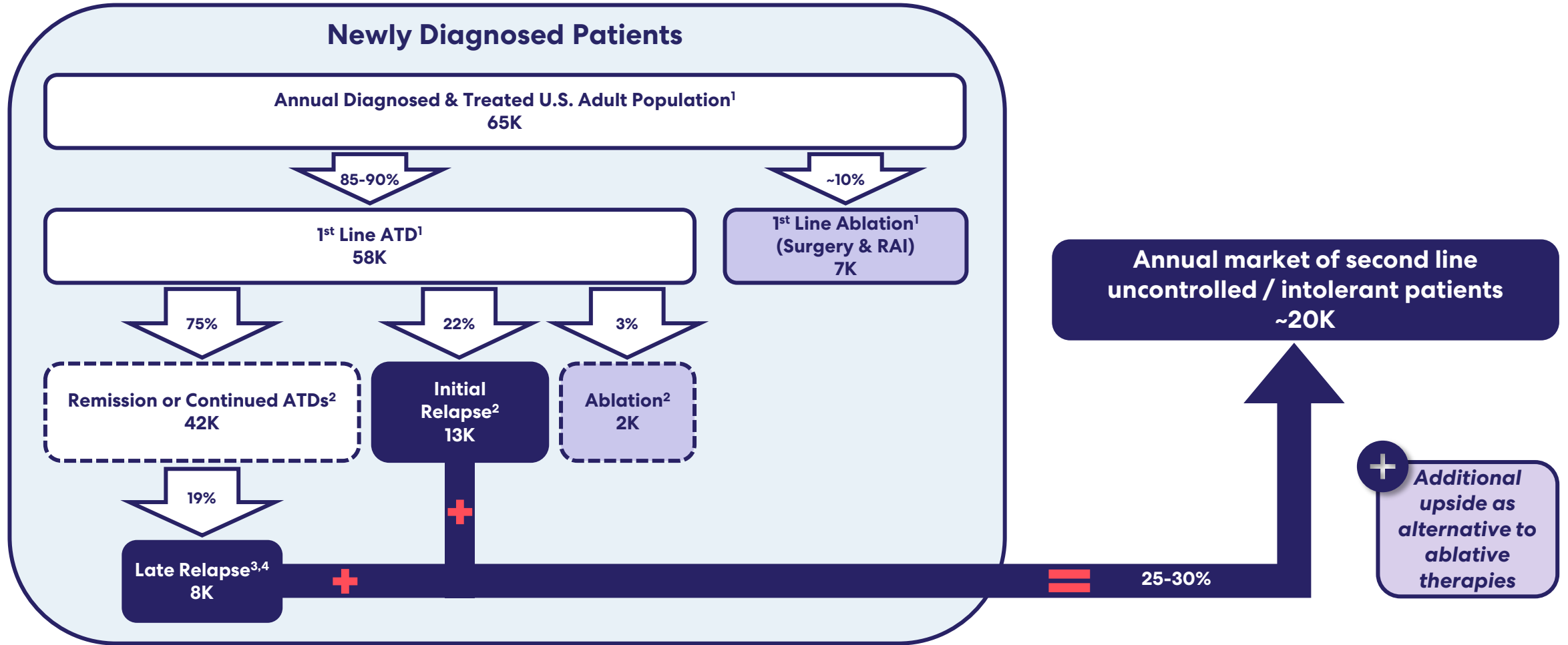
Patient survey of 100 diagnosed Graves' Disease patients indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

# Real World Claims Analysis Indicates a Substantial Untapped Opportunity in the Prevalent Treated Graves' Disease Market



1. Roivant Claims Analysis – 2022 prevalent patient population based on a two-year lookback for diagnosis  
 2. Of the 120K patients ablated, ~80K were ablated prior to 2021 and ~40K were ablated in 2021/2022  
 3. Azizi et al. (2019): Relapse rate was calculated as a weighted average considering relapse rate in patients on ATDs <18months is 53% compared to patients on ATDs >18months is 15%. Of the 570K patients treated with ATDs, ~470K are on ATDs <18months and ~100K are on ATDs for >18months. Rates have been applied proportionally.  
 4. Bandai et al. (2019): Of the ~190K patients previously treated with ATDs and currently monitored off-therapy, ~40% experience relapse, which is 75K.  
 5. Grove-Laugesen et al. (2023): 3.4% of ATD relapse patients will pursue ablation. 3.4% applied to the ~340K ATD treatment relapse patients is ~10K

# Real World Claims Analysis Conservatively Estimates an Incident US Population of ~65K Leading to an Annual Second Line Market of ~20K Patients



1. Roivant Claims Analysis – 2021 incident patient population, first-line treatment is primary treatment in the first-year post diagnosis, claims review included a five-year lookback to define the incident population
2. Grove-Laugesen et al. (2023): Completer rates for combined arms: ATD remission 56.0%, continuing ATD 18.8%, ATD relapse of 21.8%, ablation of 3.4%. Of the 58K 1st line ATD patients, a total of ~75% are either in remission (56.0%: 32.5K) or continued ATDs (18.8%: 10.9K)
3. Azizi et al. (2019): ATD remission for patients on long-term ATDs is 85%. Of the 10.9K patients who continued ATDs, 15% relapse (1.6K) and 85% go into remission (9.3K). These 9.3K patients in remission will have a 15% rate of relapse resulting in 1.4K relapses. From the original 10.9K patients who continued on ATDs, there will be a total of 3K (1.4K +1.6K) relapses.
4. Stokland et al. (2023): Relapse post remission 15%. Of the 42K patients who are in remission, 15% will relapse (6.3K). In total, the late relapses from remission and continued ATDs will be ~9.3K, resulting in a weighted average relapse rate of ~19% (6.3K relapses from the 32.5K patients in remission averaged with the 3K relapses from the 10.5K patients who continued on ATDs).

# Recent KOL Feedback Affirms Large Unmet Medical Need

## Low quality of life with current treatment options...

“For our patients who still require relatively high doses of ATDs it can be a difficult situation with a lot of fluctuating thyroid hormone levels, a lot of dose changes, so that gets sometimes **complicated and frustrating for clinicians and for patients alike**”  
- Dr. Lupo, LifeSci KOL call<sup>1</sup>

“Some patients [tolerate ATDs], but others don't. And it could be very **disruptive**. I've had people actually **go on disability** because of this or **drop out of work**. They can't function because they're all over the place and they're just **feeling lousy**.”  
- Dr. Cooper, JPM KOL call<sup>2</sup>

“After surgery [and] radioactive iodine, [patients] are **completely dependent life-long on thyroid hormone replacement**... Those patients generally have a **lower quality of life** than the norm data for quality of life for that population.”  
- Dr. Lupo, LifeSci KOL call

## ...Without addressing underlying disease pathophysiology

“[ATD, surgery, and radioactive iodine do not] hit that underlying issue of the immune system is producing something that stimulates and tricks the thyroid into making too much thyroid hormone, so we're kind of approaching this topic by either slowing the thyroid down or destroying the thyroid and not looking at the immune system directly.  
**Having something else to offer would be great.**”  
- Dr. Lupo, LifeSci KOL call

“**We need something that gets the underlying core of the disease.** I mean, what we have right now is just treating the manifestations. We're just treating the production of thyroid.”  
- Dr. Cooper, JPM KOL call

# Proof of Concept Achieved in Graves' Disease, Positioning IMVT-1402 to Potentially be Best-in-Class and First-in-Class



**>75% Response Rate in Patients Uncontrolled on Anti-Thyroid Drugs (ATDs):** T3 and T4 rapidly normalized by Week 12 without an increase in ATDs in 76% of patients



**>50% of Patients are ATD-Free Responders:** 56% of patients not only achieved normal T3 and T4 levels but also ceased ATD therapy entirely by 12 weeks



**Lower is Better:** Deeper IgG reductions drove meaningfully higher response rates, positioning IMVT-1402 to potentially be best-in-class



**High Unmet Need Yields Attractive Commercial Opportunity:** 25-30% of Graves' Disease patients per year are uncontrolled on / intolerant to ATDs with no pharmacologic options



**IMVT-1402 IND Cleared:** Received FDA greenlight, enabling straight to pivotal transition



# Batoclimab Phase 2 Proof-of-Concept Trial: The First and Only Anti-FcRn Program Targeting Graves' Disease<sup>1,2</sup>

## Inclusion<sup>3</sup>

- Subjects with active GD as documented by presence of elevated stimulatory TSH-R-Ab
- Subjects on an ATD for ≥12 weeks before the Screening Visit
- Subjects hyperthyroid despite ATD

Screening (4 weeks)

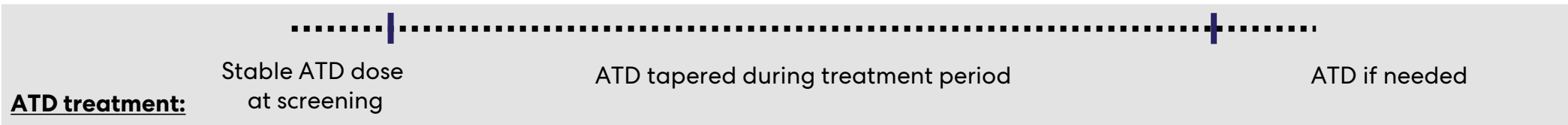
Treatment Period: (24 weeks)  
N = up to 40

Two doses tested  
over 24 weeks



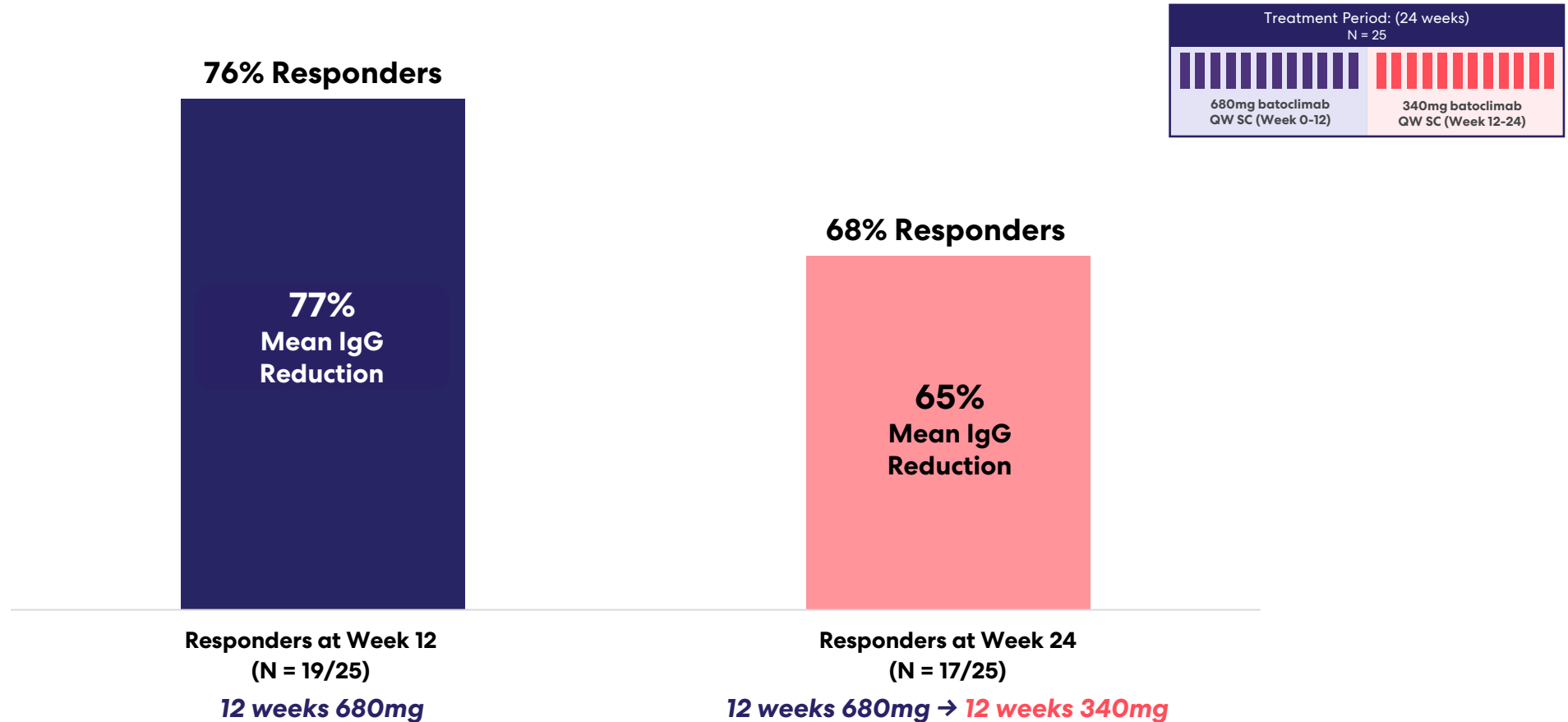
Follow-up Period

**Primary endpoint:**  
Proportion of participants who achieve normalization of T3 and T4 at Week 24 with ATD dose < baseline ATD dose



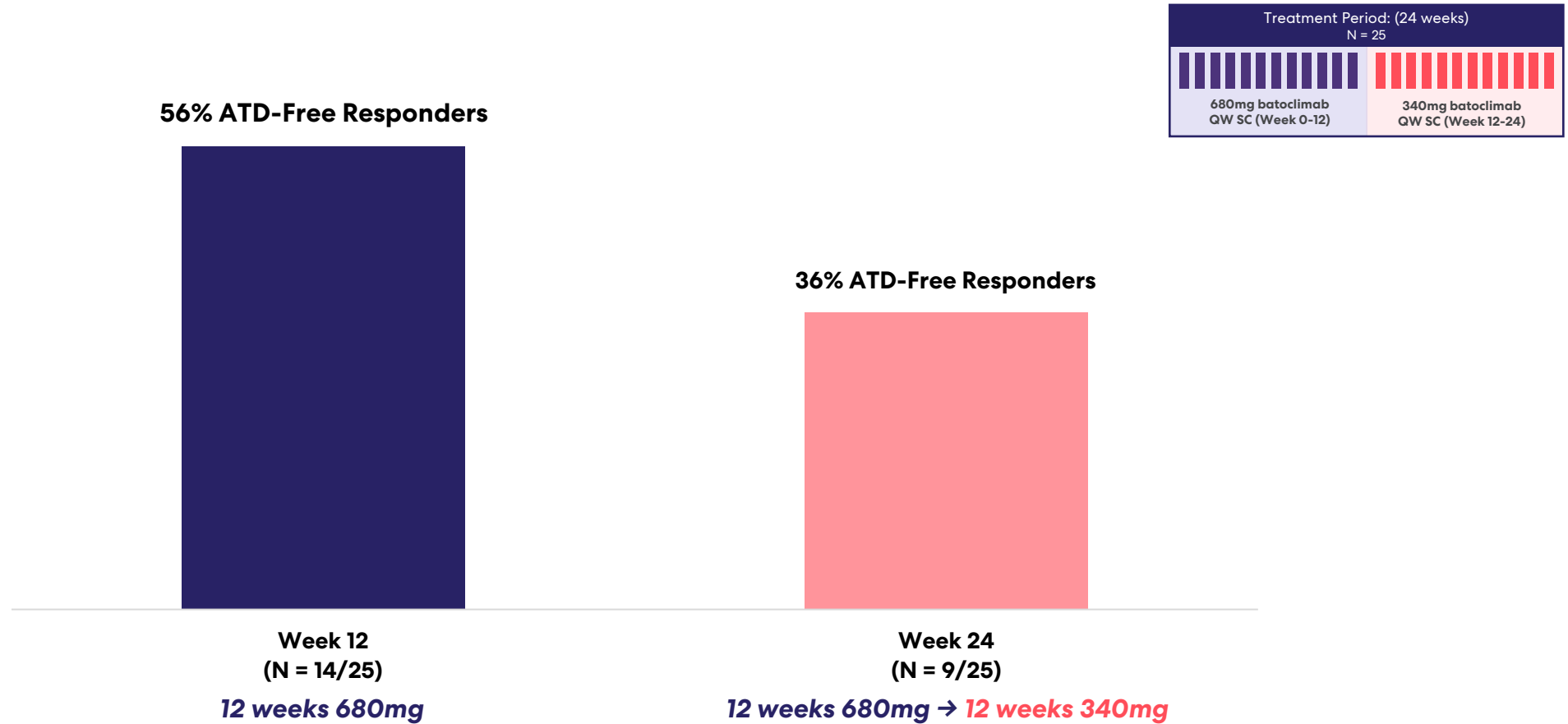
# Batoclimab Demonstrated Potentially Transformational Results in ATD- Uncontrolled Patients with Greater Response Driven by Higher IgG Lowering

% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, without increase in ATD



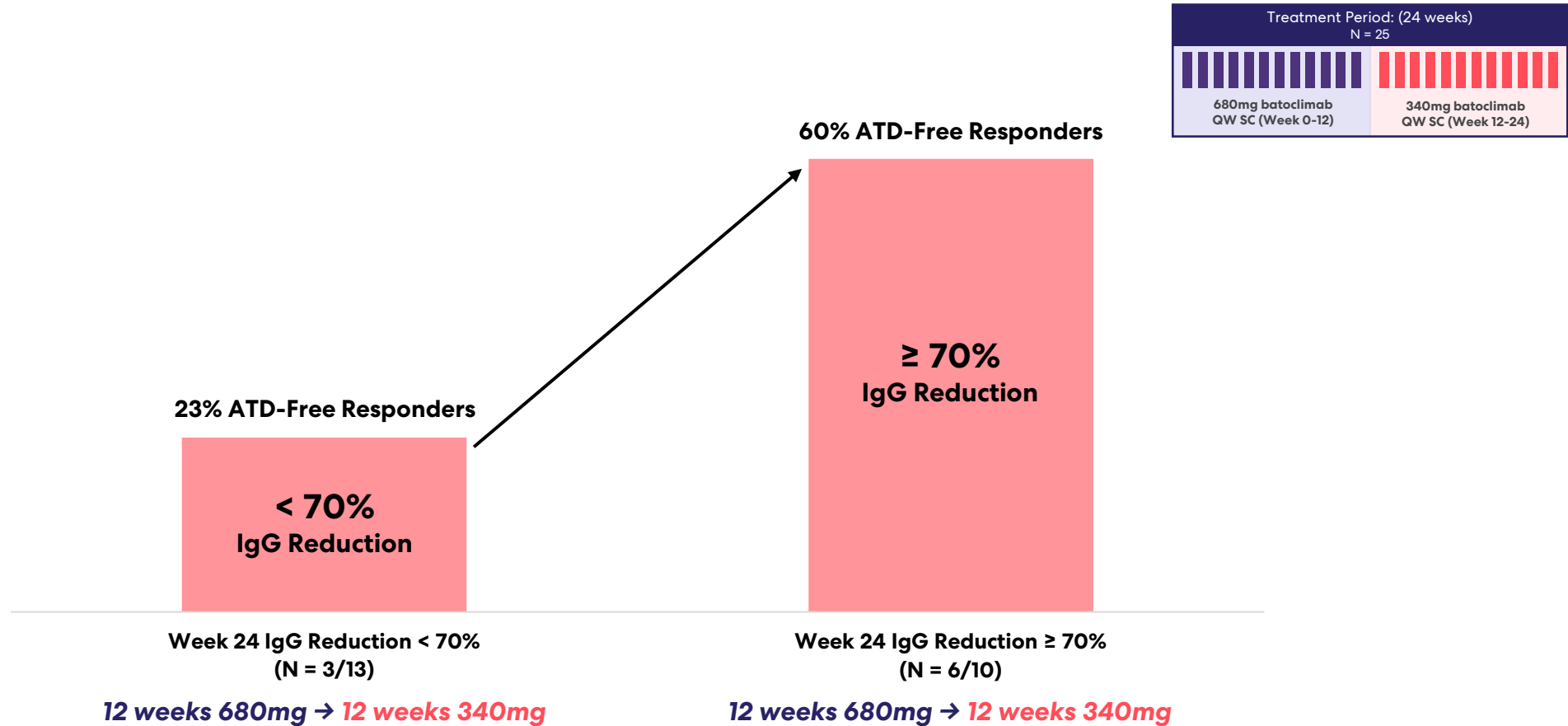
# >50% of Patients Receiving High-Dose Batoclimab Not Only Achieved Normal T3 and T4 Levels but Also Ceased ATD Entirely by 12 weeks

% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, and ceased all ATD medications

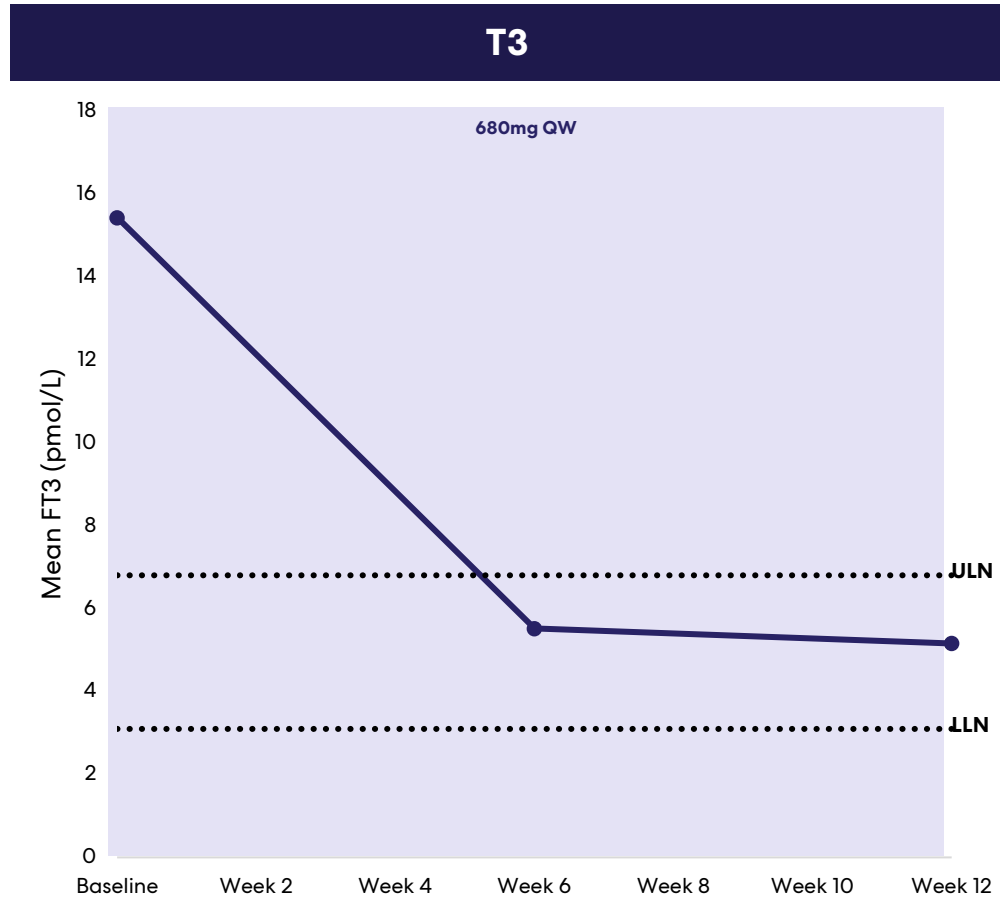


# Deeper IgG Reduction at 24 Weeks Was Associated with a Meaningfully Higher ATD-Free Responder Rate

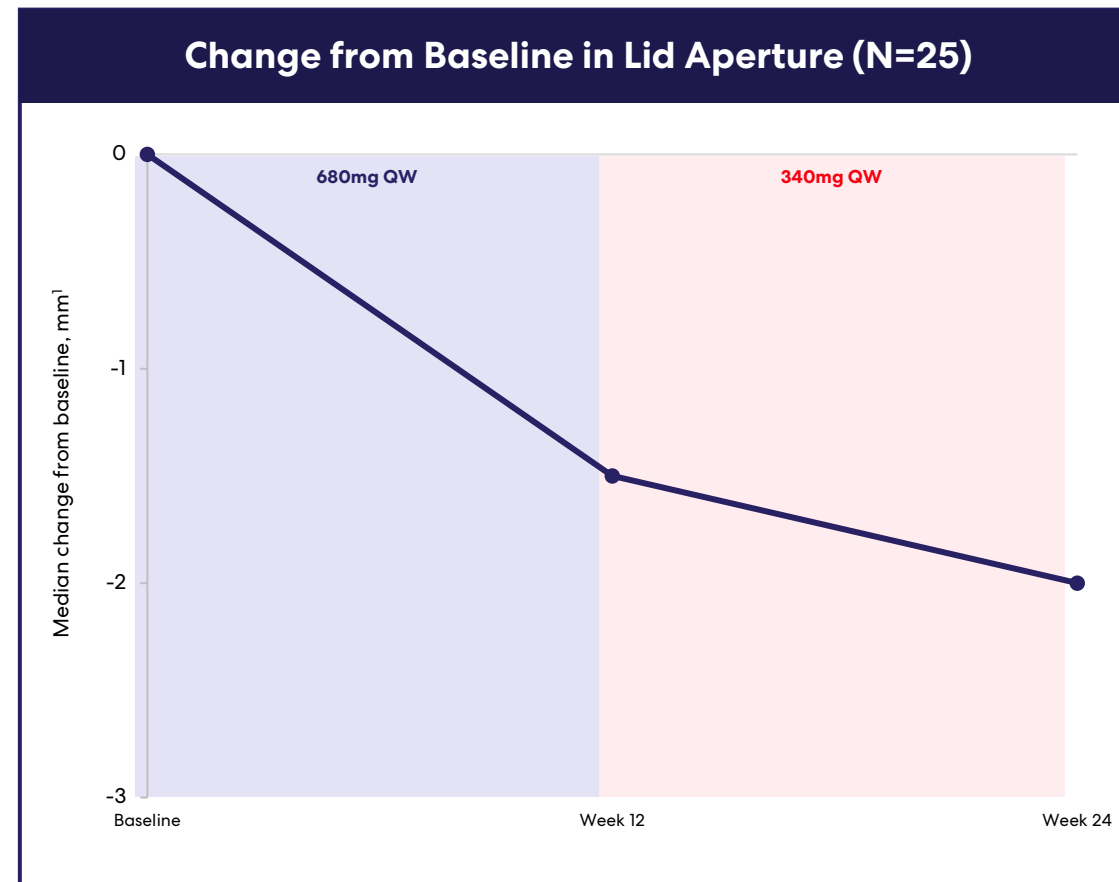
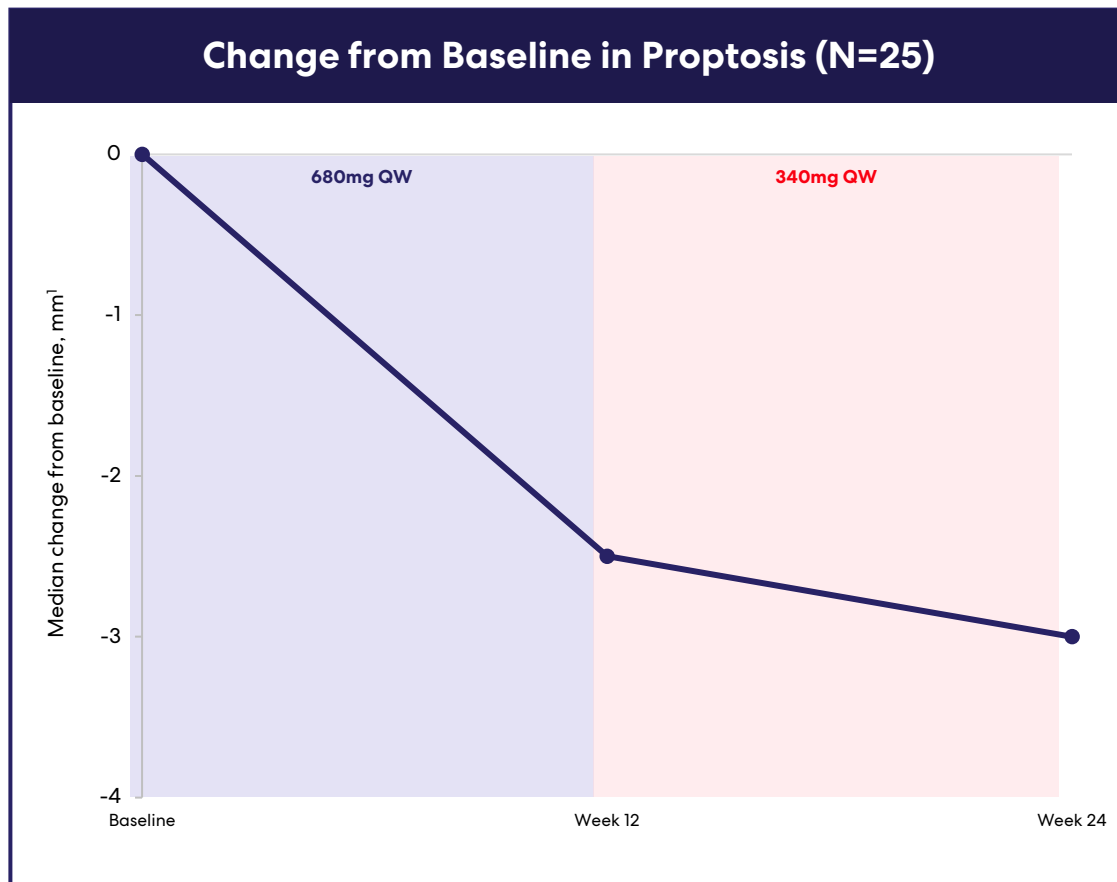
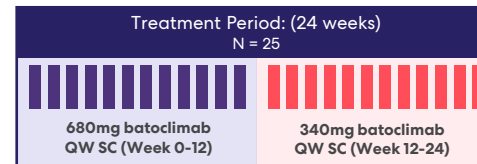
**% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, and ceased all ATD medications**



# High-Dose Batoclimab Drives Rapid Normalization of T3 and T4 and ATD Tapering



# Batoclimab Drove Meaningful Improvements in Proptosis and Lid Aperture in Graves' Disease Patients



# Batoclimab was Well-Tolerated with no New Safety Signals Identified

	Batoclimab SC QW N = 25
Patients with any TEAE, n (%)	25 (100)
Patients with any Serious TEAE	1 (4)
Patients with any Treatment-related Serious TEAE	0
Patients with any Treatment-related TEAE Leading to Study Drug Withdrawal	0
Patients with any TEAE Leading to Study Drug Dose Reduction or Interruption <sup>1</sup>	1 (4)
Patients with any TEAE Leading to Study Discontinuation <sup>2</sup>	1 (4)
Deaths	0

**All treatment-related TEAEs were mild or moderate with no serious treatment-related TEAEs reported**

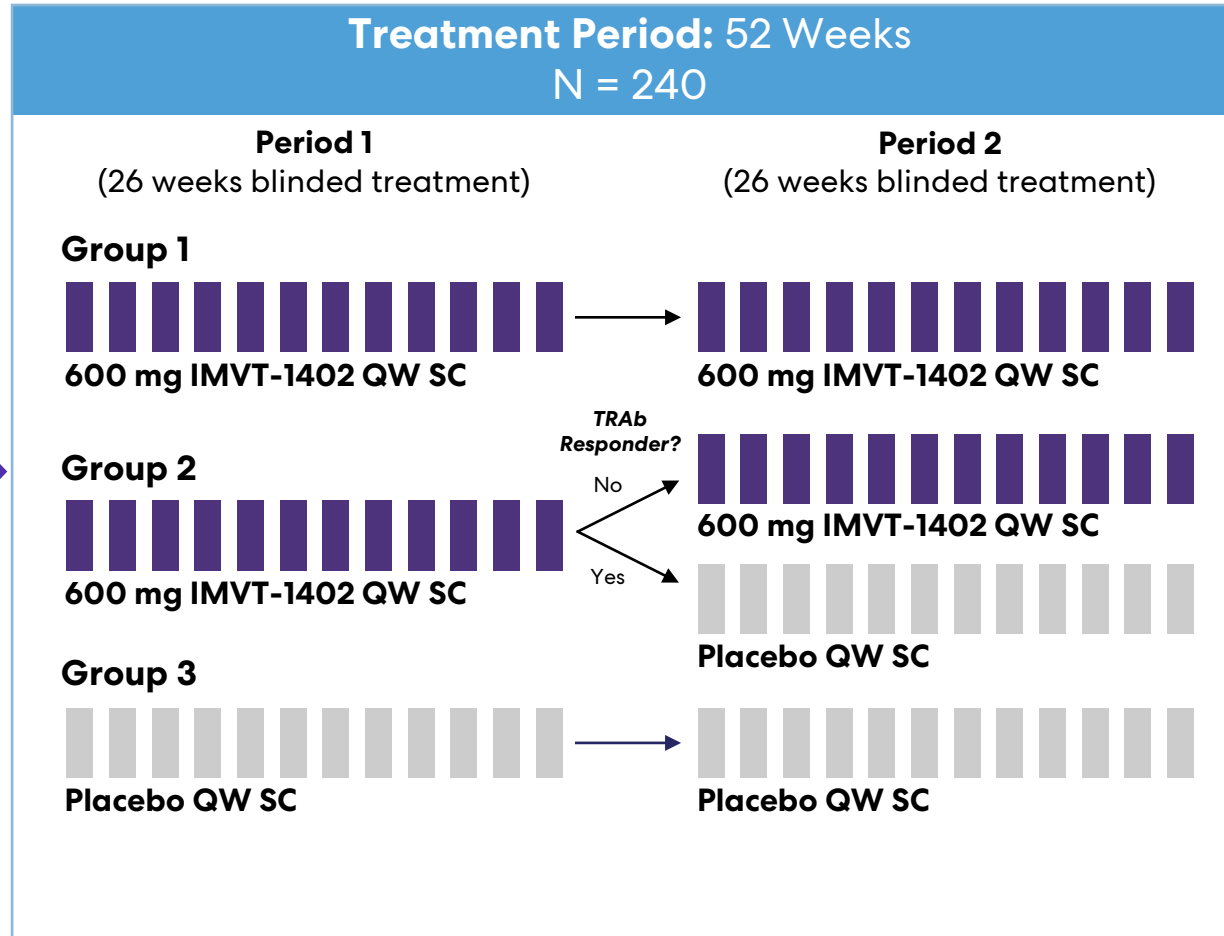


# First Pivotal Trial for IMVT-1402 in Graves' Disease

## Inclusion<sup>1</sup>

- Adults with active Graves' Disease as documented by presence of TSH-R binding autoantibodies
- Subjects on an ATD for  $\geq 12$  weeks before the Screening Visit
- Subjects who are hyperthyroid based on suppressed TSH despite ATD

Randomization (1:1:1)



Off-Treatment Follow-Up (52 Weeks)

**Primary Endpoint:**  
Proportion of participants who become euthyroid<sup>2</sup> and stop ATD at week 26

**Key Secondary Endpoint:**  
Proportion of participants who become euthyroid<sup>2</sup> and stop ATD at week 52

**Design enables study of remission as upside**

ATD titration to lowest effective dose (including 0 mg/day) to maintain euthyroidism

# Difficult-to-Treat Rheumatoid Arthritis

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# Despite Tremendous Progress in the Treatment of Rheumatoid Arthritis (RA), a Subset of Patients do not Respond Well to Available Therapies

## Key Takeaways<sup>1</sup>

- RA is a chronic, progressive disease that causes joint inflammation and pain
- Most common systemic autoimmune disease, affecting 18M globally and 1.5M in the US
- Medical therapy is used to help control joint inflammation; treatment options include a variety of conventional oral, targeted synthetic and biologic DMARDs
- Inadequate disease control can result in irreversible joint erosions

## Significant Impact



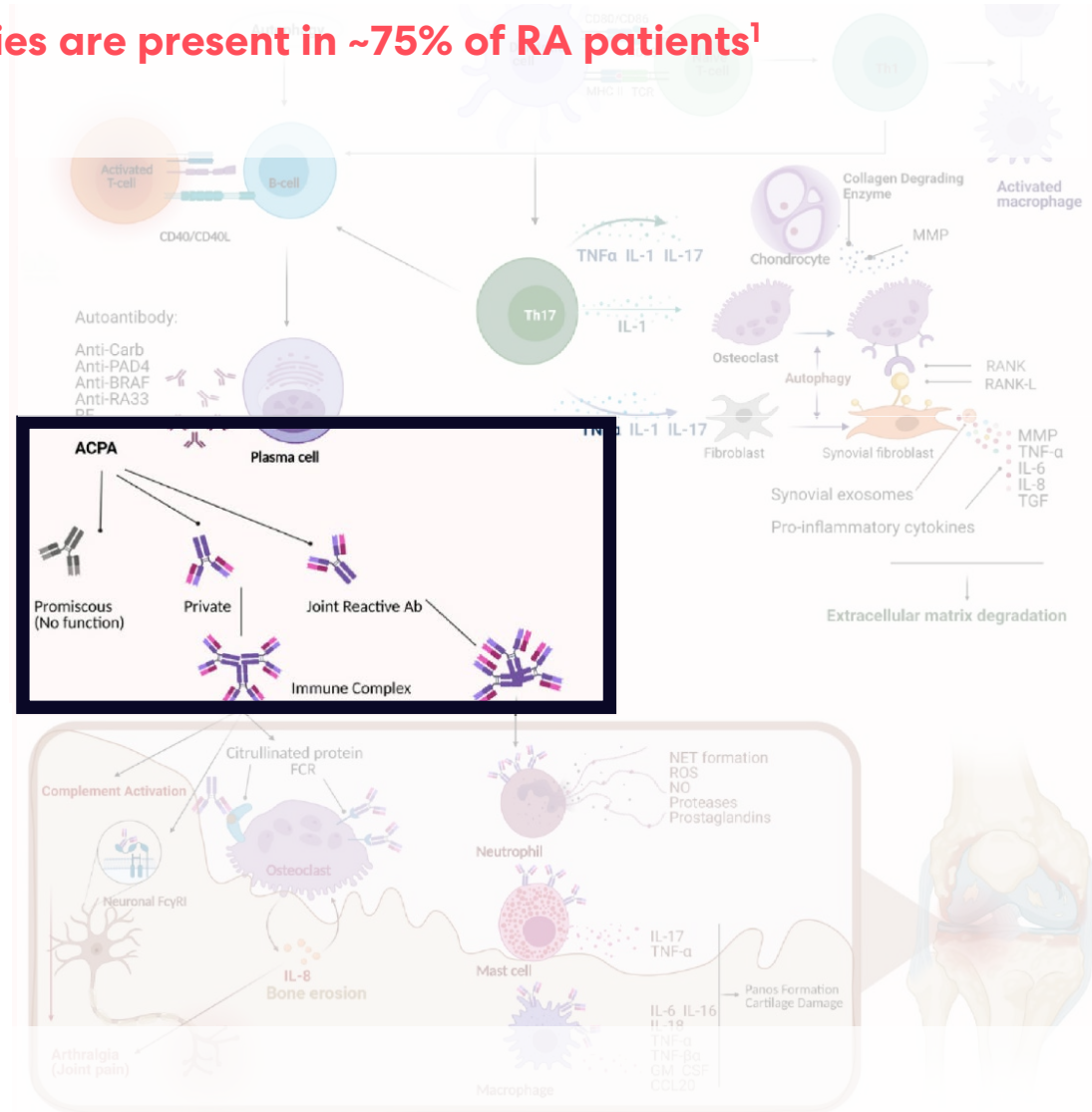
PA view of the hands shows joint space narrowing, erosions, and diffused osteoporosis

Source: Nakshabandi N al. et al. Radiology in Rheumatology, 2021.

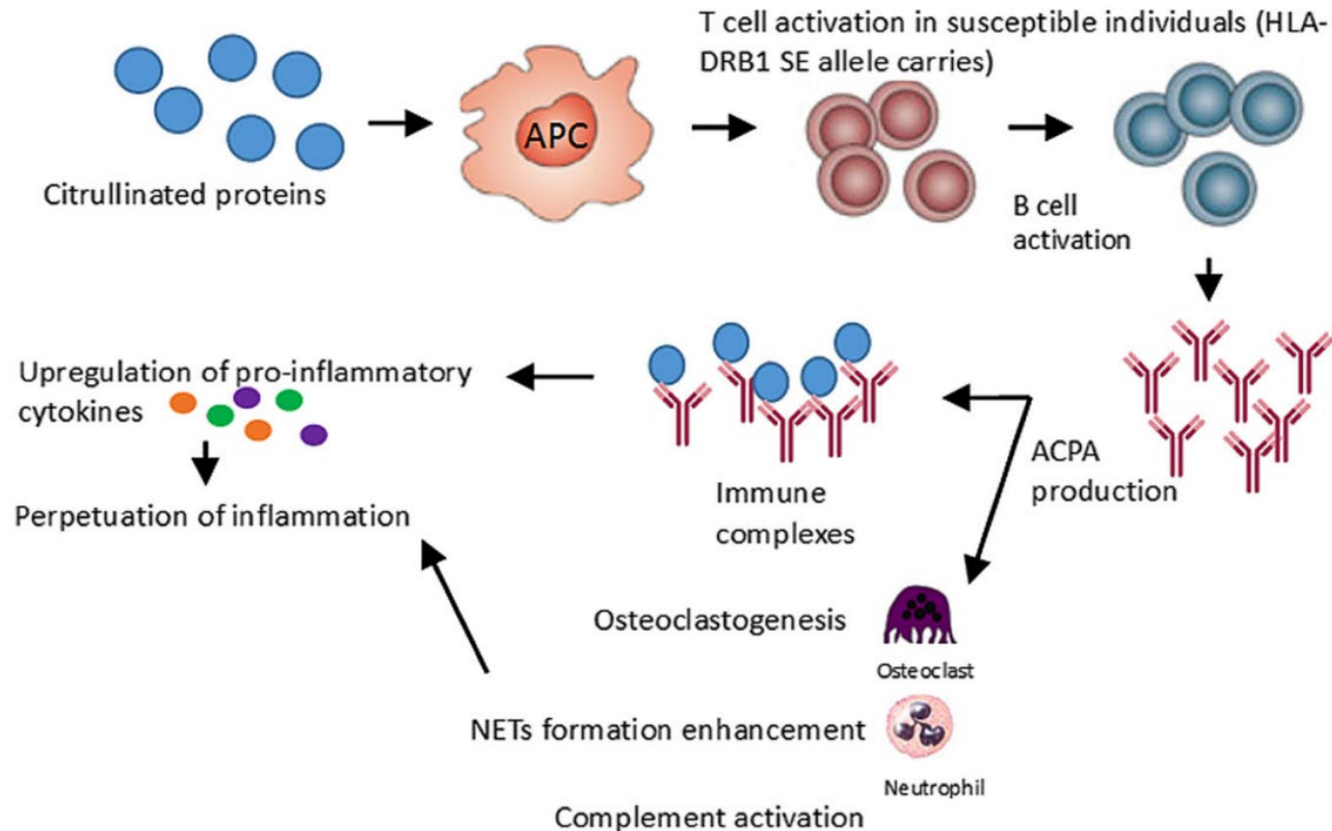
# In Addition to Cellular Autoimmunity and Cytokine Dysregulation, Autoantibodies Also Play a Role in the Pathophysiology of RA

Rheumatoid factor (RF) and ACPA autoantibodies are present in ~75% of RA patients<sup>1</sup>

Anti-FcRn mechanism may lower pathogenic IgG autoantibodies and immune complexes



# Understanding the Pathophysiologic Relevance of ACPA Autoantibodies in RA



- Antigen presenting cells (APCs) process and present citrullinated peptides to T cells
- T cells activate B cells to generate autoantibodies
- Immune complex formation upregulates pro-inflammatory cytokines
- ACPA may bind to osteoclasts and thereby promote bone erosion

# What is Difficult-to-Treat RA and Why is Innovation Needed?

## High Unmet Need

- Estimated 5-20% of patients remain symptomatic despite multiple treatment rounds<sup>1</sup>
  - These patients need new therapies and approaches, according to a global survey of 410 rheumatologists
- Difficult-to-treat (D2T) RA defined by EULAR as:<sup>2</sup>
  - Multiple DMARD failures
  - Signs suggestive of active/progressive disease
  - Symptom management viewed as problematic to doctor and/or patient

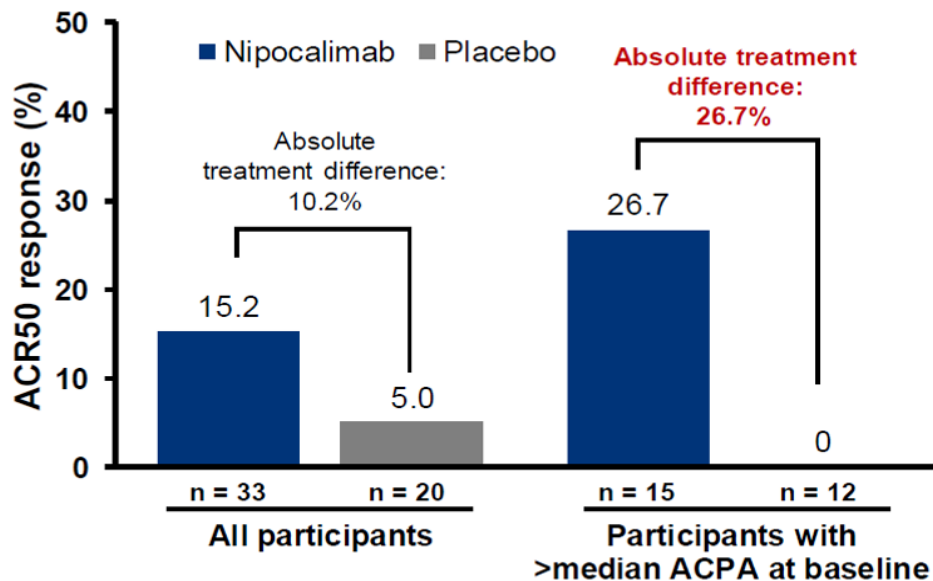
## D2T RA Patient Population

- At least moderate disease activity as defined by composite endpoints which include tender and swollen joint counts
- Progressive joint damage on imaging
- Inability to decrease chronic glucocorticoid therapy below 7.5mg/day
- Ongoing RA symptoms and QoL impact despite therapy

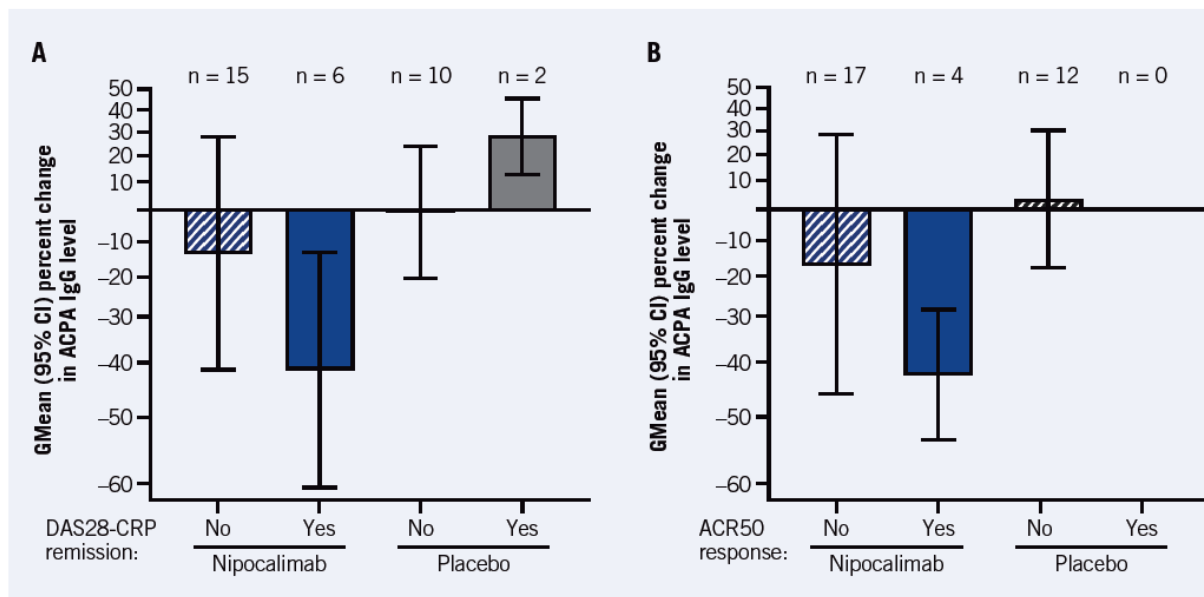
# Publicly Available Nipocalimab Data in RA Demonstrated Proof of Mechanism and Showed that Deeper ACPA IgG Reduction Correlated with Clinical Response<sup>1</sup>

Select results from a study of FcRn inhibition vs placebo in biologic experienced RA patients

Proportions of Participants Who Achieved ACR50 Response at Week 12 by ACPA



Percent Changes from Baseline at Trough in ACPA IgG Levels versus (A) DAS-28 CRP Remission and (B) ACR50 Response at Week 12

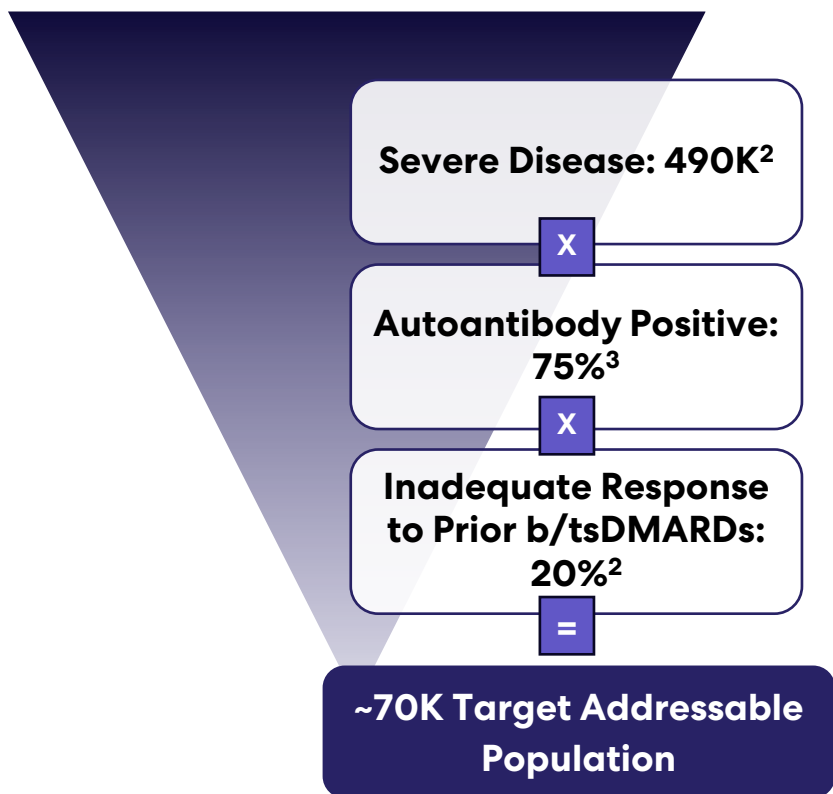


ACPA, anti-citrullinated protein autoantibody; ACR50, ≥50% response in American College of Rheumatology response criteria; anti-CCP2, anti-cyclic citrullinated peptide 2 antibody; CI, confidence interval; DAS28-CRP, Disease Activity Score 28 using C-reactive protein; GMean, geometric mean; IgG, immunoglobulin G.



# Of the 1.5M US RA Patients<sup>1</sup>, a Subset Progresses to D2T Status in a Relatively Short Period of Time and Requires New Therapeutic Options

## Epidemiology



## Patient Journey Learnings

**Fewer than 50% of RA patients remain on first therapy**

~50% of patients fail their first b/tsDMARD therapy within the first year of treatment<sup>4,5</sup>

**D2T emerges for some in ~4 years**

In a large US registry, the median time to meeting D2T criteria was 4 years, in those who were D2T<sup>6</sup>

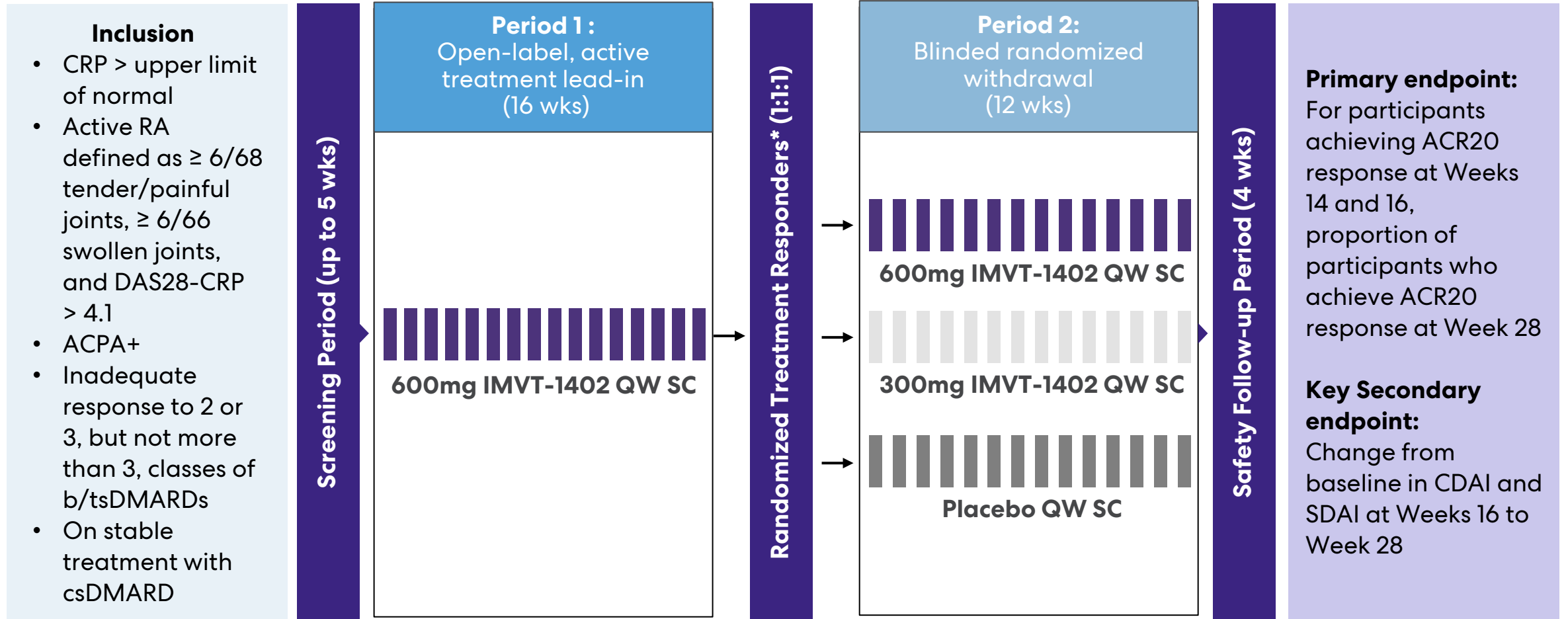
**5% - 20% of RA patients are D2T**

5% – 20% of all RA patients meet the criteria for D2T in the US<sup>6</sup>



# First Pivotal Trial for IMVT-1402 in Difficult-to-Treat Rheumatoid Arthritis

Global Trial with N=120 Participants



# IMVT-1402 Has the Potential to Achieve a Best-in-Class Profile for Patients with Difficult-to-Treat RA

## High Unmet Need Subgroup

5-20% of RA patients are difficult-to-treat (D2T) (failed at least 3 therapies)<sup>1</sup>

## Autoantibody Pathology

ACPA positive RA is associated with severe disease and poor outcomes; publicly disclosed, in-class data from another FcRn inhibitor encouraging<sup>2</sup>

## Enhanced Study Design

Open label lead-in with randomized withdrawal attractive for D2T population that is enriched for higher baseline ACPA levels

## Lower is Better

We believe deeper ACPA antibody reduction expected to correlate with improved clinical efficacy within the anti-FcRn class

## IMVT-1402 IND Active

Received FDA IND clearance, enabling planned study initiation by March 31<sup>st</sup>, 2025

# Myasthenia Gravis

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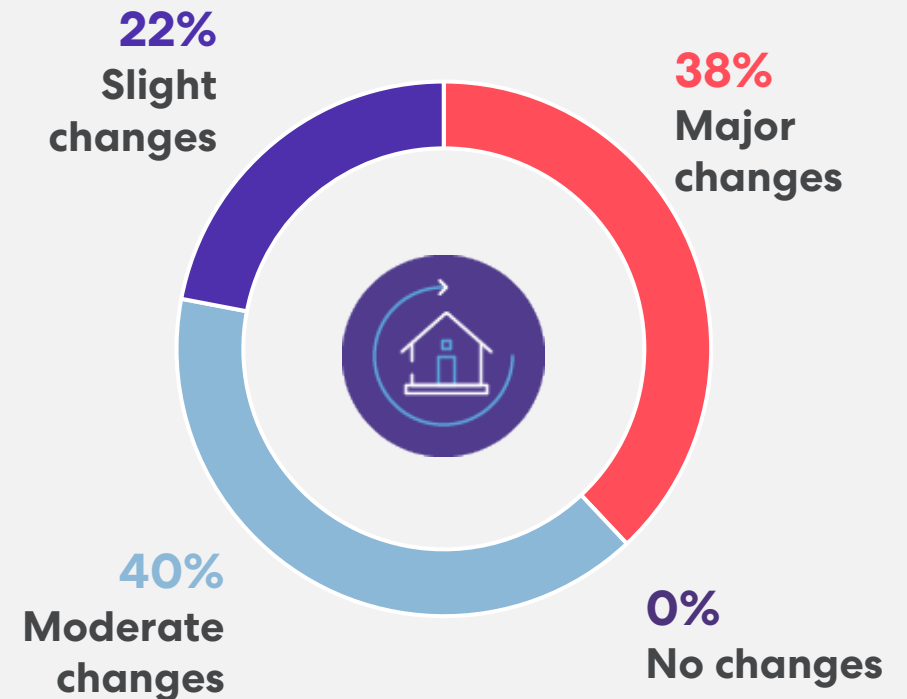
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# Myasthenia Gravis (MG): IgG-Mediated Autoimmune Disease that Typically Requires Lifestyle Changes

## Key Takeaways<sup>1</sup>

- One of the larger IgG-mediated autoimmune diseases
  - ~59,000 to 116,000 patients estimated in the US
- ~80% of patients require lifelong therapy
- Substantial share of population on steroids and first-line immunosuppressants
- Shift towards immunosuppressants and immunoglobulin therapy as disease severity increases

## Extent of Lifestyle Modifications<sup>2</sup>



# Batoclimab Phase 3 Trial Designed to Address Unmet Patient Needs

Flexible design first for a Myasthenia Gravis trial but common in immunology



## INDUCTION PHASE

### Gain control

High doses included, designed to achieve maximum efficacy at beginning of treatment



## MAINTENANCE PHASE

### Keep control

Lower dose designed to maintain efficacy with potentially fewer side effects



## LONG-TERM EXTENSION

### Optimize control

Rescue therapy available

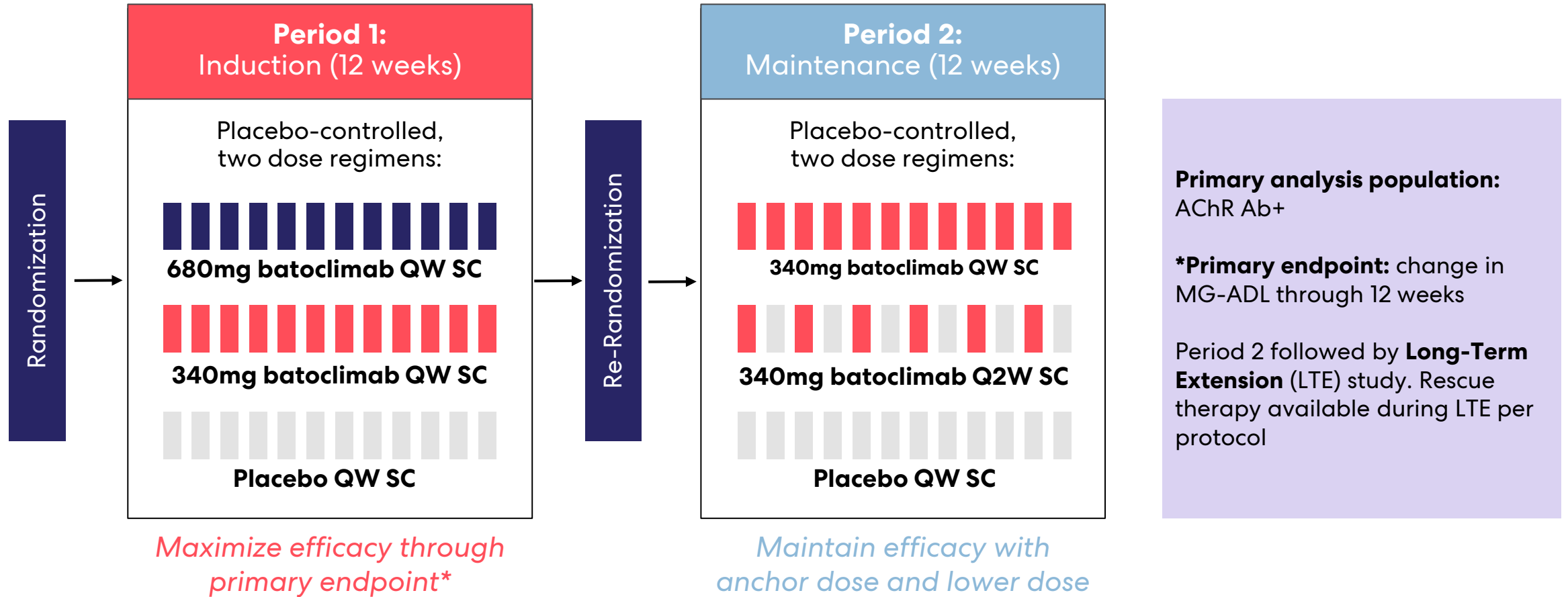


## Unmet Patient Needs

- Ease of administration
- Quick, deep response to gain initial control
- Sustainable long-term disease control
- Flexible dosing in chronic phase for disease fluctuations

# Registrational Phase 3 Trial of Batoclimab Designed to Offer MG Patients Tailored Dosing<sup>1</sup>

Batoclimab MG pivotal trial enrollment is complete; topline data and initiation of a potentially registrational program for IMVT-1402 in MG are on track for March 31, 2025



# Chronic Inflammatory Demyelinating Polyneuropathy

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# CIDP: A Complex Chronic Neurological Disease & Exciting Opportunity for Anti-FcRn Class

CIDP is an autoimmune associated with pathogenic, complement-activating IgG and IgM autoantibodies that target myelin and other neuronal proteins that affects up to 16,000<sup>1,2</sup> people in the United States

## Clinical Presentation and Unmet Need

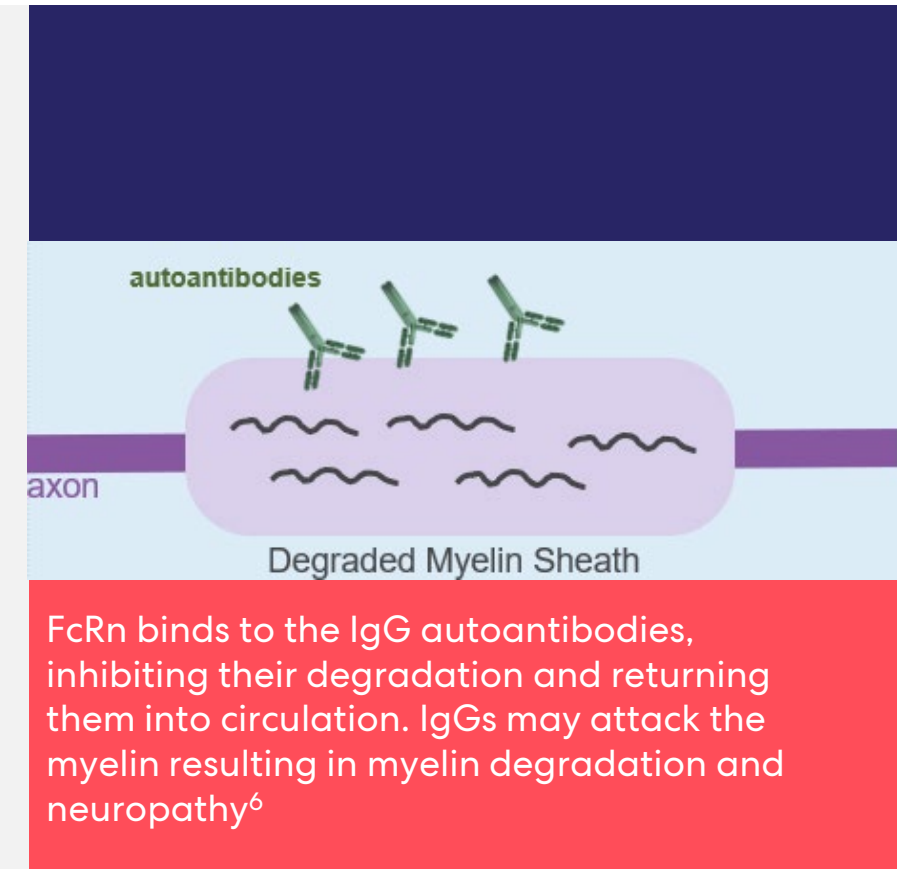
CIDP is characterized by predominant demyelination of motor and sensory nerves. Although the root cause of CIDP is unknown, significant evidence suggests that the disorder(s) are immunologically mediated<sup>3</sup>

CIDP is a progressive degenerative disease if left untreated; patients experience worsening motor weakness and sensory loss in arms and legs; some patients need walking canes or wheelchairs

Current therapies (IVIG, plasma exchange and steroids) are effective, but have significant side effects and logistical limitations (IVIG & plasma exchange)

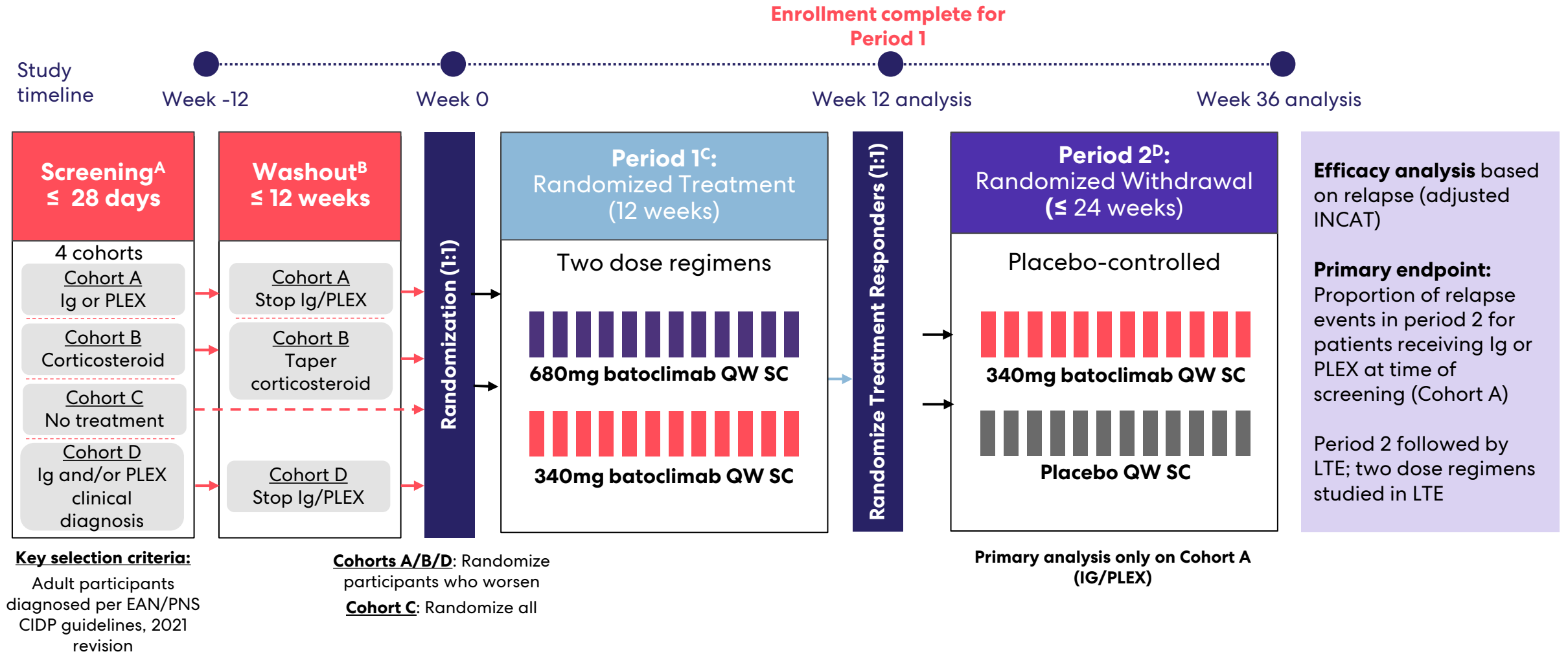
- 70% of CIDP patients require ongoing treatment<sup>4</sup>
- CIDP represents 22% of total IVIg market by volume
  - \$3B in global annual sales for IVIG in CIDP<sup>5</sup>

An effective treatment that could be administered via a simple subcutaneous injection would represent a meaningful improvement for patients with CIDP





# Batoclimab Pivotal Phase 2b Trial to Develop Potentially Best-in-Class Chronic Anti-FcRn Therapy in CIDP



# Thyroid Eye Disease

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# TED: A Heterogeneous Condition that Presents with a Variety of Clinical Symptoms

TED is a rare autoantibody mediated inflammatory disease that affects between 15,000 and 20,000<sup>1,2</sup> new patients each year in the United States

## Clinical Presentation and Unmet Need

Clinical features include eye bulging (“proptosis”), eye pain, double vision (“diplopia”) and light sensitivity<sup>4</sup>

Progressive disease marked by inflammation that can lead to fibrosis and may become sight-threatening if untreated<sup>5</sup>

Caused by IgG autoantibodies that activate cell types present in tissues surrounding the eye<sup>5</sup>

While Tepezza shows a validated US market opportunity (2021 net sales of \$1.7 billion and expected annual peak net sales over \$3 billion)<sup>6</sup>, many TED patients can benefit from a new therapy

- In a Phase 3 extension study, 44% of patients who were proptosis responders following 24 weeks of treatment were no longer responders after 48 weeks off treatment<sup>7</sup>
- Warning added to FDA label for teprotumumab on severe hearing impairment including hearing loss, which in some cases may be permanent, could enable greater market share capture by competitor<sup>8</sup>

Patients with less severe disease not yet treated with Tepezza and those with recurrent or residual symptoms may benefit from new therapies (8K-18K addressable patient population)<sup>6,9-12</sup>



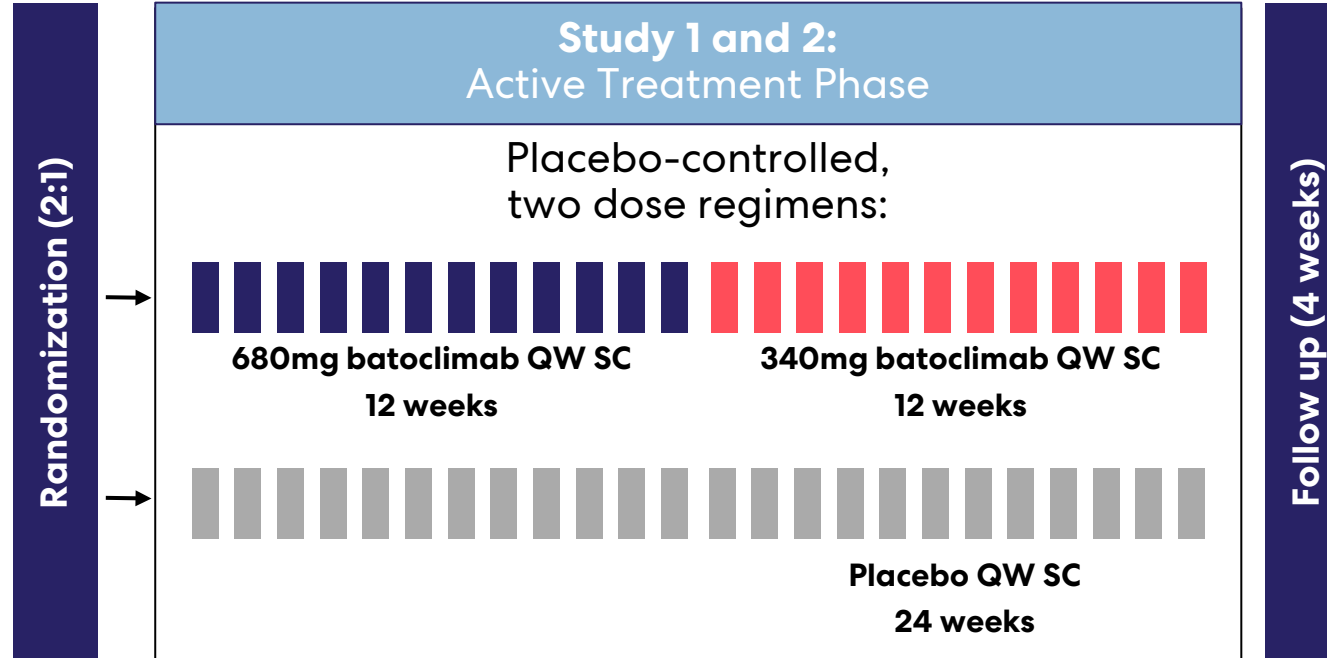
**Proptosis, eye edema and chemosis<sup>3</sup>**  
Typical complications in TED patients

# Two Phase 3 Clinical Trials of Batoclimab in TED Ongoing

Top-line data from both trials expected in the second half of 2025

## Inclusion

- Subjects with clinical diagnosis of TED (active, moderate to severe TED with a **CAS**  $\geq 4$ )
- Moderate to severe active TED (not sight-threatening but **has an appreciable impact on daily life**)
- Graves' disease as evidenced by **positive anti-TSHR-Ab titers**



## Primary endpoint:

Proptosis responders at Week 24 vs placebo where responders defined as  $\geq 2$  mm reduction from baseline in proptosis in the study eye without deterioration ( $\geq 2$  mm increase) in the fellow eye

Participants that complete the active treatment phase may enter an open-label extension study, which will evaluate the response rate and durability of response over time

# Brepocitinib

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# Oral Brepocitinib Overview

Potential multi-billion dollar rare and orphan autoimmune disease franchise with upcoming catalysts in 2025

## Six Positive Placebo-Controlled Phase 2 Studies Conducted

- Clinically meaningful efficacy demonstrated in Psoriasis, Alopecia, Psoriatic Arthritis, Ulcerative Colitis, Hidradenitis Suppurativa and Crohn's disease
- Did not meet primary endpoint in Systemic Lupus Erythematosus
- Safety in line with other JAKs

## Registrational Data in DM Expected in 2025

- **Dermatomyositis:** Large orphan indication with no NCEs approved in past 60 years and no other oral therapies in late-stage development
- Phase 3 VALOR enrollment complete, making it the largest interventional DM trial conducted to date; data expected to read out in 2H2025 and be sufficient for NDA filing

## Phase 3 Program in NIU Ongoing

- **Non-infectious uveitis:** Large orphan indication with only one approved therapy and no other oral therapies in late-stage development
- First patients enrolled in Phase 3 program in non-infectious uveitis

## Potential for Multiple Additional Large Market Orphan Indications with Rapid Path to Market

- NEPTUNE results in NIU reinforce relevance of TYK2/JAK1 inhibition for highly inflammatory indications with high morbidity
- Development plans in other indications expected to be announced in 2025

## Strong Intellectual Property Position

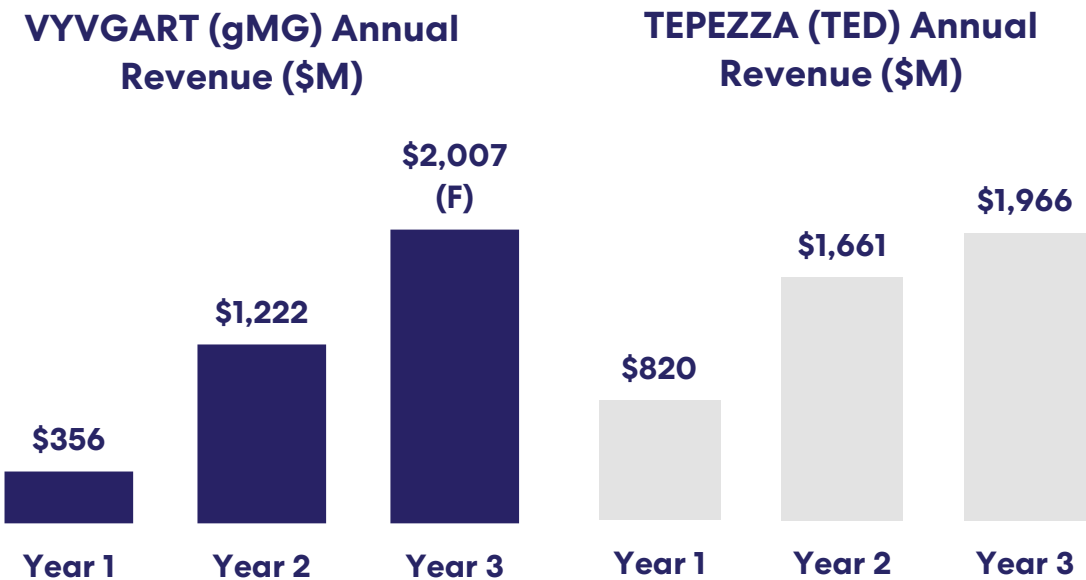
- IP protection expected until at least 2039\*

# Brepocitinib Phase 3 Programs in DM & NIU Advancing in Context of Two Broader I&I Tailwinds

Since 2020, JAK Inhibitors have quietly become one of the most successful therapeutic categories in autoimmune disease<sup>1</sup>

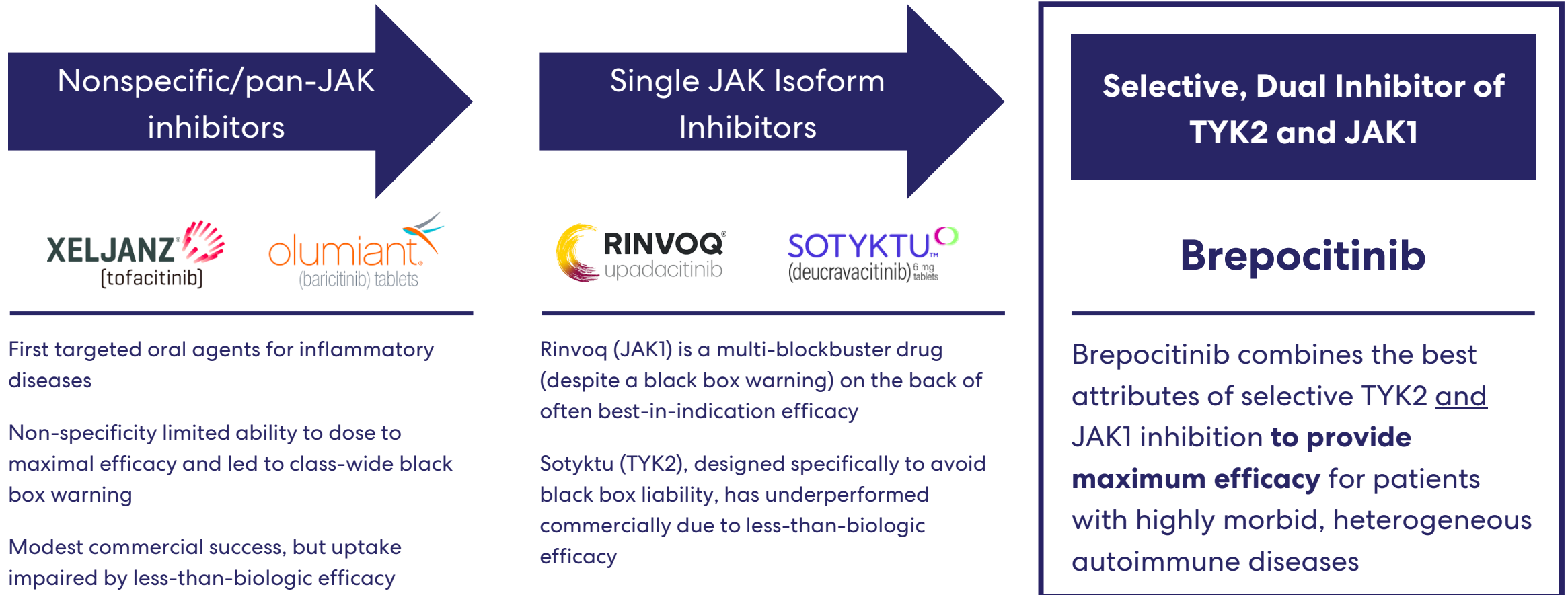
Orphan autoimmune diseases are defining a new category of blockbuster indication with rapid path to >\$1BN annual revenue

	JAK Inhibitors	
	2020	2023
Approved Indications	4	12
US Treated Patients <sup>2</sup>	~61K	~103K
US Annual Net Revenue	\$2.4BN	\$4.2BN (75% Growth)
Global Annual Net Revenue	\$3.8BN	\$6.7BN (77% Growth)



# Brepocitinib Is A Potential First-In-Class Dual Selective TYK2/JAK1 Inhibitor, Representing Next Generation of JAK Inhibition

Evolution of JAK inhibitor field highlights demand for efficacy in treating patients with the most debilitating symptoms





# Clinical Experience Suggests Oral Brepocitinib is Highly Active and Able to Generate Clinical Benefit in TYK2- and JAK1-Driven Indications

## Seven Positive Phase 2 Studies

Study Population	N <sup>1</sup>	Brepocitinib Dose	Brepocitinib Primary Endpoint Result	
<b>Alopecia Areata</b> <i>Patients with moderate-to-severe AA</i>	94 <sup>2</sup>	30 mg once daily <sup>3</sup>	49.18 placebo-adjusted CFB in SALT Score at week 24	P < 0.0001 <sup>4</sup>
<b>Psoriatic Arthritis</b> <i>Patients with active PsA</i>	218	30 mg once daily	23.4% placebo-adjusted ACR20 RR at week 16	P = 0.0197
<b>Ulcerative Colitis</b> <i>Patients with moderate-to-severe UC</i>	167	30 mg once daily	-2.28 placebo-adjusted CFB in Mayo Score at week 8	P = 0.0005
<b>Plaque Psoriasis</b> <i>Patients with moderate-to-severe PsO</i>	212	30 mg once daily	-10.1 placebo-adjusted CFB in PASI Score at week 12	P < 0.0001
<b>Hidradenitis Suppurativa</b> <i>Patients with moderate-to-severe HS</i>	100	45 mg once daily <sup>5</sup>	18.7% placebo-adjusted HiSCR Rate at week 16	P = 0.0298 <sup>4</sup>
<b>Crohn's Disease</b> <i>Patients with moderate-to-severe CD</i>	151	60 mg once daily <sup>6</sup>	21.4% placebo-adjusted SES-CD 50 Rate at week 12	P = 0.0012 <sup>4</sup>
<b>Non-infectious Uveitis</b> <i>Patients with active non-infectious intermediate-, posterior-, and panuveitis</i>	26	45 mg once daily	29.4% Treatment Failure Rate at week 24	



1. Overall study N represents patients randomized to all brepocitinib dose levels or placebo and excludes patients randomized to other agents  
 2. Includes patients from initial 24-week study period only  
 3. 60 mg QD for 4 weeks followed by 30 mg QD for 20 weeks  
 4. One-sided p-value (pre-specified statistical analysis)

5. Brepocitinib 45 mg once daily was the only brepocitinib dose evaluated in this study  
 6. Brepocitinib 60 mg once daily was the only brepocitinib dose evaluated in the induction period of this study  
 Note: CFB: change from baseline; RR: response rate  
 Note: The non-infectious uveitis study was conducted by Priovant; all other studies shown here were conducted by Pfizer

# Brepocitinib Indications

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# Dermatomyositis

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# Dermatomyositis: Key Features in Common with Recent Orphan I&I Launches that Rapidly Achieved Blockbuster Revenue



## High tens-of-thousands prevalence

Prevalence of approximately 40,000 adults in US<sup>1</sup> with approximately 35,000 patients receiving advanced chronic therapy<sup>2</sup>

## High morbidity with poor/no modern treatment options

Skin and muscle disease lead to pain, disfigurement, highly impaired mobility, and extensive comorbidities (e.g., cardiometabolic, GI, depression)

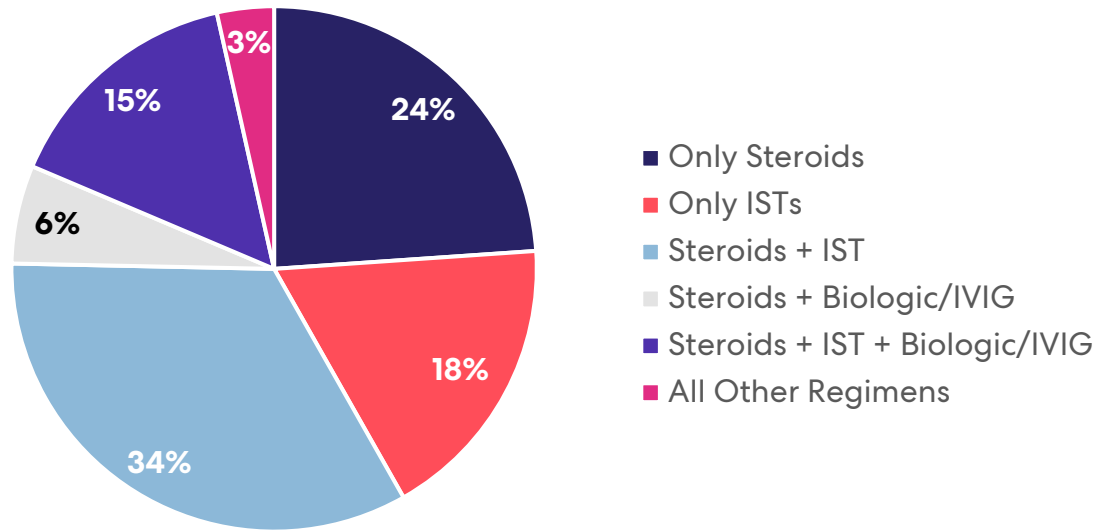
## Orphan price point and concentrated prescriber base

Approximately half of treated DM patients at ~200 tertiary centers of excellence<sup>2</sup>

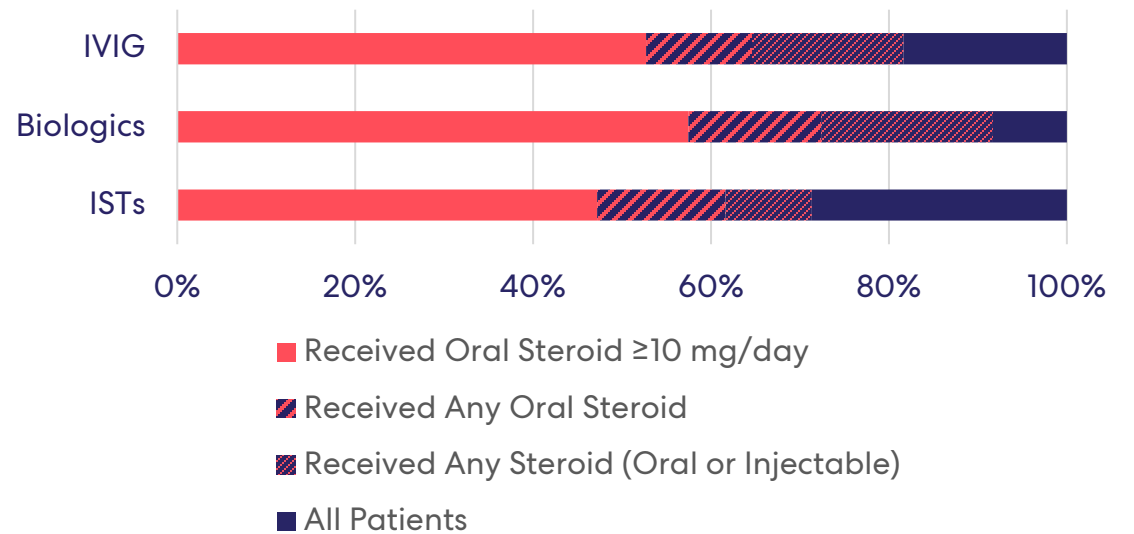
# Dermatomyositis Pharmacy Claims Highlight Widespread Polypharmacy Use And Large Steroid Burden Among DM Patients

Given limitations of current therapies, all DM patients in active treatment funnel would be potential candidates for treatment with brepocitinib if approved

**Therapies Received by ~34K Treated Dermatomyositis Patients in 2022**



**Steroid Use Among Patients Receiving Steroid-Sparing Therapy**



**Despite widespread use of multi-drug steroid-sparing therapy combinations, 62-72% of patients receiving steroid-sparing therapy still use oral corticosteroids, with most requiring doses  $\geq 10$  mg/day for  $\geq 100$  days/year**

# Strong Rationale For Brepocitinib in DM Gives Confidence in PoS With Direct To Phase 3 Approach

Dual TYK2/JAK1 Inhibition Is Particularly Well-Suited To Address Underlying DM Pathobiology

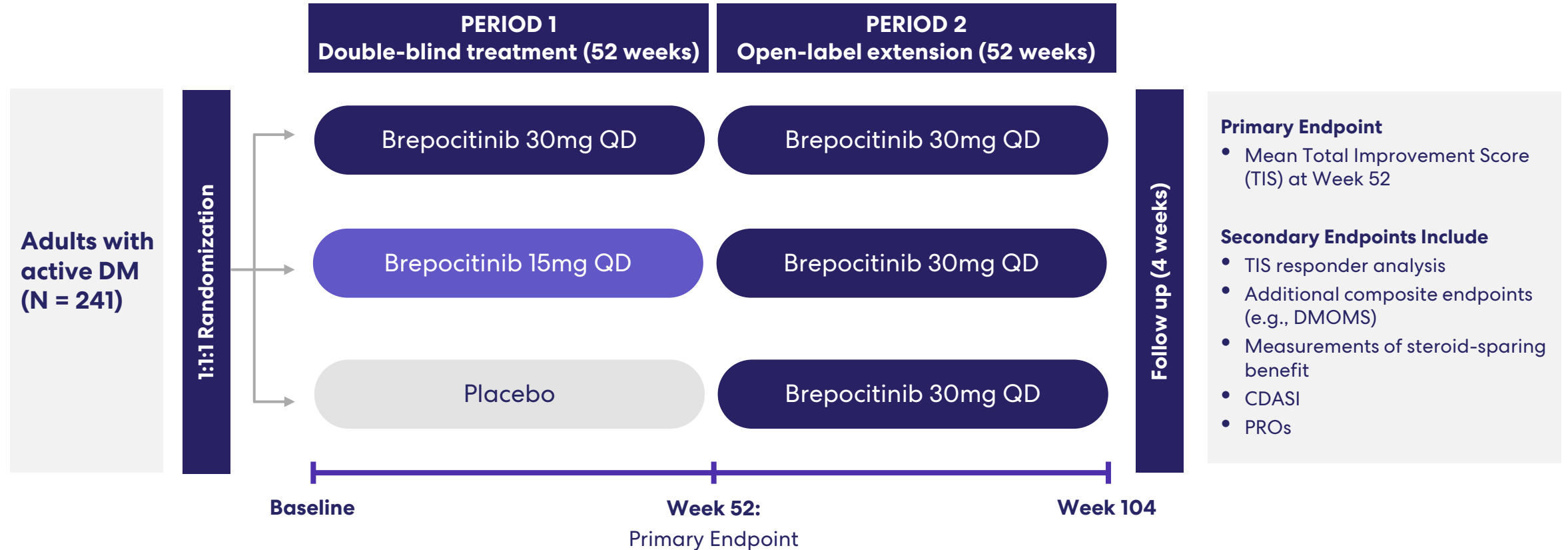
Pathogenic Cytokine	Role in DM Pathogenesis	Brepocitinib	Selective JAK1 Inhibitor	Selective TYK2 Inhibitor	Type I IFN Antibody
Type I IFN (IFN $\alpha/\beta$ )	Lymphocyte Activation	✓✓	✓	✓	✓✓
Type II IFN (IFN $\gamma$ )	Th1 Lymphocyte Polarization	✓	✓	✗	✗
IL-12		✓	✗	✓	✗
IL-6	Th17 Lymphocyte Polarization	✓✓	✓	Partial	✗
IL-23	B Cell Activation	✓	✗	✓	✗

JAK inhibition is clinically validated in DM across >600 case reports and three independent IITs (one evaluating tofacitinib (JAK1/3), one evaluating ruxolitinib (JAK1/2) & baricitinib (JAK1/2)), and another evaluating baricitinib)<sup>1-4</sup>

- Meaningful clinical benefit consistently observed on skin and muscle disease, along with reductions in muscle edema as measured by diffusion weight imaging<sup>5</sup>

# VALOR: A Single Phase 3 Study of Brepocitinib in Adults with Dermatomyositis

Pivotal study fully enrolled and topline data expected 2H 2025 → potentially next approved drug of any modality for dermatomyositis



# Non-Infectious Uveitis

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# Non-Infectious Uveitis: Key Features in Common with Recent Orphan I&I Launches that Rapidly Achieved Blockbuster Revenue



## High tens-of-thousands prevalence

Approximately 70,000-100,000 prevalent patients in the US, with >40,000 patients receiving biologic therapy<sup>1</sup>

## High morbidity and few treatment options

Fourth-leading cause of blindness among working-age population in developed world<sup>2</sup>

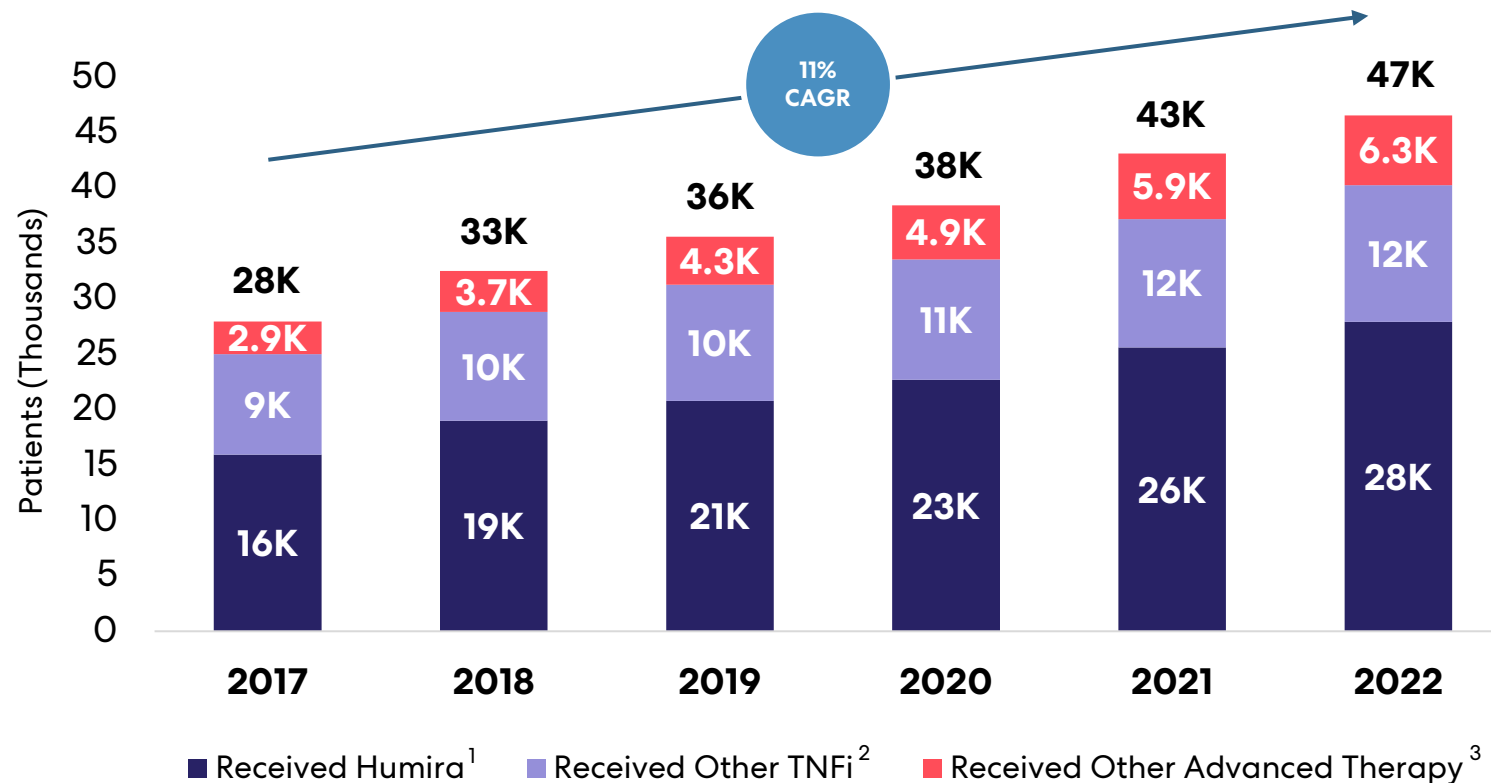
Only approved modern therapy (Humira) has limited efficacy, with >50% ultimately experiencing treatment failure<sup>3</sup>

## Orphan price point and concentrated prescriber base

High concentration of patients treated at dedicated uveitis specialty centers; most of remainder treated by retina specialists

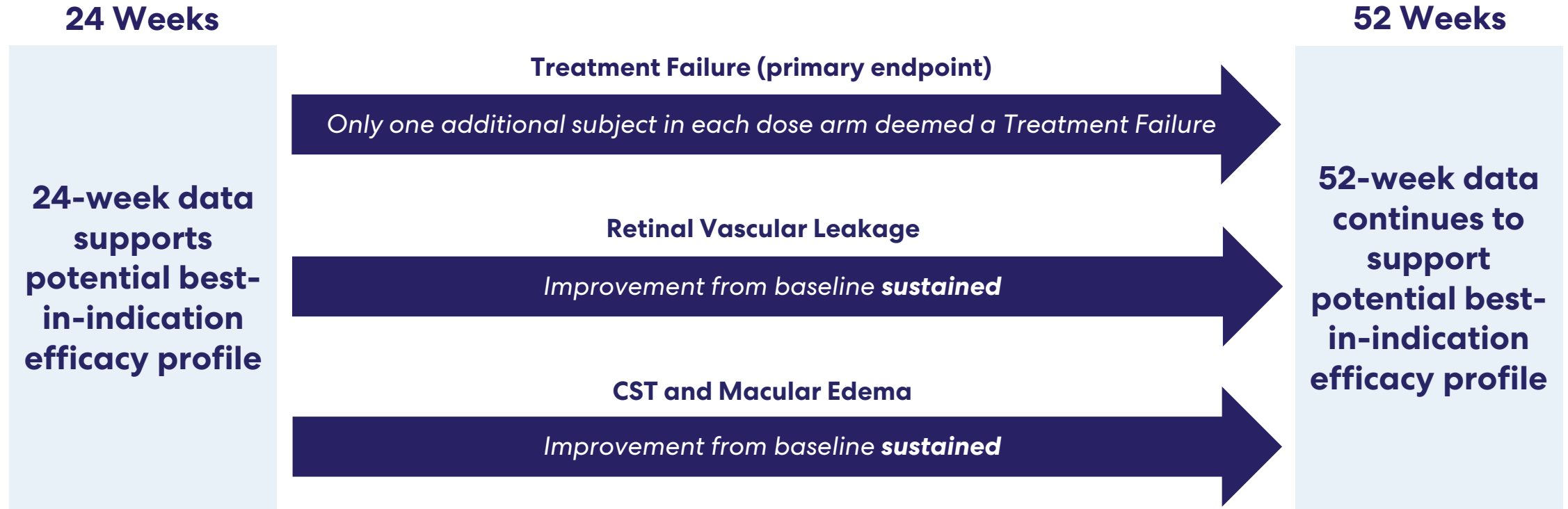
# IQVIA Analysis of the NIU Market Confirms >40,000 Patients Receiving TNFi for NIU, with >10% CAGR for Advanced Therapies

## NIU Patients Treated with Advanced Therapy by Year



- Widespread use of advanced systemic medication for NIU treatment
- Large commercial opportunity in TNF-refractory population alone, given high TNFi failure rate (>50% in clinical studies)
- Additional potential blockbuster opportunity in broader non-anterior NIU population

# 52-Week Data from the Phase 2 NEPTUNE Study of Brepocitinib in NIU Showed Potential Best-in-Indication Efficacy Sustained to One Year

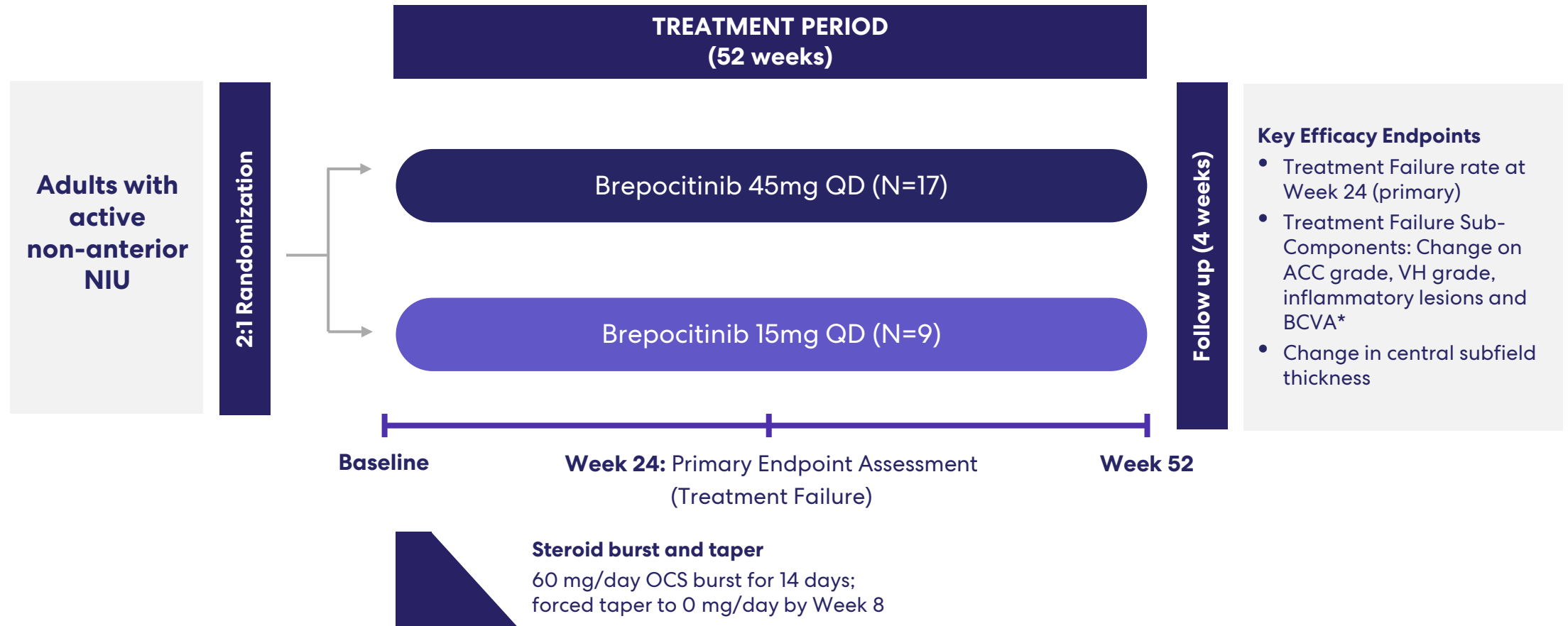


No new safety or tolerability signals at 52-weeks; brepocitinib safety database comprises >1,400 exposed subjects and patients, with safety profile that appears consistent with approved and widely prescribed JAK inhibitors

Received Fast Track Designation from FDA in NIU and began enrolling patients in the Phase 3 NIU study (CLARITY) in September 2024

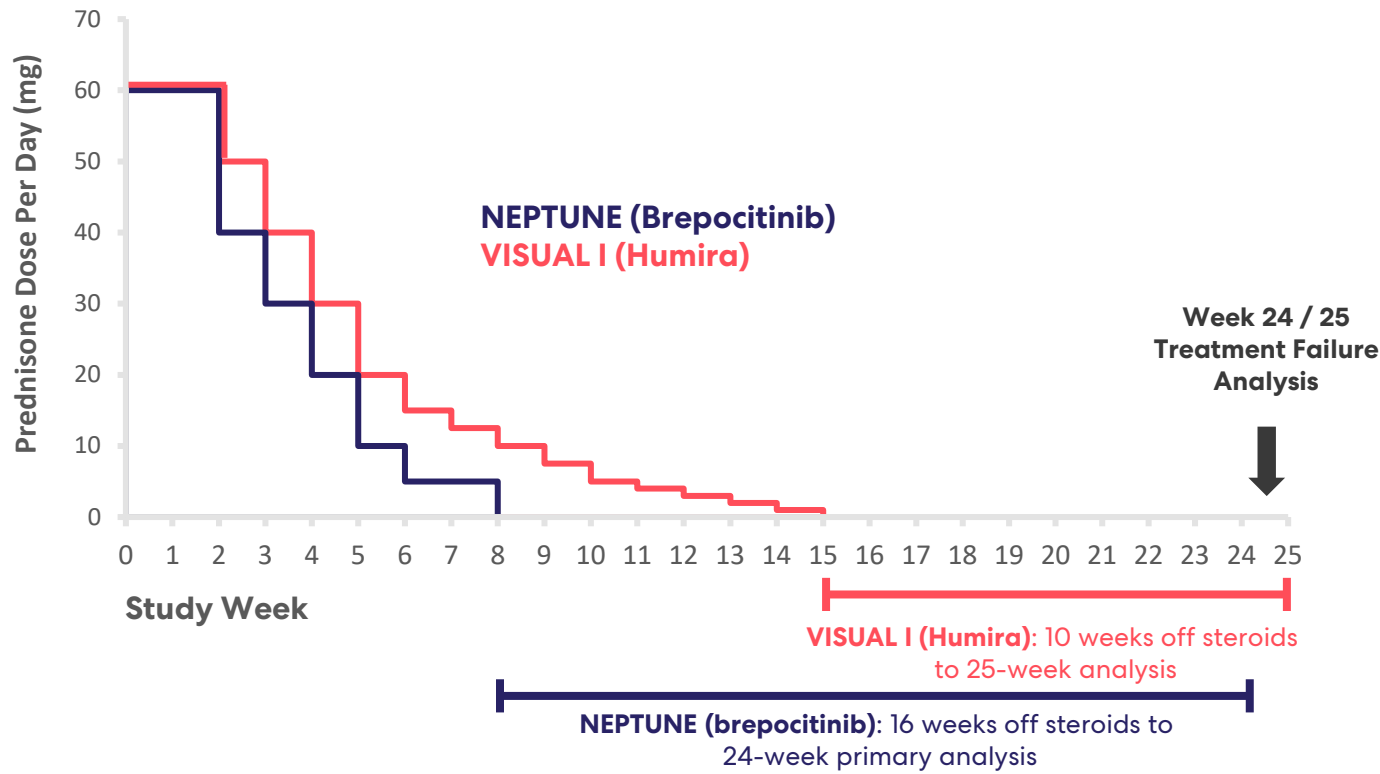
# Design Of Phase 2 NEPTUNE Study of Brepocitinib in Non-Infectious Uveitis

A Phase 2 Randomized, Double-Masked, Dose-Ranging Study to Investigate the Safety and Efficacy of Oral Brepocitinib in Adults with Active Non-Infectious Intermediate-, Posterior-, and Panuveitis



# Steroid Taper Sets Higher Bar for Brepocitinib Compared to Precedent Studies

NEPTUNE (brepocitinib) study is modeled on VISUAL I (active uveitis registrational study for Humira) with one key exception – brepocitinib steroid taper was more than twice as fast



## KEY IMPLICATIONS OF DIFFERENT TAPERS

Brepocitinib patients tapered from 60 mg/day to 0 mg/day more than twice as quickly as Humira/placebo patients in VISUAL I (6 weeks compared to 13 weeks) → **much higher risk of flares**

- Requires that brepocitinib act more quickly
- Requires brepocitinib meet higher efficacy bar to prevent flares

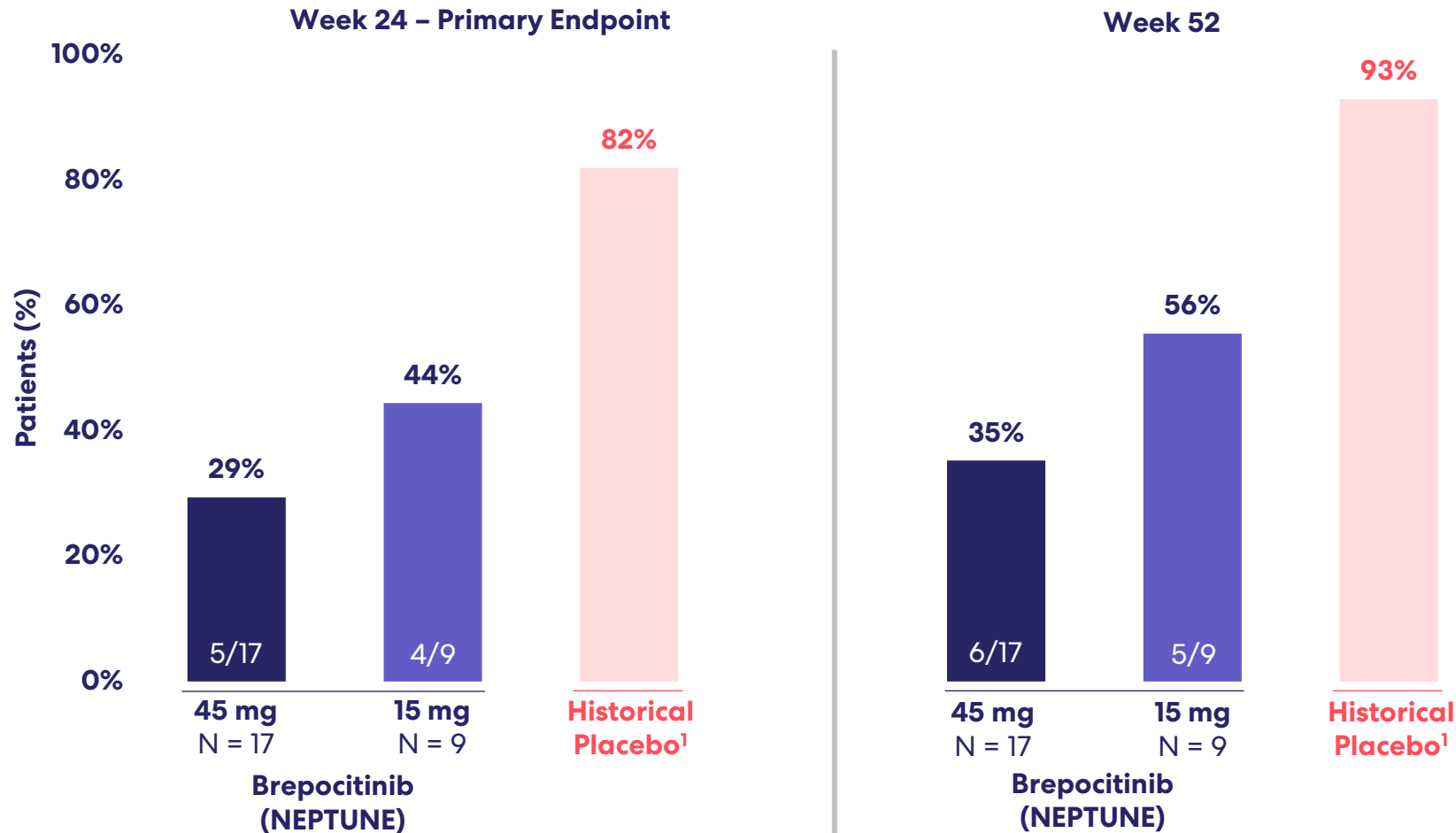
Brepocitinib had to provide steroid-free benefit for >50% longer to prevent treatment failure by week 24

- Requires that brepocitinib demonstrate more durable steroid-sparing benefit

# Phase 2 NEPTUNE Study of Brepocitinib in NIU Showed Potential Best-in-Indication Efficacy Sustained to One Year

Treatment Failure compared to historical placebo\*

Lower failure rate = greater treatment benefit



## Reminder:

Better Treatment Failure results for brepocitinib in NEPTUNE achieved despite 6-week steroid taper in NEPTUNE compared to 13-week taper in precedent studies, in both cases following two-week steroid burst

- Requires that brepocitinib act more quickly
- Increases difficulty of maintaining best state achieved
- Reduces steroid burden

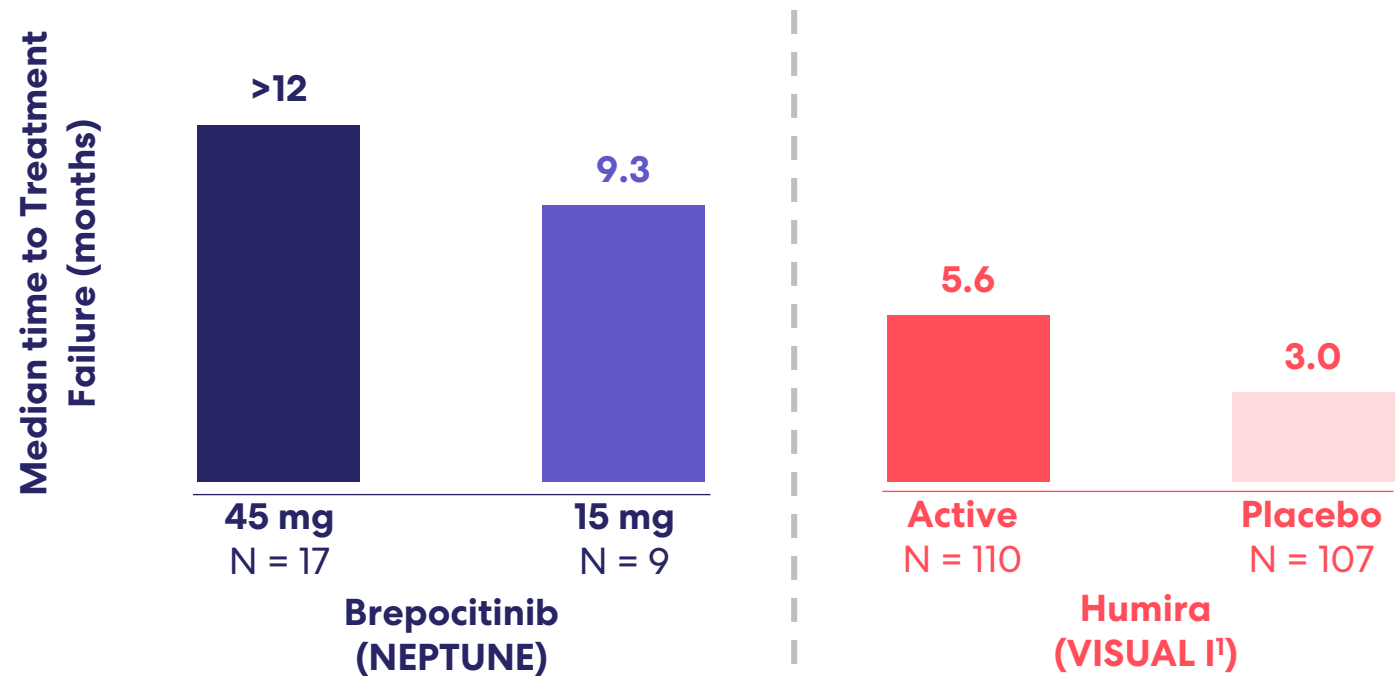
*Disclaimer:* Figure reflects cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.

\*Treatment Failure calculations include all discontinuations as failures, per pre-specified endpoint definition in NEPTUNE study  
 1. Historical placebo data from Humira VISUAL 1 study - Jaffe et al, NEJM, 2016. Placebo failure rate was calculated by subtracting the reported No. of patients remaining over the total initial placebo population from 1 at weeks 25 and 55 (n=107)

# Brepocitinib Potential Best-In-Indication Efficacy Profile Also Seen On Median Time-To-Treatment Failure

## Time to Treatment Failure, compared to VISUAL I Study\*

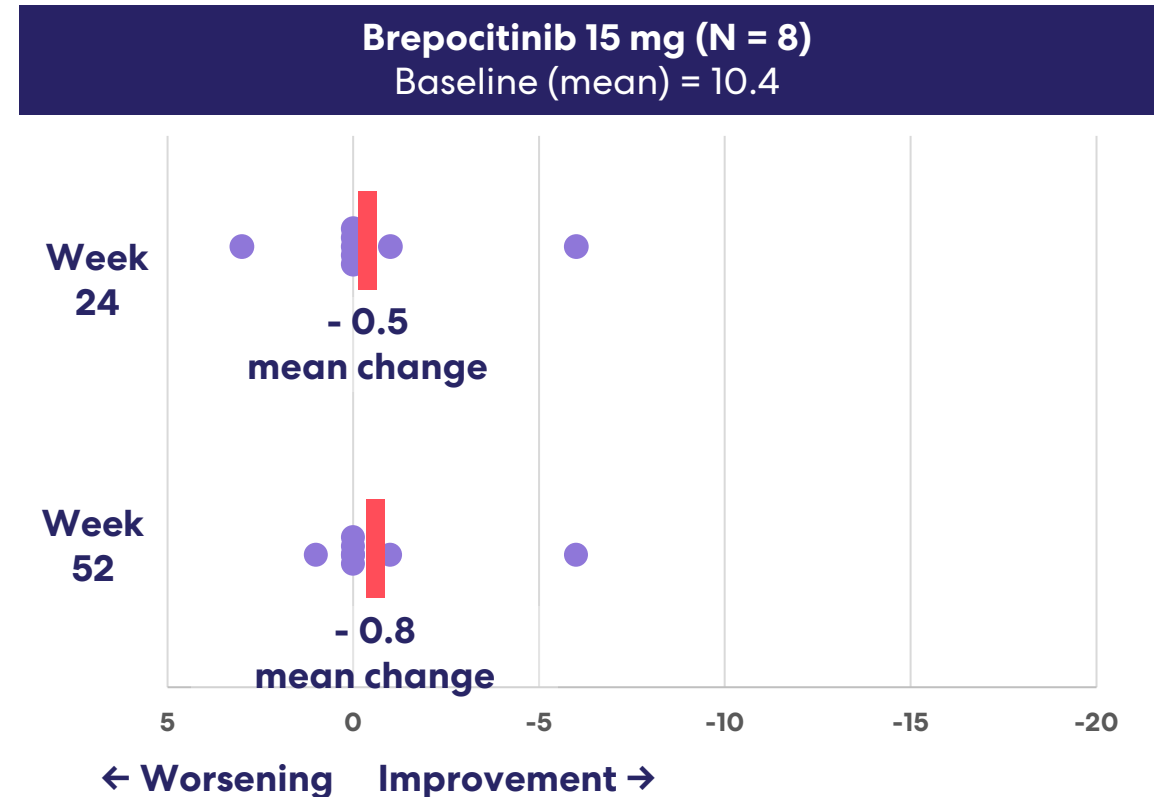
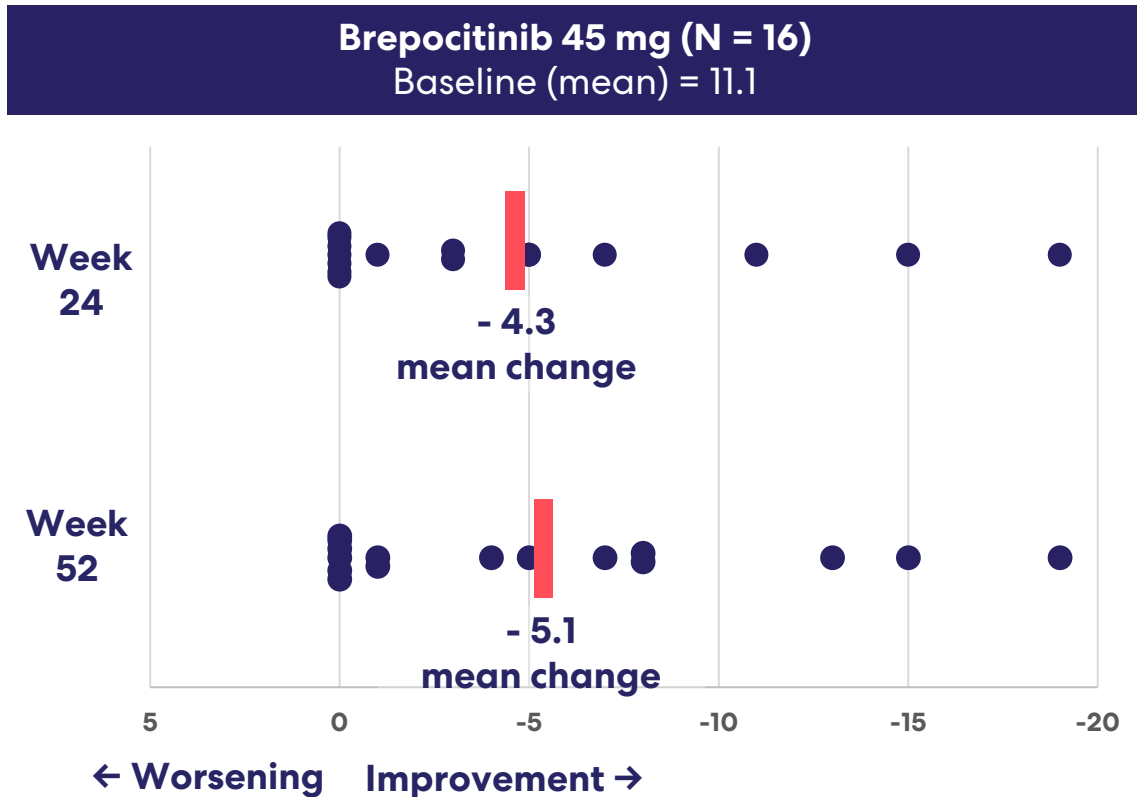
Higher time-to-treatment failure = greater treatment benefit



*Disclaimer: Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.*

# Dose Dependent Benefit on Posterior Segment Inflammation Seen, with Sustained Improvement at 52 Weeks

Measurement of retinal vascular leakage by wide-field fluorescein angiography (FA) score change from baseline at Week 24 and Week 52; centrally assessed using ASUWOG, a multi-domain, semi-quantitative scoring system<sup>1</sup>





# Potential Brepocitinib Benefit on Prevention and Treatment of Macular Edema Also Sustained to 52 Weeks

## 45 mg at Baseline

**10 patients**

did not have macular edema (CST < 300  $\mu\text{m}^1$ )

**7 patients**

had macular edema (CST  $\geq$  300  $\mu\text{m}$ )

## 45 mg at Week 24

**0 patients**

developed macular edema  
**(0% occurrence rate)**

**3 of 7 patients**

had resolution of macular edema  
**(43% resolution rate)**

## 45 mg at Week 52

**0 patients**

developed macular edema  
**(0% occurrence rate)**

**3 of 7 patients**

had resolution of macular edema  
**(43% resolution rate)**

## By comparison:

In the Humira VISUAL I study, among patients who did not have macular edema at baseline, **50% of placebo patients developed macular edema after 6.2 months**

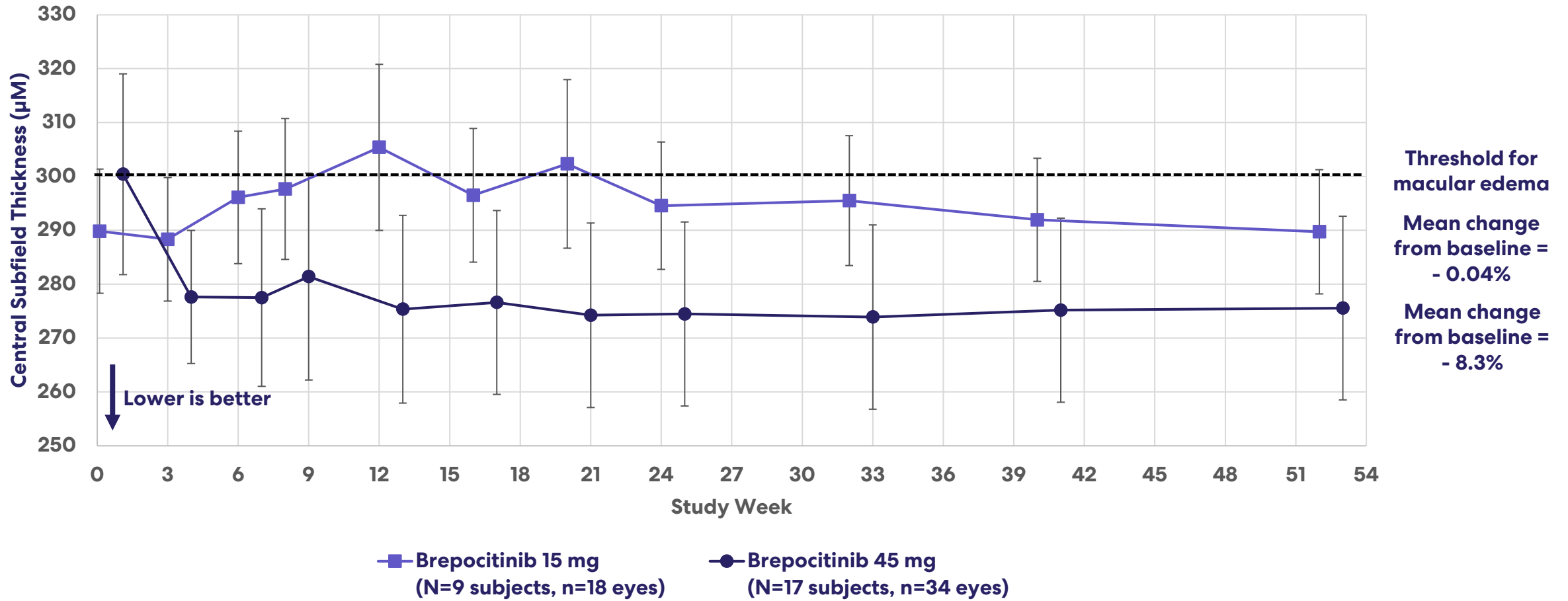
- 50% of Humira patients developed macular edema after 11.1 months<sup>2</sup>

In a different study of patients with uveitic macular edema at baseline, **Humira resolution rates at Month 6 were 22%**<sup>3</sup>

*Disclaimer: Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.*

# Brepocitinib 45 mg Associated with Sustained Improvement in Central Subfield Thickness through Week 52

Mean CST ( $\pm$  SEM) by Dose Group



# NEPTUNE Data Supports Potentially Differentiated Product Profile for Brepocitinib: Potential Early Treatment Option for Physicians Looking to Intervene Aggressively to Prevent Vision Loss

NIU treatment paradigm places premium on efficacy, given particularly high morbidity

**Aggressive Early Treatment Following Diagnosis Given Risks of Blindness**

60+ mg/day steroid burst; transition patients as quickly as possible onto chronic therapies, without causing treatment failure

**Try Multiple ISTs and Biologics With Mixed Efficacy to Treat Multiple Disease Manifestations**

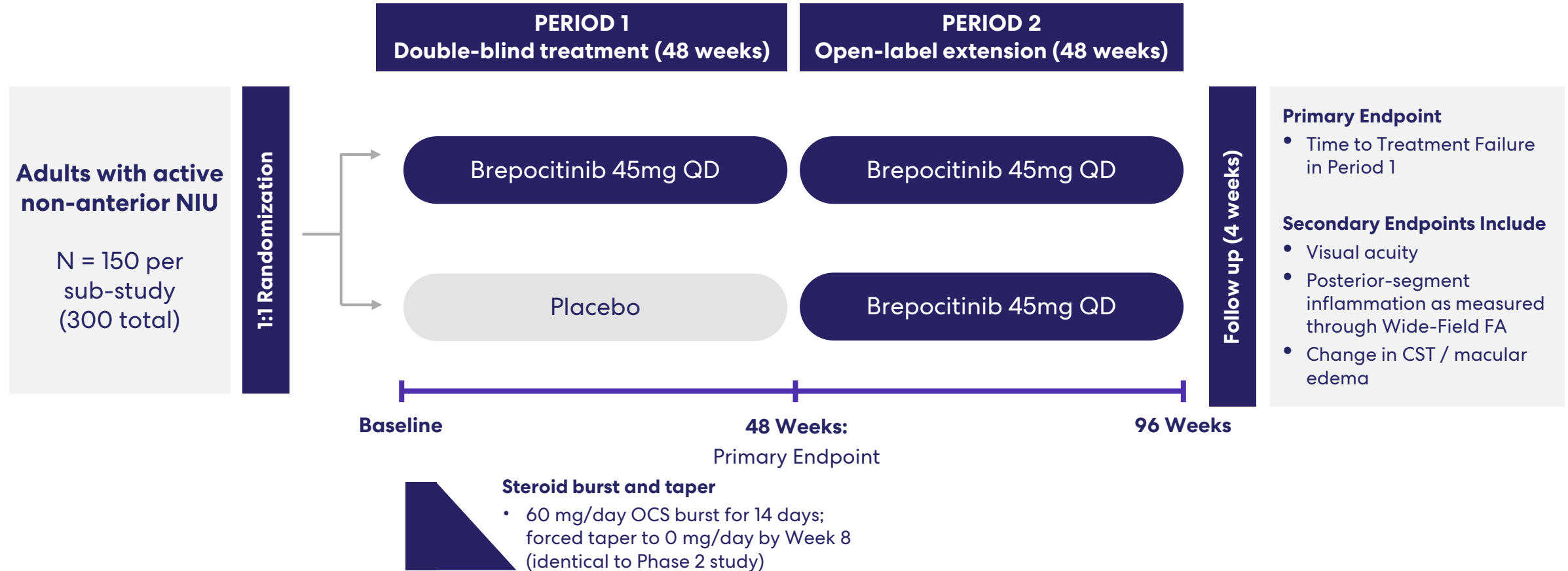
Large number of biologic-treated patients (~40,000) with high failure/relapse rate (~50%)

## NEPTUNE Data Supports Potential Brepocitinib Use Early In Treatment Paradigm And In Refractory Population

- Low treatment failure rates, even with rapid steroid taper
- Potential benefit across multiple disease manifestations: inflammation and preventing onset of macular edema
- Observed steroid-free benefit sustained over time: potential long-term quiescence

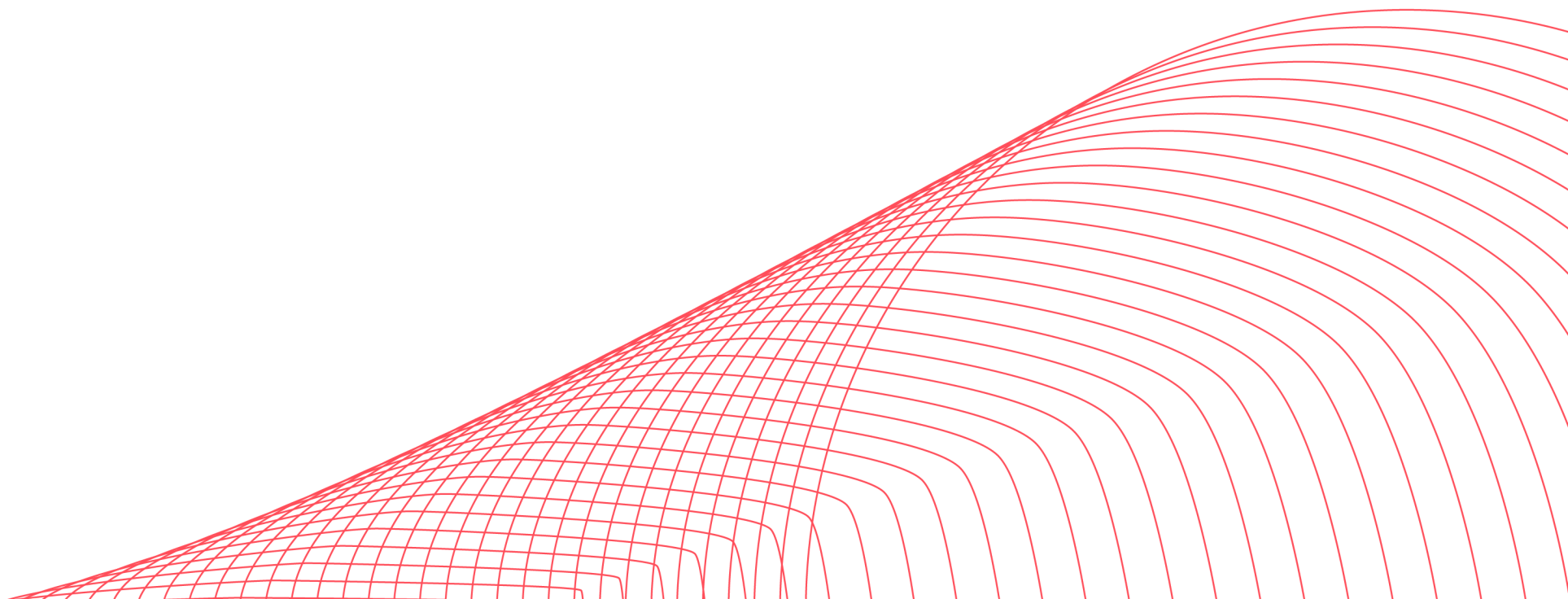
# CLARITY: A Phase 3 Study of Brepocitinib in Adults with Active, Non-Infectious, Non-Anterior Uveitis

Two identical sub-studies, CLARITY-1 and CLARITY-2, under a single protocol; very closely modeled on successful Phase 2



# Mosliciguat

roivant



# Moslicigat: Phase 2-Ready Inhaled, Once-Daily, Soluble Guanylate Cyclase (sGC) Activator with Potential to Transform Pulmonary Hypertension (PH)

## Moslicigat has Potential to be First-in-Class

- Moslicigat is an inhaled sGC activator specifically designed for lung-targeted effects
- sGC pathway activation results in vasodilatory, anti-inflammatory and anti-fibrotic effects
- Unlike sGC stimulators, moslicigat does not require heme or NO to work and retains efficacy even in conditions associated with oxidative stress

## Large and Well-Validated Market Opportunity

- Focusing initially on high unmet need in Group 3 PH, a large population with limited or no treatment options
- Initiating clinical program with a Phase 2 PHocus study in pulmonary hypertension associated with interstitial lung disease (PH-ILD) – optimized trial design and patient population will maximize probability of success

## Compelling Clinical Data in Phase 1b ATMOS study

- Some of the highest reductions to date in pulmonary vascular resistance (PVR)<sup>1</sup>
- Favorable safety profile with no clinically relevant changes seen in systemic vascular resistance or blood pressure
- Phase 1b (n=38) data, including PVR reductions, were presented at European Respiratory Society (ERS) Congress
- Robust and well-characterized program, with safety database of 170 subjects to date

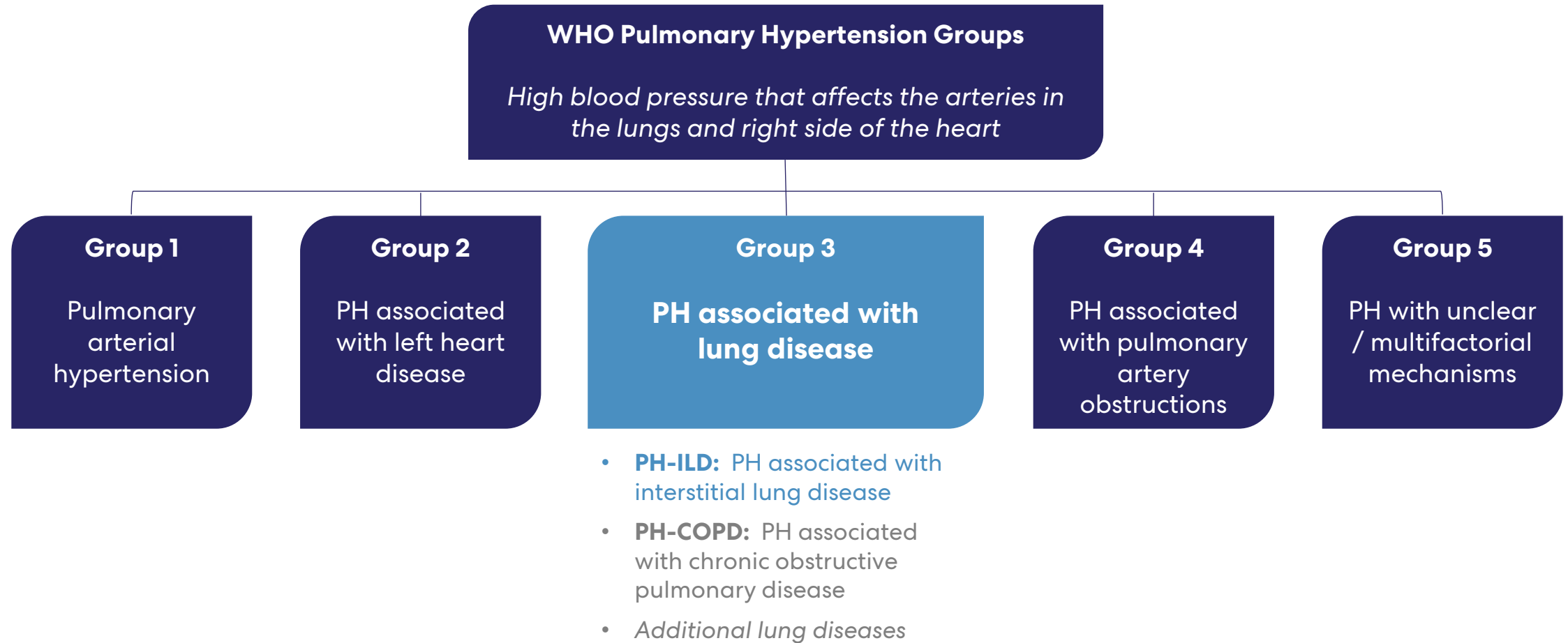
## Differentiated Dosing Profile

- ~40-hour half-life allows convenient, one puff per day dosing with a dry powder inhaler (DPI)
- Targeted delivery directly to lungs reduces risk of systemic side effects

## Favorable Transaction Structure with Strong IP

- Global rights licensed from Bayer for \$14M upfront and up to \$280M in development, regulatory, and commercial milestones, and tiered high-single digit royalties
- Granted patents and pending applications, if issued, provide protection out to 2042, before potential PTE

# Initially Focusing on Group 3, PH Associated with Lung Disease; Potential for Multiple Other PH Expansion Opportunities



# PH-ILD Patients Have Limited Treatment Options with Reduced Quality of Life and Less Than 5-Year Median Survival



**PH-ILD is a particularly severe subgroup of PH<sup>1</sup>**

- Lung disease is the second most common cause of PH<sup>1</sup>
- Structural lung changes and chronic hypoxia lead to pulmonary vascular remodeling and PH in ILDs<sup>2</sup>

*“Even if progression of ILD seems to be slowing with the antifibrotics, I am pretty aggressive with treatment given how fast they can decline when PH is present.” - Physician*



**< 5-year median survival<sup>3</sup>**

- Compared to patients with PAH, PH-ILD patients have<sup>3</sup>:
  - Increased risk of mortality & morbidity
  - Reduced functional capacity and health related QoL
- Elevations in PVR are associated with worse mortality in PH-ILD patients<sup>4</sup> – reducing PVR should improve outcomes

*“My medical problems are consuming my everyday life.” - PH-ILD patient*



**Limited or no approved treatment options**

- No approved therapies in major ex-US markets
- Only 1 approved therapy in the US, which requires 4x daily dosing and causes cough in patients whose lungs are already compromised
- Other than inhaled treprostinil, Group 1 PH drugs have generally not shown clinical benefit in patients with Group 3 PH<sup>5</sup>

*“Efficacy [of approved therapy] is not amazing ... it’s all we have, but there is definitely room to improve.” - Physician*

1. Humbert et al., European Heart Journal, 2022

2. Kacprzak et al., Diagnostics, 2023







3. Nikkho et al., Pulm Circulation, 2022; Klinger et al., Cardiol Clin., 2016; Hoepfer et al., PLoS One, 2015; Gall et al., J. Heart and Lung Transplantation, 2017

4. Olsson et al., Eur Respir. J., 2021; Alhamad et al., J Clin Med., 2020

5. Humbert et al., Eur Respir J., 2023; Dhont et al., ERJ Open Res., 2022



# PH-ILD is Even More Prevalent than PAH (~\$6BN Market) but Has Only One Approved Therapy in US and None Ex-US

	<b>PAH</b> <i>Group 1</i> <i>Idiopathic PAH or Connective-Tissue Disease Associated PAH</i>	<b>PH-ILD</b> <i>Group 3</i> <i>PH associated with interstitial lung disease</i>
<b>US &amp; EU Patient Population</b>	70 – 100k patients <sup>1</sup> 	Up to ~200k patients <sup>2</sup> 
<b>Competitive Landscape</b>	15+ approved therapies, across five drug classes 	<b>High unmet need</b> Only 1 approval in PH-ILD (US only, among major markets) 
<b>Commercial Validation<sup>4</sup></b>	Generated multiple blockbuster products 	Only approved therapy approaching \$1BN in annual US PH-ILD sales just ~3 years into launch 
<b>Market Size</b>	~\$6BN <sup>3</sup>	<b>Potentially &gt;\$6BN<sup>4</sup></b>

# Moslicigat has an Ideal Target Product Profile, with Potential to Differentiate Across All Three Key Domains – Efficacy, Convenience and Safety/Tolerability

## Efficacy

### “Big Gun”

- Group 1 PH experience shows that the ability to reduce PVR is a predictor of success
- Tyvaso Phase 3 INCREASE study in PH-ILD confirms this principle translates to Group 3 PH for inhaled therapies<sup>1</sup>
- Moslicigat is able to generate greater PVR reductions than any product to date in a single-dose setting (exceeding what many can do even with repeat dosing)

## Convenience

### One Puff per Day

- A single dose of moslicigat is able to drive sustained cGMP elevation through 24 hours, while every other approved inhaled product requires between one and twelve breaths given 4x per day
- Moslicigat is delivered via DPI, preferable to cumbersome nebulizers

## Safety / Tolerability

### Safe and Well Tolerated

- Inhaled prostacyclins carry class AEs that preclude many patients from reaching maximally effective doses and lead to significant rates of discontinuation
- sGC modulation has been shown to be safe and well tolerated when delivered as an inhaled therapy (minimizing systemic exposure)

**Moslicigat well-positioned for front-line use in PH-ILD;  
Tyvaso’s consensus ~\$1.5-\$2BN peak sales for PH-ILD sets floor for opportunity**

No head to head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Robust Phase 1 Program Demonstrates that Mosliciguat is a Potent sGC Activator with a Favorable Safety Profile

Given to 170 healthy volunteers and patients with PH<sup>1</sup>

Trial (Population)	N <sup>1</sup>	Duration	Findings
<b>SAD</b> (HVs)	62	Single dose	<ul style="list-style-type: none"> <li>Inhaled dose range of 0.06-4.0 mg well tolerated</li> <li>Dose-dependent increase in cGMP</li> </ul>
<b>MAD</b> (HVs)	27	7-day	<ul style="list-style-type: none"> <li>Inhaled dose range of 0.48-2.0 mg well tolerated</li> <li>Accumulation and dose-dependent increases in cGMP confirms <b>effective once-daily dosing</b></li> </ul>
<b>Bioavailability</b> (HVs)	26	Single dose	<ul style="list-style-type: none"> <li><b>Determined inhaled bioavailability</b></li> <li>Inhaled, oral and intravenous dosing well tolerated</li> </ul>
<b>MAD</b> (HVs)	17	14-day	<ul style="list-style-type: none"> <li>Well tolerated over 14 days</li> <li>Steady state of cGMP production <b>achieved in &lt;14 days</b></li> </ul>
<b>ATMOS</b> (Group 1 / 4 PH)	38	Single dose	<ul style="list-style-type: none"> <li>Data presented at ERS</li> <li>Primary endpoint: PVR reduction</li> </ul>
<b>Total</b>	<b>170</b>		

# sGC Modulation is Ideally Suited for Disease Modification in Pulmonary Hypertension

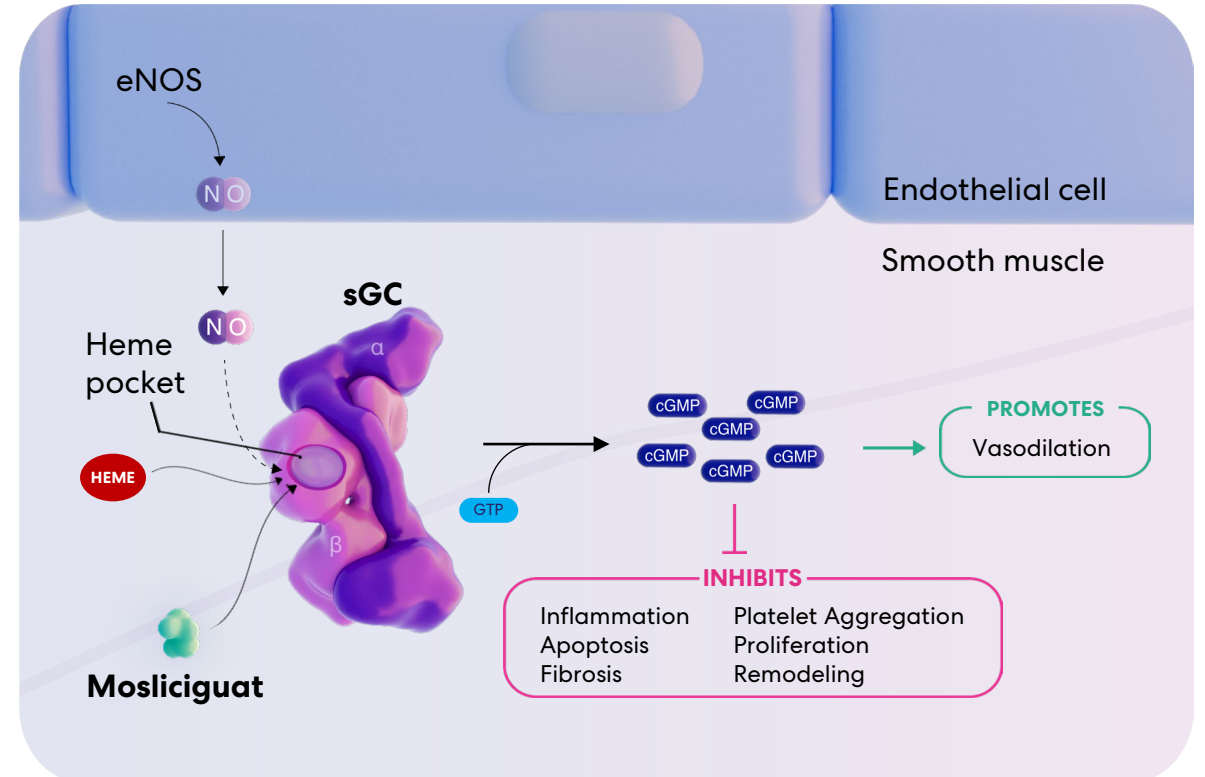
sGC is a key enzyme in the nitric oxide (NO) and cyclic guanosine monophosphate (cGMP) signaling pathway that helps maintain vascular homeostasis

sGC catalyzes conversion of GTP to cGMP, a key messenger molecule responsible for a wide variety of desirable outcomes<sup>1</sup>

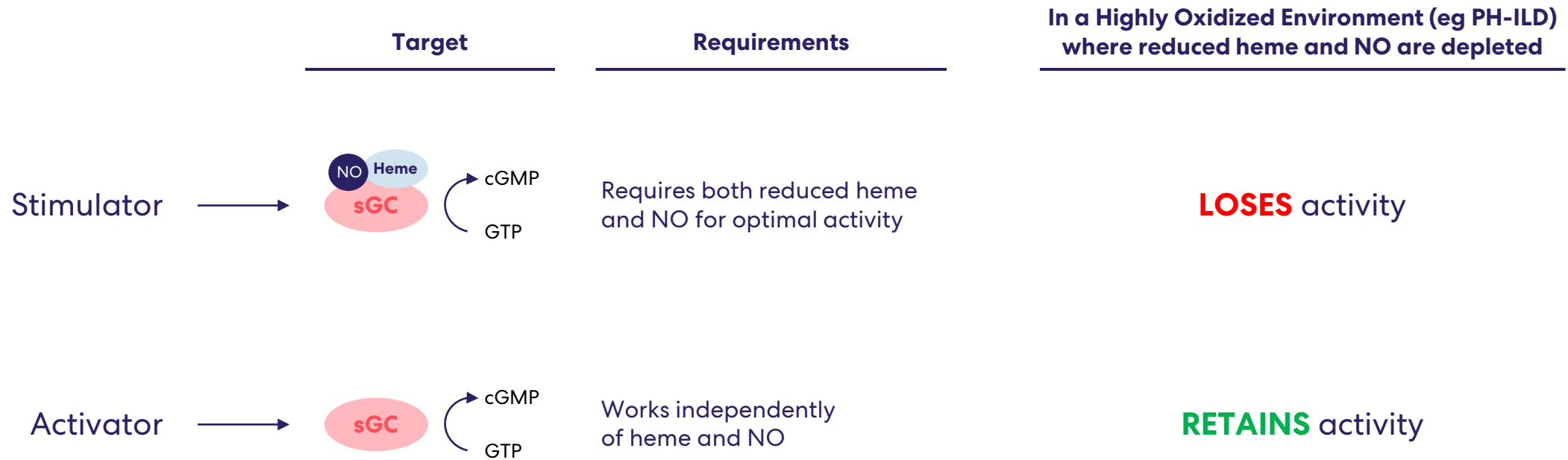
Both reduced heme and NO are required for maximal sGC activity

PH and lung disease are often associated with high oxidative stress, leading to impaired sGC activity and insufficient levels of cGMP

sGC modulation restores impaired sGC activity and recovers cGMP levels



# Mosliciguat, an sGC Activator, Should Outperform an sGC Stimulator in the Oxidative Environment of PH-ILD



Broad applicability makes mosliciguat the “go to” sGC modulator

# Mosliciguat has Shown Among the Highest PVR Reductions Ever Seen in the Single or Repeat Dose Setting

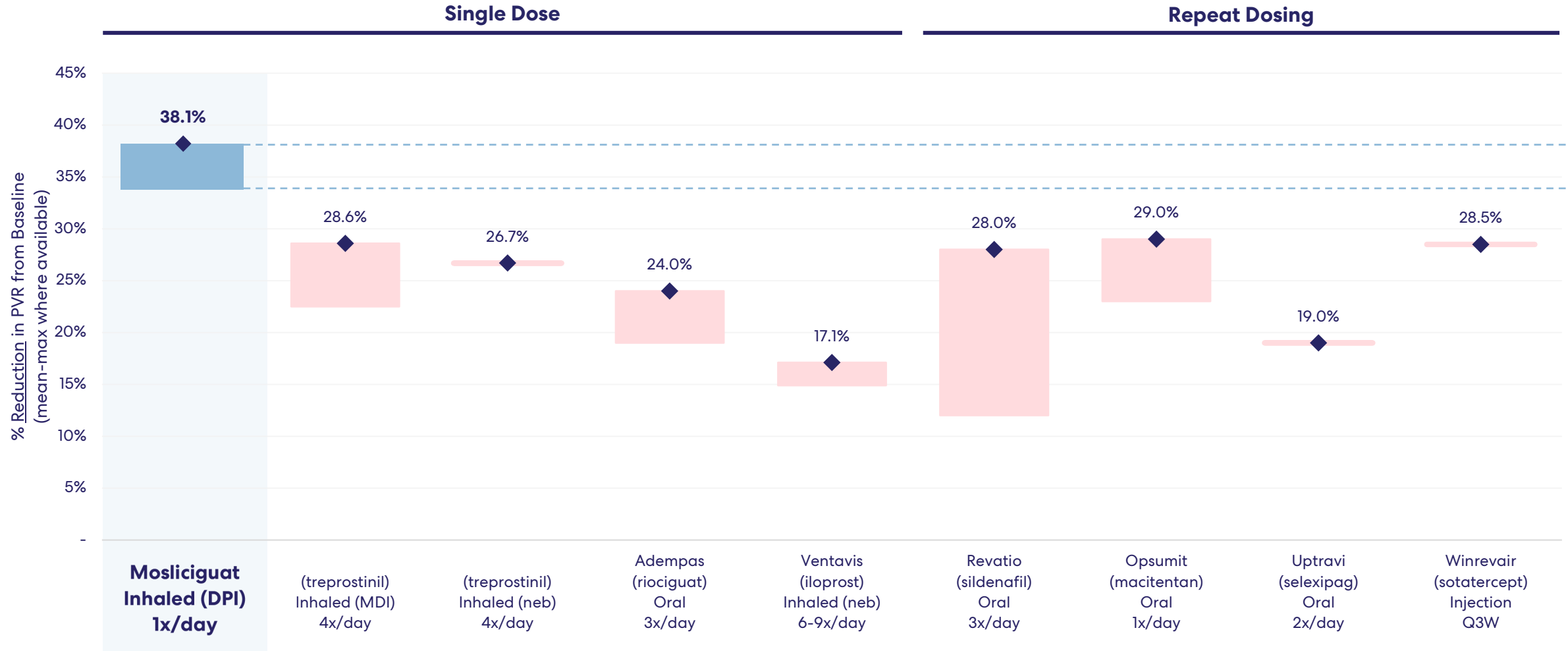
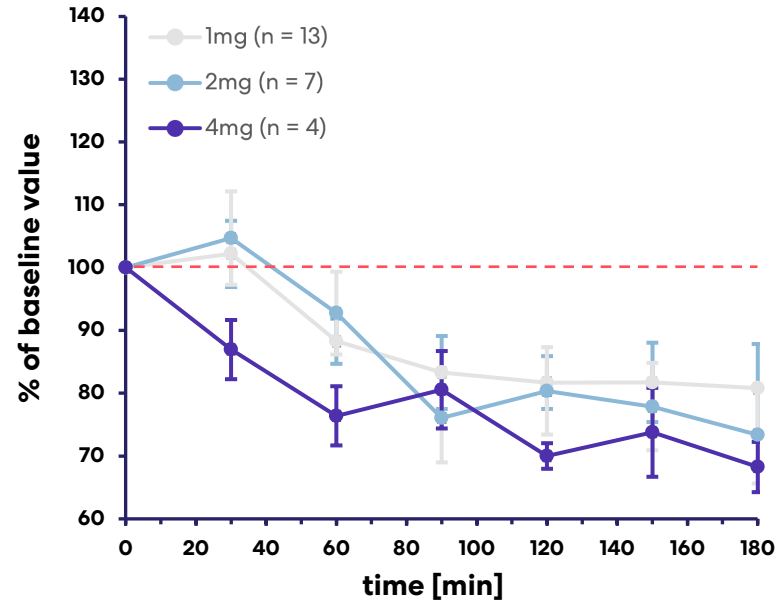


Figure represents a cross-study comparison and not a head-to-head study. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Mosliciguat Pairs Best-In-Category PVR Reductions with a Superior Dosing Profile and Formulation

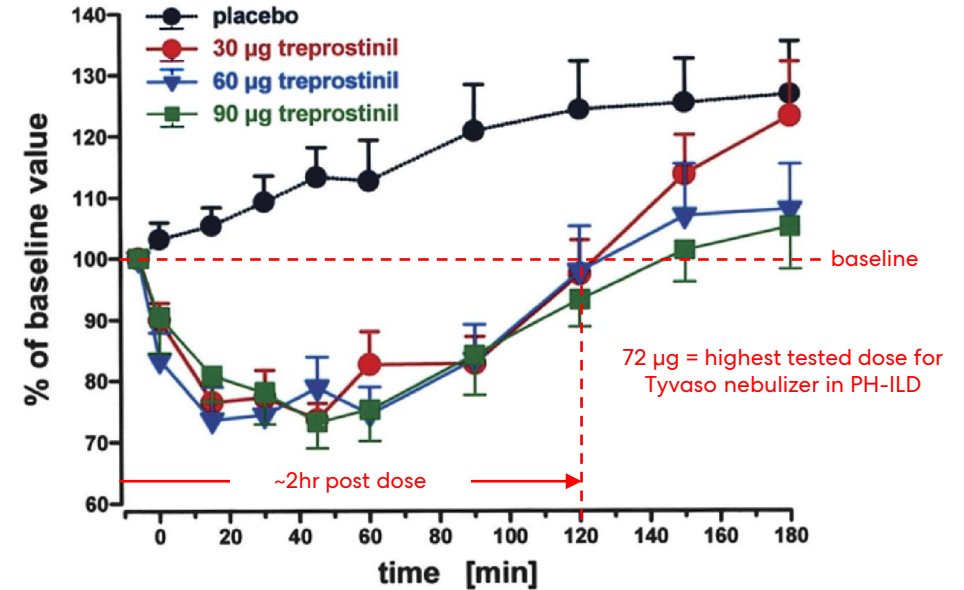
Single dose of mosliciguat has shown...



- >30% PVR reductions continue to deepen as of last time point measured (3 hours post-dose)
- $C_{max}$  at ~2-2.5 hours with extended half-life in blood of ~40+hr
- cGMP levels peak 8 hours post-dose, are sustained through 24 hours and rise with repeat dosing

**24-hour coverage allows highly convenient “one puff per day” dosing**

Single dose of inhaled treprostinil has shown...



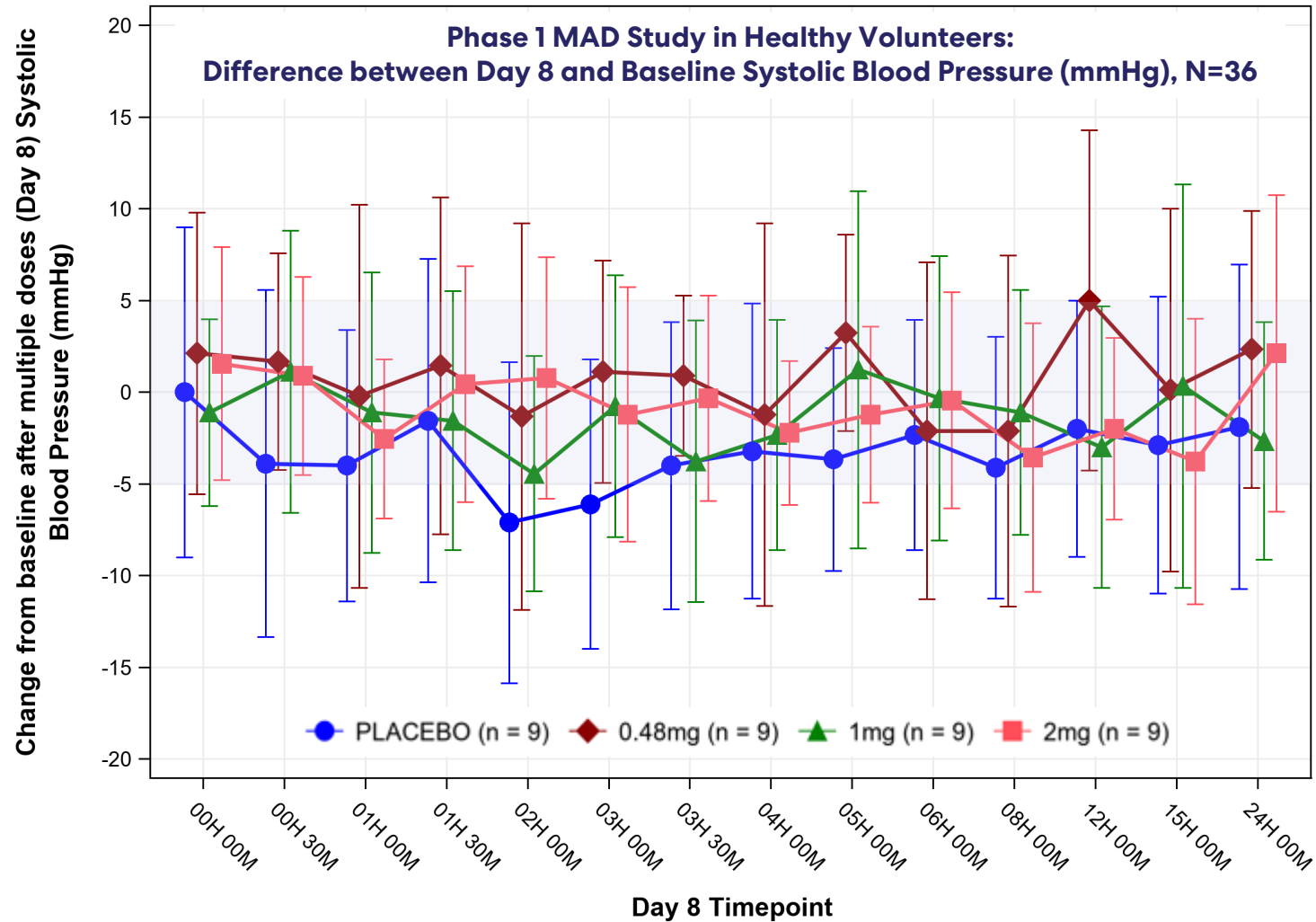
- A short half-life, leading to small window of effect: PVR back to baseline in as little as 2 hours<sup>1</sup>
- $\delta$ MWT effects are reduced at trough exposures<sup>2</sup>

**Tyvaso has 4x daily dosing, with majority of day still spent with suboptimal PVR reductions**

No head-to-head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Moslicigat's Pulmonary Vascular Benefits Appear Lung-Specific, as No Clinically Significant Changes Were Observed in Systemic Blood Pressure

No difference between day 8 and pre-dose systolic blood pressure compared to placebo with 7 days of dosing





# Safety Data Indicate All Dose Levels of Mosliciguat Were Well-Tolerated in Both Healthy Volunteers and Patients with PH

## Mosliciguat SAD/MAD and ATMOS Phase 1b Data Show Clean Safety and Tolerability Profile







- Majority of treatment emergent adverse events were mild
- Continuous dosing in healthy volunteers (HV) for 7-14 days did not reveal relevant additional events compared to single-dose experience in HV and PH patients
- No clinically significant changes to blood pressure or heart rate suggest successful minimization of systemic side effects
- All doses tolerated as inhaled dry powder without significant cough
- “One Puff per Day” dosing further mitigates risk of cough

## Tolerability Concerns for Inhaled Prostacyclins as a Class

- Inhaled prostacyclin-related AEs include high rates of cough, throat irritation, oropharyngeal pain and headache
- These AEs are likely to occur with any inhaled prostacyclin, regardless of frequency of administration or formulation
- In Tyvaso’s Phase 3 PH-ILD study (INCREASE) with 4x/day nebulizer:<sup>1</sup>
  - ~45% of Tyvaso patients had cough
  - less than half reached the top dose level (72 µg), likely due to poor tolerability
- In the INCREASE OLE, AEs led to 22% of patients discontinuing drug<sup>2</sup>

No head to head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Potential for Best-in-Category Profile with Robust Efficacy, Favorable Tolerability and Safety, and a Convenient, One Puff per Day Dosing Regimen

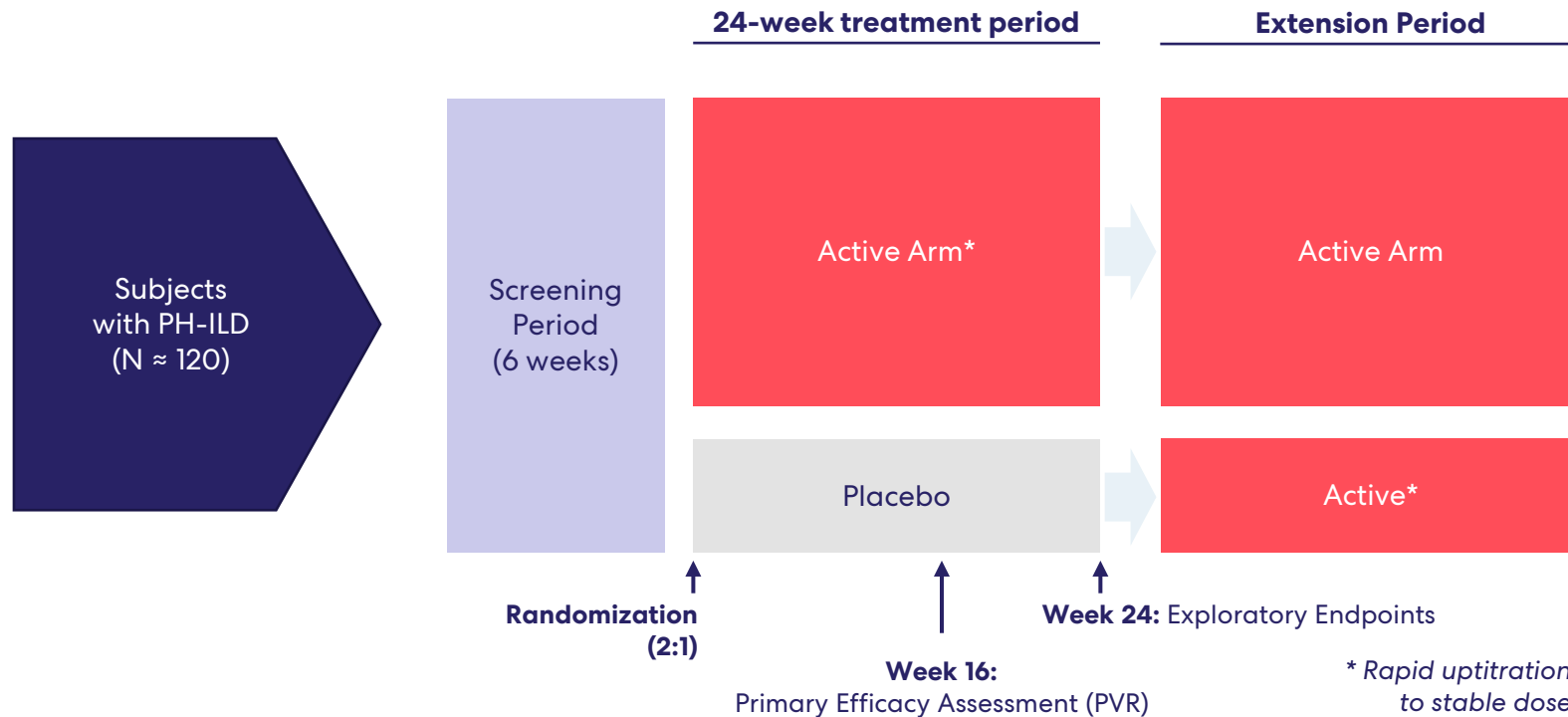
	Moslicigat	Tyvaso + Other Inhaled Prostacyclins <sup>1</sup>	Seralutinib <sup>2</sup>	MK-5475 <sup>3</sup>
<b>Company</b>		  		
<b>Group 3 PH Stage of Development</b>	Phase 2	Marketed or Pending Phase 3	Pending Phase 3	Phase 2 (in PH-COPD only)
<b>MOA</b>	sGC activator	Prostacyclin	PDGFR $\alpha/\beta$ , CSF1R and c-KIT inhibitor	sGC stimulator
<b>Administration</b>	Inhaled	Inhaled	Inhaled	Inhaled
<b>&gt;30% PVR Reductions with Once Daily Dosing</b>	✓	✗	✗	✗
<b># Inhalations / Day</b>	1	Up to 48	Up to 12	TBD
<b>Half-life</b>	~40+ hours	~0.5–9 hours	~3–6 hours	~2–3 hours
<b>Tolerability</b>	✓	✗	~	✓

No head to head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Phase 2 PHocus Study of Mosliciguat Initiated

Multi-center, global trial in ~120 PH-ILD patients

phocus



## Eligible Patients

Eligible participants diagnosed with PH-ILD

## Inclusion/Exclusion Criteria

- Confirmed ILD (IIP, CHP, ILD-CTD)
- Elevated baseline PVR
- Pre-defined extent of fibrosis and emphysema as measured by CT

## Primary Endpoint

Change from Baseline PVR

## Secondary / Exploratory Endpoints

- Change from baseline 6MWD
- Change from baseline NT-proBNP
- Time-to-clinical-worsening (TTCW) at W24
- QoL

If Phase 2 is positive, we believe a single registrational study will be sufficient for approval

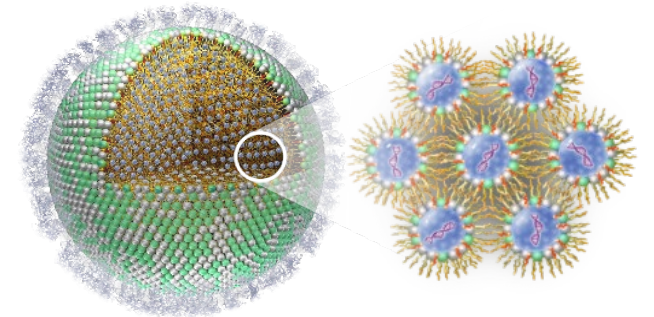
# Genevant/LNP Patent Litigation

**roivant**










A decorative graphic in the bottom right corner consisting of a grid of thin red lines. The grid is composed of vertical and horizontal lines that curve and warp as they move towards the right, creating a sense of depth and movement. The lines are evenly spaced and extend from the bottom left towards the top right of the page.

# Genevant is a Leading Nucleic Acid Delivery Solutions Company

- Genevant was formed in 2018 by Roivant and Arbutus and licensed Arbutus's LNP technology and patent portfolio
- Deep expertise in delivery systems for mRNA and other nucleic acids
- Without adequate protection, nucleic acids degrade quickly in the body before accessing their target cells – long known to be a significant obstacle to accessing their therapeutic potential
- Many years ago, a team of research scientists at an Arbutus predecessor company began to take on this challenge
  - Years of effort led to the innovative solution — tiny particles made of four carefully selected lipid types, now commonly known as **lipid nanoparticles** or **LNP**
  - Genevant's technology became the first LNP to be included in an FDA-approved RNA product in 2018, Alnylam's Onpattro® developed under LNP license from Arbutus
- LNPs are now the primary means for delivering the industry's mRNA pipeline, as well as a key delivery approach for gene editing
- Core members of the team behind the early LNPs now lead Genevant's R&D efforts, collaborating with leading companies to develop innovative nucleic acid medicines



# Genevant Collaborates with Leading Companies for Access to its LNP Technology to Develop Medicines for a Variety of Diseases and Disorders

Partner	LNP Collaborations Outside of COVID-19	Publicly Disclosed Financials*
 Takeda	Nucleic acid therapeutics directed to specified targets in HSCs to treat liver fibrosis <sup>1</sup>	Royalty rate: undisclosed Upfront & milestones: \$600M
 gritstone	Self-amplifying RNA (samRNA) for an unspecified indication <sup>2</sup>	Royalty rate: low to mid-single digits <sup>†</sup> Upfront & milestones: \$73M
 gritstone	Self-amplifying RNA (samRNA) for various infectious disease vaccines <sup>3</sup>	Royalty rate: mid to high-single digits <sup>†</sup> Option exercise fee: single-digit millions Milestones: \$136M/product
 gritstone	Self-amplifying RNA (samRNA) COVID-19 vaccine program <sup>4</sup>	Royalty rate: mid-single to mid-double digits <sup>†</sup> Upfront & milestones: \$192M/product
 BIONTECH	mRNA for a specified number of oncology targets; co-dev in up to five rare diseases <sup>5</sup>	Milestones and royalties (amounts undisclosed); 50:50 on co-development programs
 KORRO BIO	RNA editing therapy for Alpha-1 Antitrypsin Deficiency (AATD) <sup>6</sup>	Royalty rate: mid-single digits <sup>6</sup> Upfront & milestones: \$100M
 novo nordisk	Gene editing therapy for hemophilia A <sup>8</sup>	Royalty rate: mid-single digits <sup>†</sup> Upfront & near-term option: \$10M + milestones
 Repair Biotechnologies	mRNA Cholesterol Degrading Platform (CDP) for atherosclerosis <sup>9</sup>	Total deal value: \$107M Royalty rate: mid-high single digits
 editas MEDICINE	Gene editing therapy (CRISPR Cas12a) for two undisclosed targets <sup>10</sup>	Total deal value: \$238M Royalty rate: undisclosed

\*Includes publicly disclosed terms only and therefore does not reflect all payments that may be applicable and received by Genevant (e.g., reimbursements for FTE support, field expansion fees, etc.). All potential payments are contingent upon achievement of specified milestones

†Depending on the circumstances

Note: All trademarks are property of their respective owners

- Genevant press release, March 15, 2021
- Gritstone Oncology 8-K, October 20, 2020
- Gritstone press release, August 15, 2023
- Genevant and Gritstone joint press release, January 20, 2021

5. BioNTech Form F-1, July 21, 2020

6. Genevant and Korro Bio joint press release, March 7, 2023

7. Korro Bio S-1/A SEC Filing, December 20, 2023

8. Genevant press release, November 6, 2023. Agreement arose from the exercise of an option under agreement between Genevant and 2seventy bio and later assigned by 2seventy bio to Novo Nordisk.

9. Genevant press release, September 26, 2024

10. Genevant press release, October 21, 2024

# Updates on Genevant IP Litigation

## Moderna

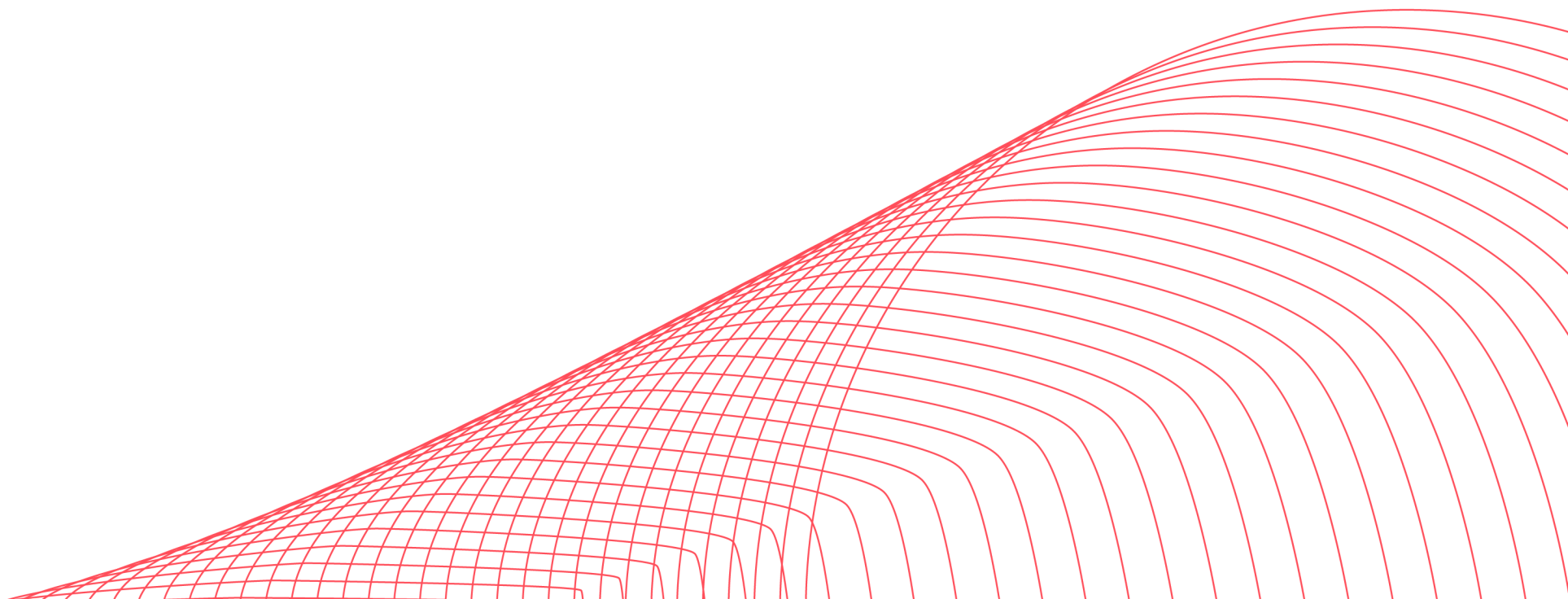
- In February 2022, Genevant and Arbutus jointly filed a complaint against Moderna in the U.S. District Court for the District of Delaware asserting infringement of six patents
- In November 2022, the Court issued an opinion and order denying Moderna's partial motion to dismiss the suit based on the government-contractor defense under 28 U.S.C 1498 (Section 1498), which was an attempt by Moderna to shift liability for an unspecified portion of its alleged infringement to the US government and taxpayers
- In February 2023, the United States Government filed a Statement of Interest urging the Court to rule that Section 1498 does apply to Moderna's first vaccine contract with the Government to shield Moderna from liability for patent infringement related to that contract and require that infringement claims based on that contract be brought against the Government in the Federal Court of Claims
- In March 2023, the Court reaffirmed the analysis and conclusions in its November 2022 opinion and order and its denial of Moderna's partial motion to dismiss
- In February 2024, the Court in the Moderna case held a Markman hearing to construe four disputed terms within the claims of the asserted patents
- On April 3, 2024, the Court issued its Markman ruling, in which it agreed with Genevant and Arbutus' proposed constructions for three of the four disputed terms
- Summary judgment phase expected 2Q-3Q 2025. Trial is scheduled for September 2025

## Pfizer

- In April 2023, Genevant and Arbutus jointly filed a complaint against Pfizer and BioNTech in the U.S. District Court for the District of New Jersey asserting infringement of five patents; discovery is ongoing
- The Court in the Pfizer case has scheduled a Markman hearing for December 2024



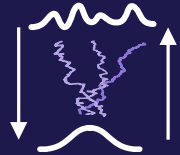
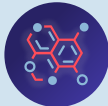



**VantAI**

**roivant**





# VANTAI | Continued Progress at VantAI Underscores Unique Opportunity

 <p>Proximity Modulators</p>	 <p>Pre-clinical milestones hit <b>on every major collaboration</b> with \$3.6B+ in total potential upside<sup>1</sup></p>
 <p>Generative AI</p>	 <p><b>Predict and engineer protein surfaces</b> to modify <b>protein-protein interactions</b> with proprietary data and world-class AI team</p>  <p>Enable development of <b>proximity modulators</b>, with focus on <b>rational molecular glue design</b></p>
 <p>Structural Proteomics</p>	 <p>Unprecedented <b>proprietary data moat</b>, perfectly matched to unlock Proximity Modulation at scale with AI</p>

## Select recent milestones



Entered into collaboration to **accelerate molecular glue drug discovery with generative AI. Eligible to receive up to \$674M** in discovery, development, clinical, regulatory, and sales milestone payments plus tiered royalties from BMS



Expanded partnership on **heterobifunctionals and molecular glues with \$1.25B potential upside**



World-leading SAB with Ian Churcher, Bradley Pentelute, Fan Liu, Bruno Correia and Philippe Schwaller

1. All partnerships where work began prior to February 2024

Thank you.

roivant

