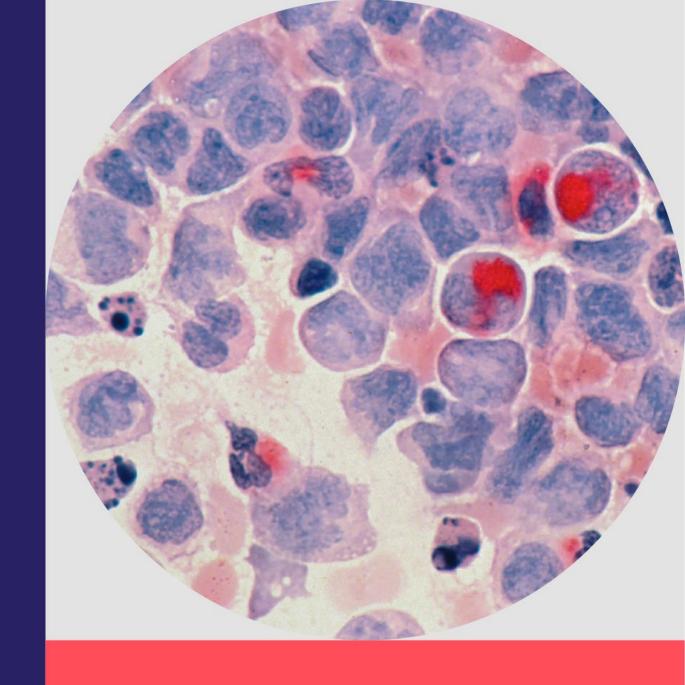
# Roivant Overview

April 2024



roivant

### **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 and conduct of our ongoing and planned preclinical studies and clinical trials for our products and product candidates, including the information presented in this presentation with respect to (i) the ADORING 1, ADORING 2 and ADORING 3 topline study results, (ii) initial data from a Phase 1 trial of IMVT-1402 and the potential for IMVT-1402 to be best-inclass with respect to IgG lowering and with respect to albumin and LDL impact and (iii) the NEPTUNE topline study results and any commercial potential of our 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. The ADORING 1, ADORING 2, ADORING 3, and NEPTUNE topline study results presented here are based on an initial analysis of key efficacy and safety data and such data may not accurately reflect the complete results of the ADORING 1, ADORING 2, ADORING 3, and NEPTUNE studies.

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 <a href="https://www.sec.gov">www.sec.gov</a> and 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 certain of our products or product candidates, including VTAMA, IMVT-1402, and brepocitinib as compared to certain other products and product candidates generated from separate, independent studies and that do not come from head-to-head analysis. Differences exist between study or trial designs and subject characteristics and caution should be exercised when comparing data across studies. Data regarding other products and product candidates is based on publicly available information.

VTAMA cream is only FDA-approved for the topical treatment of plaque psoriasis in adults but is under clinical investigation for the treatment of atopic dermatitis in adults and children aged two (2) years old and above.

#### **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.



### Roivant: Developing and Commercializing Transformative Medicines



**Vant model** aligns incentives to drive fast, high-quality execution and rigorous capital allocation



Proven track record with 10 consecutive positive Phase 3 trials and 6 FDA approvals<sup>1</sup>



Consolidated cash, cash equivalents and restricted cash of \$6.7BN at December 31, 2023



Capital infusion leaves company in position of strength to **expand our pipeline**, **as well as pursue additional investments and potentially return capital to shareholders** 

### 2024 Will Be a Year of Expansion for Roivant



Deliver Clinical Data for Leading Anti-FcRn Franchise and Announce Development Plans for 1402

Anticipate that deeper IgG suppression may lead to greater efficacy across multiple indications with readouts for batoclimab in CIDP and MG



Advance Clinical
Development In a
Range of
Underappreciated
Pipeline Opportunities

Expect clinical trial readouts for brepocitinib and namilumab to inform portfolio expansion decisions



File VTAMA sNDA in AD & Accelerate PsO Revenue Growth

sNDA submitted; accelerate PsO revenue growth through script expansion and GTN yield accretion



Expand Pipeline
Through Mid-LateStage Business
Development

Bolster pipeline through creative, win-win deals with partners, enabled by execution track record and strong balance sheet



Finalize Capital
Allocation Strategy
Across Best Value
Creation
Opportunities

Plan to be prudent and thoughtful; will prioritize optimizing shareholder base for next era of Roivant growth

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

Exciting late-stage pipeline with 6 ongoing registrational trials in multi-billion dollar markets and 4-5 additional potentially registrational programs with IMVT-1402 expected by March 2025

		Modality	Preclinical	Phase 1	Phase 2	Phase 3	Approved
8	VTAMA Psoriasis   Dermavant	Topical					<b>&gt;</b>
8	VTAMA Atopic Dermatitis   Dermavant	Topical				sNDA Submitted	
Y	BATOCLIMAB Myasthenia Gravis   Immunovant	Biologic				<b>&gt;</b>	
W	BATOCLIMAB Thyroid Eye Disease   Immunovant	Biologic				•	
W	BATOCLIMAB Chronic Inflammatory Demyelinating Polyneuropathy   Immunovant	Biologic			<b>&gt;</b>		
Y	BATOCLIMAB Graves' Disease   Immunovant	Biologic			<b>&gt;</b>		
W	IMVT-1402 Numerous Indications   Immunovant	Biologic		<b>&gt;</b>			
े	BREPOCITINIB Dermatomyositis   Priovant	Small Molecule				<b>&gt;</b>	
ं	BREPOCITINIB Non-Infectious Uveitis   Priovant	Small Molecule			<b>&gt;</b>		
ं	BREPOCITINIB Other Indications   Priovant	Small Molecule			<b>&gt;</b>		
n	NAMILUMAB Sarcoidosis   Kinevant	Biologic			<b>&gt;</b>		
ſ	UNDISCLOSED Undisclosed Indications	Undisclosed			<b>&gt;</b>		
							7



## Roivant has Announced Programs in 3 out of 6 Top Established I&I Markets and in Multiple High-Value Growth Markets

### 2028 Top US I&I Markets<sup>1</sup>

Psoriasis	<b>\$21.5</b> billion				
Atopic Dermatitis	<b>\$16.7</b> billion				
Myasthenia Gravis	<b>\$4.0</b> billion				
Crohn's Disease	\$11.9 billion				
Rheumatoid Arthritis	\$10.2 billion				
Ulcerative Colitis	\$7.0 billion				

#### **Additional Growth Markets**

Graves' Disease	~116K US Incident Pop.				
Thyroid Eye Disease	<b>~8-18K</b> New US Cases/Year				
CIDP	<b>~16K</b> US Patients				
Dermatomyositis	<b>~37K</b> US Adults				
Non-Infectious Uveitis	<b>~70-100K</b> US Patients				
Pulmonary Sarcoidosis	<b>~180K</b> US Patients				









## Charting a Path to a \$10BN+ Inflammation & Immunology Franchise

2024-2026

2026+

Multiple new approvals and 6+ Phase 2 or 3 data readouts including multiple registrational data sets each year

Wave of potential additional approvals across large established I&I and untapped high-value growth markets

Major I&I franchise with \$10BN+ aggregate peak revenue potential

#### Clear Precedents for Success in High-Value Growth Markets

TEPEZZA for Thyroid Eye Disease VYVGART for Myasthenia Gravis IMBRUVICA for Chronic Lymphocytic Leukemia SOLIRIS for Paroxysmal Nocturnal Hemoglobinuria



### 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

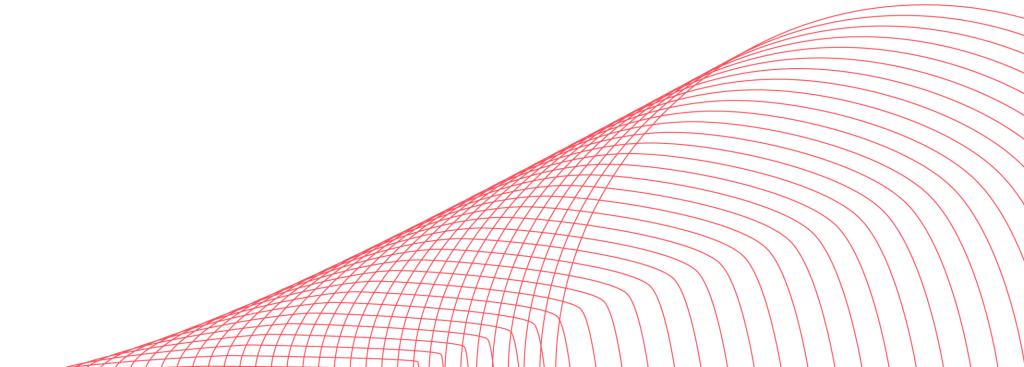


## Rich Catalyst Calendar Through 2025

Program	Vant	Catalyst	Expected Timing
VTAMA (tapinarof) cream	8	Updates on commercial launch of VTAMA in psoriasis	Ongoing
Roivant pipeline growth	ſ	New mid/late-stage in-licensing announcements	Ongoing
LNP platform	}	Updates to LNP patent litigation	Ongoing
Batoclimab	Y	Initial data from period 1 of Phase 2B trial in chronic inflammatory demyelinating polyneuropathy	2Q/3Q 2024
Namilumab	П	Topline data from Phase 2 trial in sarcoidosis	2H 2O24
Batoclimab	ं	Topline data from Phase 3 trial in myasthenia gravis	2H 2O24
Batoclimab	W	Topline data from Phase 3 trials in thyroid eye disease	1H 2025
Brepocitinib	ं	Topline data from Phase 3 trial in dermatomyositis	2025



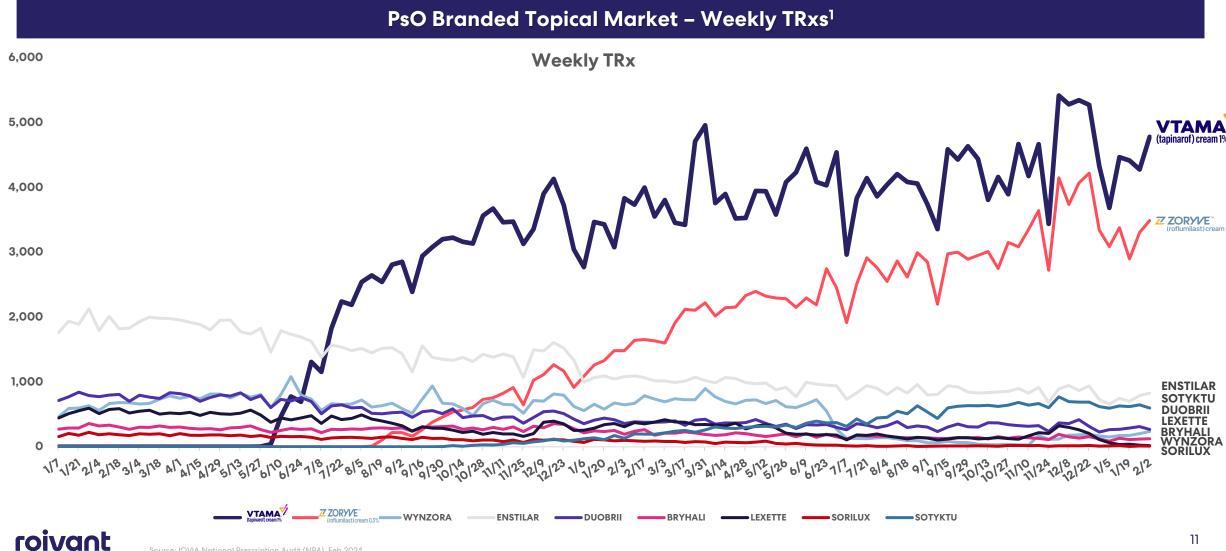
## VTAMA® Psoriasis Launch and Atopic Dermatitis Program





### **VTAMA Leads the Other Branded Topicals in Weekly TRx**

Over 300,000 VTAMA prescriptions written by approximately 14,000 unique prescribers since launch



## **Another Quarter of VTAMA Launch Execution & Strong Demand**

\$20.7M net product revenue for quarter ended Dec. 31, 2023

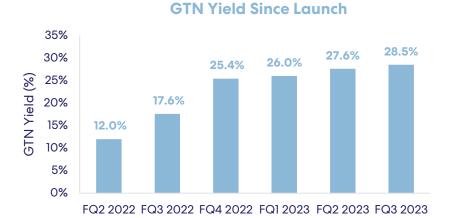
28.5% net yield for quarter ended Dec. 31, 2023

137M commercial lives covered (83% of total)

#### \$ 25 \$ 20.7 \$ 20.7 \$ 15 \$ 15 \$ 10 \$ 10 \$ 5.0

**Net Product Revenue Since Launch** 

FQ2 2022 FQ3 2022 FQ4 2022 FQ1 2023 FQ2 2023 FQ3 2023



Continued growth in product revenue shows strong patient demand and good payer progress

**\$** O

### Commercial and Government Coverage Progressing Ahead of Plan

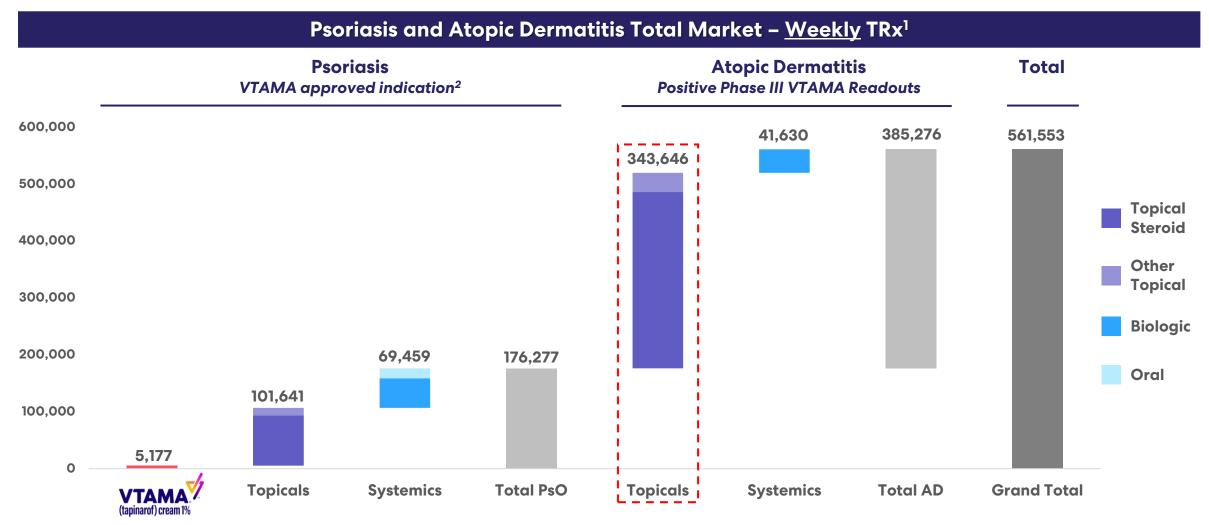
Innovation and TRx performance driving VTAMA accelerated coverage

# 137M

Commercial Lives Covered (83% of Total)

- ✓ 3 National PBM Formulary Additions
- 4 National Health Plan Formulary Additions
- ✓ 1 Regional PBM Formulary Addition
- √ 16 Regional Health Plan Formulary Additions
- ✓ 22 Blue Cross Blue Shield Plan Formulary Additions

# AD Data Supports Potential Market Expansion from ~100K Weekly Topical TRx in Psoriasis to ~450K Combined Weekly Topical TRx Market





Source: IQVIA Xponent PlanTrak & NPA. Market data 4-week trailing non-holiday weekly average TRx as of 12/15/2023. Market weekly TRx factored at the product level using ICD-10 code claim analytics.

## **VTAMA Cream Broad and Differentiated FDA-Approved Label**



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use

VTAMA® cream safely and effectively. See full prescribing information

for VTAMA.

VTAMA (tapinarof) cream, for topical use Initial U.S. Approval: 2022

-----INDICATIONS AND USAGE--

VTAMA cream, 1% is an-aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults. (1)

#### -DOSAGE AND ADMINISTRATION----

- Apply a thin layer of VTAMA cream to affected areas once daily. (2)
- VTAMA cream is not for oral, ophthalmic, or intravaginal use. (2)

–DOSAGE FORMS AND STRENGTHS--

Cream, 1% (3)

Each gram of VTAMA cream contains 10 mg of tapinarof. (3)

Broad Target Population and Use Cases Mild, moderate & severe plaque psoriasis

May be applied to all affected skin areas

Differentiated Clinical Efficacy Unlimited duration of treatment as demonstrated in clinical studies over 52 weeks

Demonstrated median <u>REMITTIVE OFF-</u> TREATMENT EFFECT of ~4 months

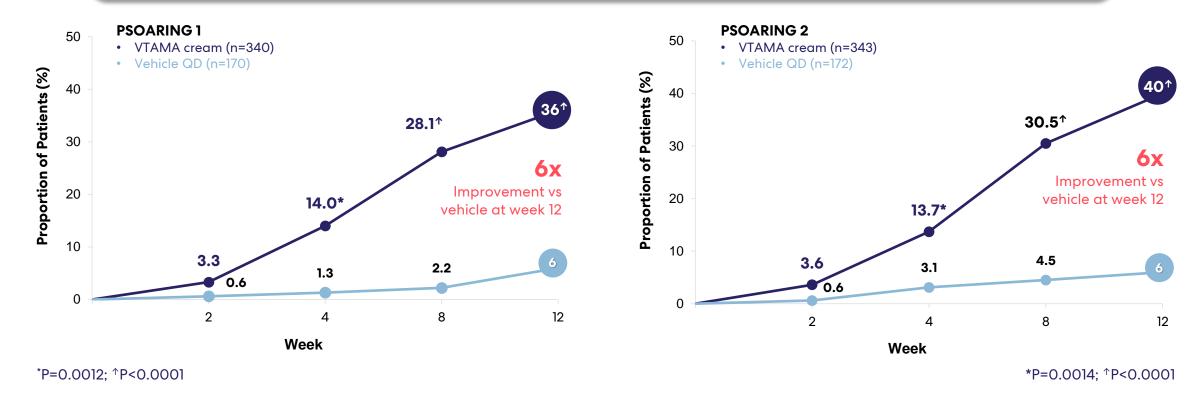
Safe and Well-Tolerated No label safety warnings or precautions

2,200+ patients treated in clinical trials



## 6x Treatment Success Rate vs. Vehicle at Week 12, With Significant Efficacy Seen as Early as Week 4<sup>1-3</sup>

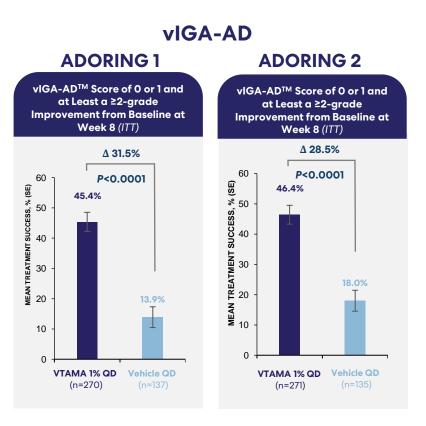
PGA treatment success: PGA score of 0 or 1 & a  $\geq$ 2-grade improvement from baseline to week 12<sup>1-3</sup>



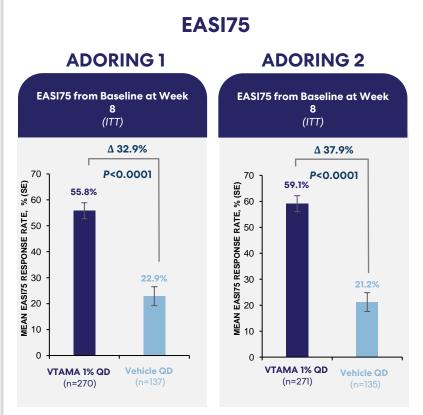
- $\triangleright$  ~40% of VTAMA cream patients achieved PGA treatment success vs ~ 6% of vehicle patients at week 12<sup>1-3</sup>
- $\sim$  80% of VTAMA cream patients achieved a >1-grade PGA improvement at week 12 vs ~35% of patients on vehicle 1-3



### **ADORING 1 and 2 Successful Across All Primary and Secondary Endpoints**



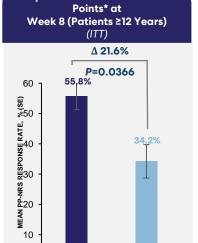
Robust efficacy demonstrated by magnitude of vIGA-AD<sup>TM</sup> treatment success\*.



Nearly 60% of patients treated with VTAMA cream achieved at least 75% improvement in eczema severity by Week 8 (mean baseline EASI 12.45 in ADORING 1 and EASI 13.33 in ADORING 2)

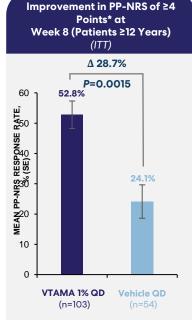
#### **PP-NRS**





VTAMA 1% QD

(n=103)



Majority of patients treated with VTAMA cream achieved clinically meaningful ≥4-point reduction in itch at Week 8 (patients aged ≥12 years, mean baseline PP-NRS 6.4 in ADORING 1 and 6.4 in ADORING 2)

Vehicle QD



\*vIGA-AD $^{TM}$  score of 0 or 1 and at least a  $\geq 2$ -grade improvement from baseline. P-value based upon Cochran-Mantel-Haenszel analysis stratified by baseline vIGA-AD $^{TM}$  score and age group. ITT, intention-to-treat; QD, once daily; SE, standard error; vIGA-AD $^{TM}$ , Validated Investigator Global Assessment for Atopic Dermatitis $^{TM}$ . Source: 14.2.1.1.1. P-Value based upon Cochran-Mantel-Haenszel analysis stratified by baseline vIGA-AD $^{TM}$  score and age group. \*Patients with baseline PP-NRS score  $\geq 4$  who achieve  $\geq 4$ -point reduction in the PP-NRS from baseline. P-value based upon Cochran-Mantel-Haenszel analysis stratified by baseline vIGA-AD $^{TM}$  score and age group. ITT, intention-to-treat; PP-NRS, Peak Pruritus Numeric Rating Scale; QD, once daily; SE, standard error; vIGA-AD $^{TM}$ , Validated Investigator Global Assessment for Atopic Dermatitis $^{TM}$ . Source: 14.2.2.4.1.

### **ADORING 1 & 2: Summary of TEAEs – Safety Population**

VTAMA 1% QD demonstrates highly favorable safety profile in AD patients down to age 2 years old

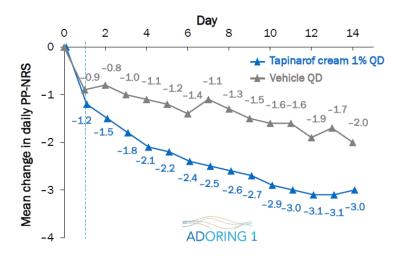
	ADORING 1		ADORING 2	
Patients, n (%)	<b>VTAMA 1% QD</b> (n=270)	<b>Vehicle QD</b> (n=137)	<b>VTAMA 1% QD</b> (n=271)	Vehicle QD (n=133)
Adverse events of special interest (treatment emergent)				
Contact dermatitis	4 (1.5)	3 (2.2)	3 (1.1)	2 (1.5)
Follicular event	27 (10.0)	1 (0.7)	24 (8.9)	2 (1.5)
Headache	19 (7.0)	3 (2.2)	4 (1.5)	0
TEAE leading to treatment discontinuation	6 (2.2)	6 (4.4)	4 (1.5)	5 (3.8)
TEAE leading to study discontinuation	5 (1.9)	5 (3.6)	4 (1.5)	4 (3.0)

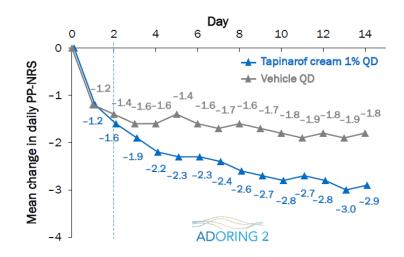
- Low rates of treatment and trial discontinuation due to adverse events
- Study and treatment discontinuation rate due to AEs greater in vehicle-treated group than VTAMA-treated group
- 91% rollover rate from ADORING 1 and 2 into the 48-week open-label, long-term extension study
- AEs in general were balanced between vehicle and treatment arms



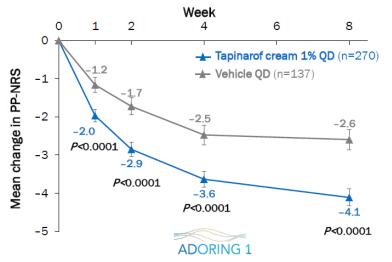
## VTAMA Demonstrated Rapid and Significant Reduction of Pruritis in AD in ADORING 1 & 2 Studies

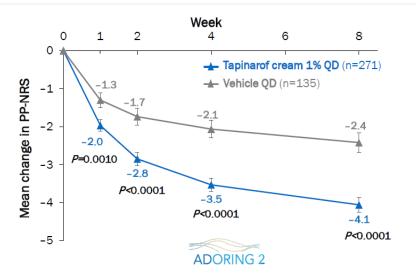
Rapid reduction in pruritis as early as <u>24</u> hours after first application





Clinically meaningful difference (≥4-point reduction in mean baseline PP-NRS score) surpassed in tapinarof groups at week 8





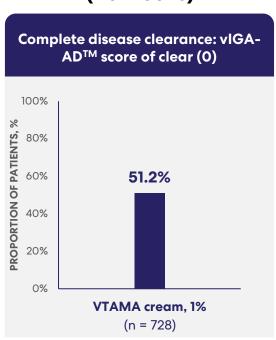


PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily

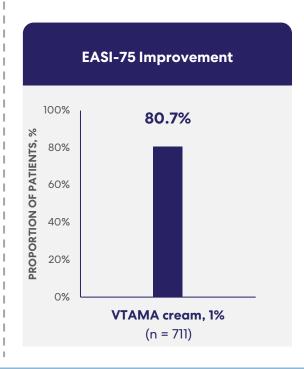
# Long-Term Positive Data Shows Continued Efficacy Improvement for VTAMA in AD with Strong Safety Profile

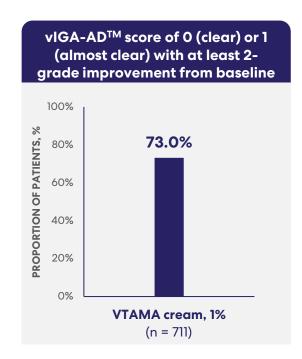
Two interim analyses of ADORING program in adults and children as young as age 2 validate that VTAMA cream may provide patients with long-term disease control

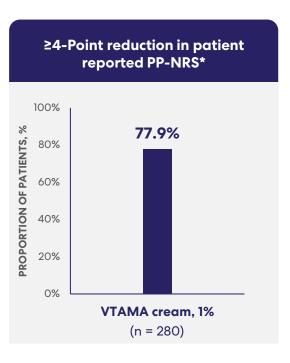
ADORING 3 Study (48 weeks)



Integrated Analysis of ADORING 1/2/3 and MUPK Studies (up to 56 weeks)



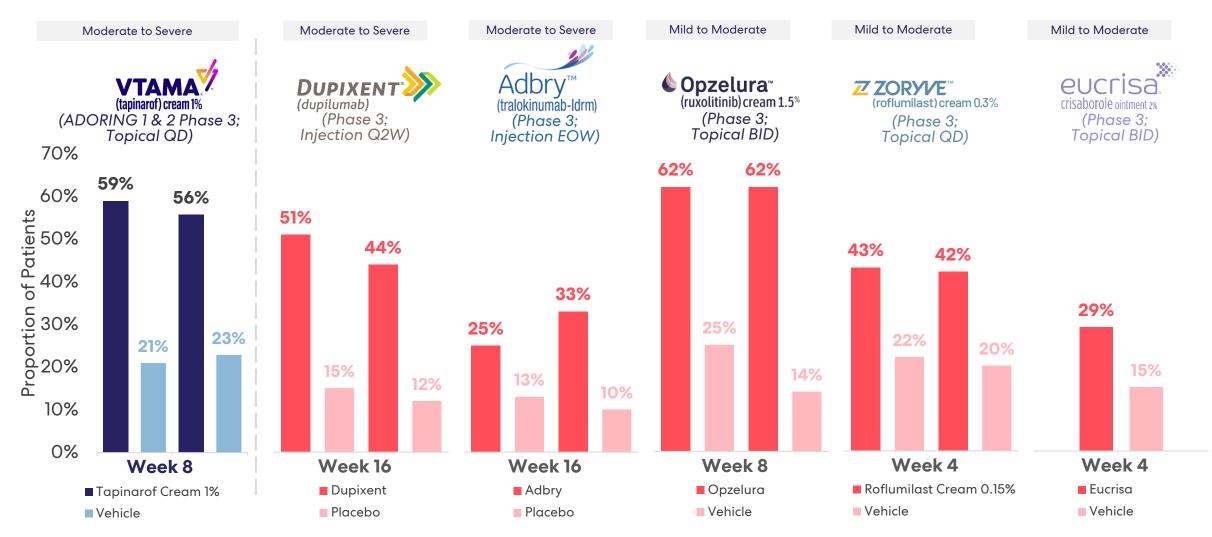




Overall adverse event profile in ADORING 3 with up to 48 weeks of treatment was consistent with ADORING 1 and 2 trials; majority of AEs were mild to moderate in nature and the discontinuation rate due to AEs was only 2.6%



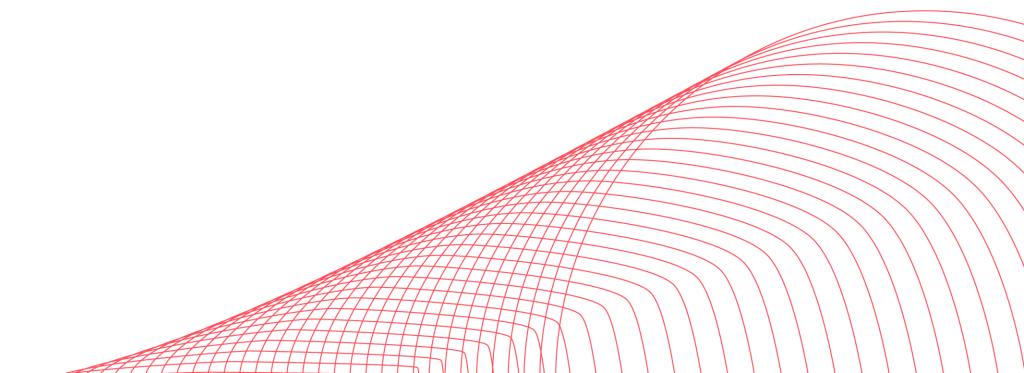
## EASI-75 Responder Rate vs Existing Topical and Systemic Therapies



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.

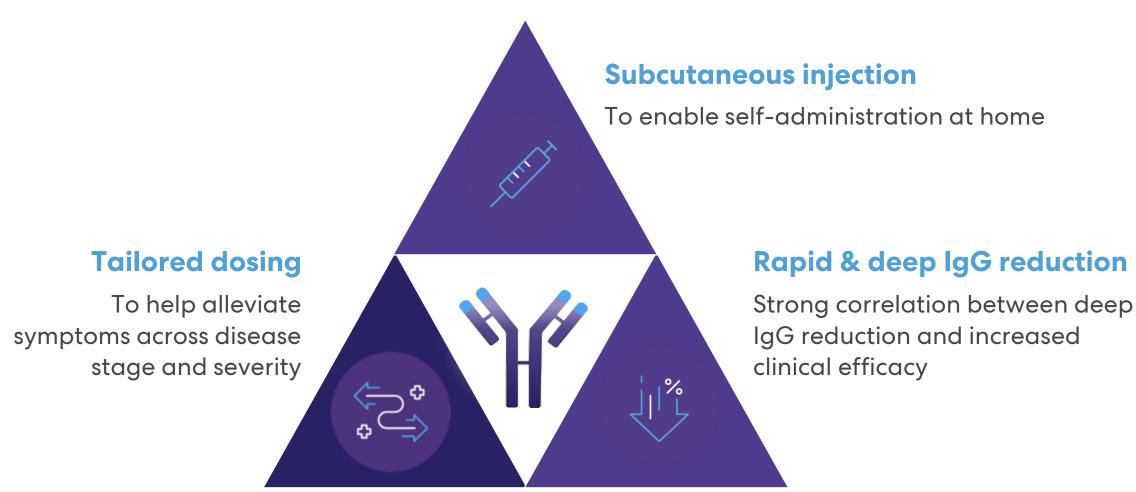


## Anti-FcRn Franchise: Batoclimab and IMVT-1402





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



### Our Market: Autoimmune Diseases Driven by Harmful IgG Autoantibodies

#### 22 indications announced or in development across the anti-FcRn class<sup>1</sup>



#### **NEUROLOGY**

Chronic inflammatory demyelinating polyneuropathy (CIDP)

Myasthenia gravis (MG)

Autoimmune encephalitis COVID-POTS Myelin oligodendrocyte glycoprotein antibody disorders (MOG-antibody disorder)



#### RHEUMATOLOGY

Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis

Myositis

Primary Sjogrens syndrome

Rheumatoid arthritis

Severe fibromyalgia syndrome

Systemic lupus erythematosus



#### **ENDOCRINOLOGY**

Thyroid eye disease (TED) Graves' disease (GD)



#### **DERMATOLOGY**

Bullous pemphigoid Pemphigus foliaceus Pemphigus vulgaris



#### **HEMATOLOGY**

Hemolytic disease of the fetus and newborn Idiopathic thrombocytopenic purpura Warm autoimmune hemolytic anemia (WAIHA)



#### **RENAL**

Antibody-mediated rejection Lupus nephritis Membranous nephropathy



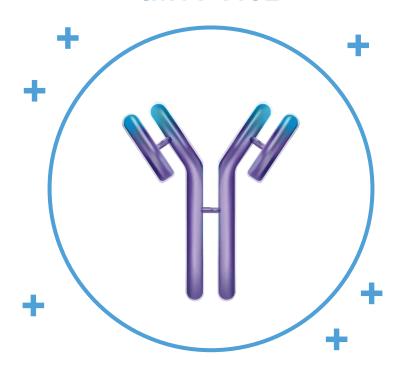
# Consistent Evidence Across Programs and Indications that Greater IgG Reduction Leads to Greater Efficacy\*

	Company	Evidence of Greater IgG Reductions Translating to Clinical Benefit
Θ	argenx yanssen	Patient-level scatter plot showed that greater IgG declines → greater MG-ADL improvements
TED	<b>M</b> IMMUNOVANT	Greater IgG reduction across arms → higher rates of anti-TSHR antibody reduction and greater clinical response rates
GD	** IMMUNOVANT	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
Ē		Greater IgG reduction across arms → greater platelet responses
RA	Janssen <b>T</b>	In those patients with greater IgG reduction → correlation with greater autoAb reduction → correlation with greater clinical response



## IMVT-1402 Has Potentially Best-In-Class Attributes to Address Large Unmet Need in Autoimmune Disease

#### **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 similar to batoclimab



**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 Pending composition of matter patent expected for IMVT-1402 to 2043\*

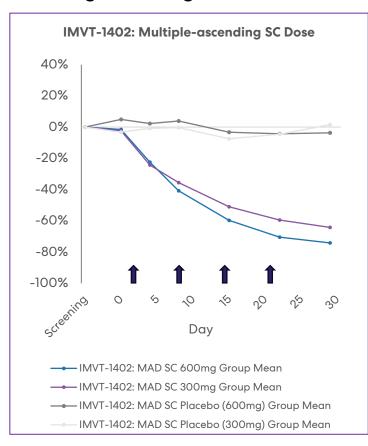
## IMVT-1402 Phase 1 Trial: Multiple-Ascending Subcutaneous Doses (Once-weekly dosing x 4 weeks)



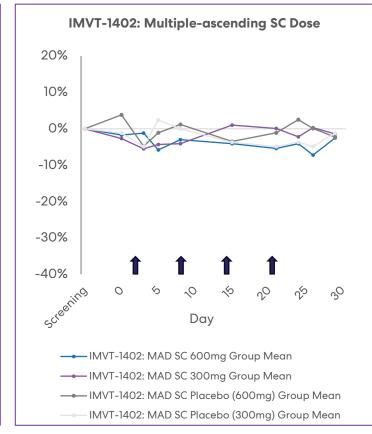
## IMVT-1402 Demonstrated Potentially Best-in-Class Profile in Initial Phase 1 Clinical Trial Data in Healthy Adults

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

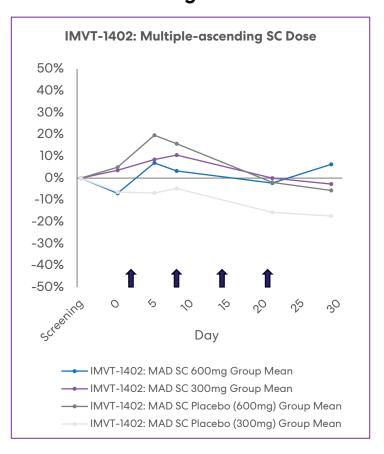
IgG % change over time



Albumin % change over time



LDL % change over time



### IMVT-1402 Showed a Favorable Safety Profile in Initial Phase 1 Data Set

	SC SAD				SC MAD			
	Placebo	300mg	600mg	Placebo 300mg		600mg		
	N = 4 n (%)	N = 6 n (%)	N = 6 n (%)	N = 4 n (%)	N = 10 n (%)	N = 10 n (%)		
Participants with at least one TEAE	3 (75)	4 (67)	5 (83)	4 (100)	7 (70)	6 (60)		
Participants with at least one TESAE	0	0	0	0	0	0		
Participants discontinued study due to TEAEs	0	0	0	0	1 (10) <sup>1</sup>	0		
Participants with dose reduction or interruption due to TEAE	0	0	0	0	0	0		
Deaths	0	0	0	0	0	0		
TEAE (≥ 2 Participants in any 1402 treated cohort)								
Injection site pain	0	1 (17)	0	1 (25)	0	3 (30)		
Catheter site bruise²	0	0	0	1 (25)	0	2 (20)		
Catheter site pain <sup>2</sup>	0	1 (17)	0	1 (25)	2 (20)	0		

All TEAEs were either mild or moderate with no severe TEAEs reported across any arm to date



<sup>1.</sup> Participant who discontinued experienced a Mild TEAE. The event was considered not related to study treatment.

## 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 MG

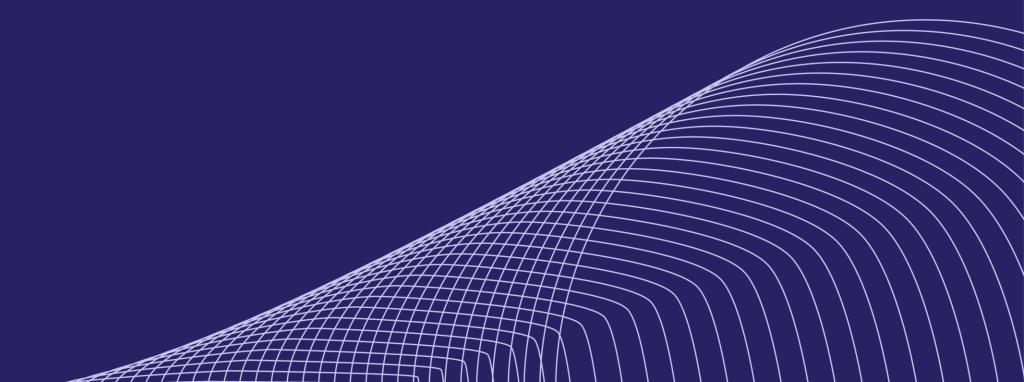
Classic autoAb, class data positive

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 Refractory rheumatoid arthritis

Other autoimmune, class data suggestive

## Indications

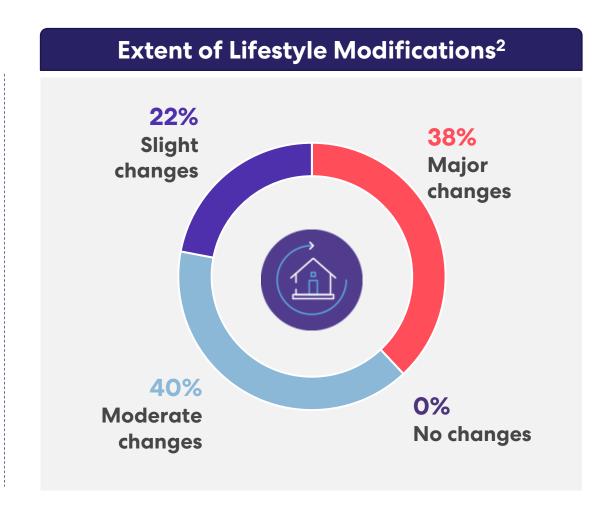




# Myasthenia Gravis (MG): IgG-Mediated Autoimmune Disease that Typically Requires Lifestyle Changes

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

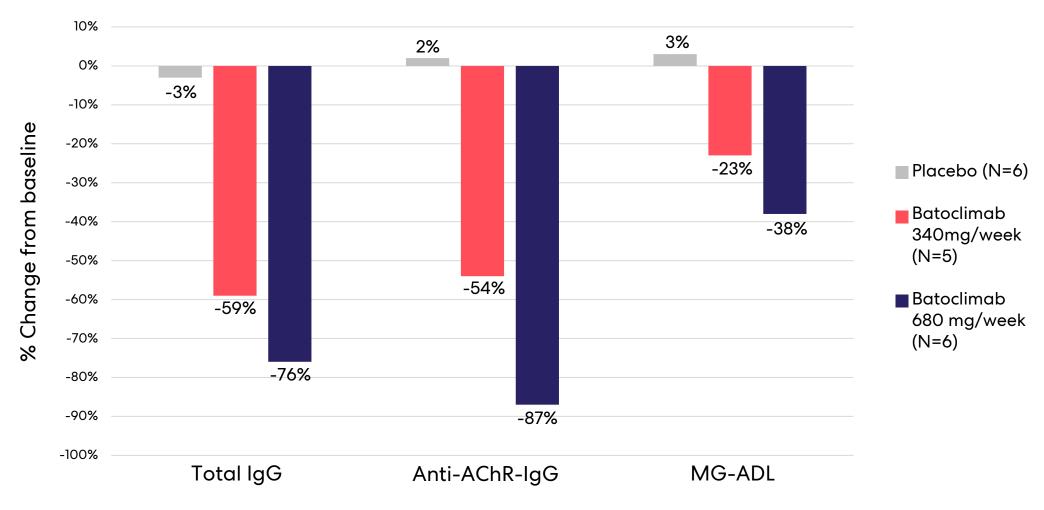
- One of the larger IgG-mediated autoimmune diseases
  - ~65,000 patients estimated in the US and
     ~100,000 in Europe
- ~80% of patients require lifelong therapy
- Substantial share of population on steroids and first-line immunosuppressants
- Shift towards immunosuppressants and immunoglobulin therapy as disease severity increases





### **Encouraging Efficacy Signals in a Phase 2 Trial of Batoclimab in MG**







### Batoclimab Phase 3 Trial Designed to Address Unmet Patient Needs

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



#### **Gain control**

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

2 MAINTENANCE PHASE

#### **Keep control**

Lower dose designed to maintain efficacy with potentially fewer side effects



## Optimize control Rescue therapy available



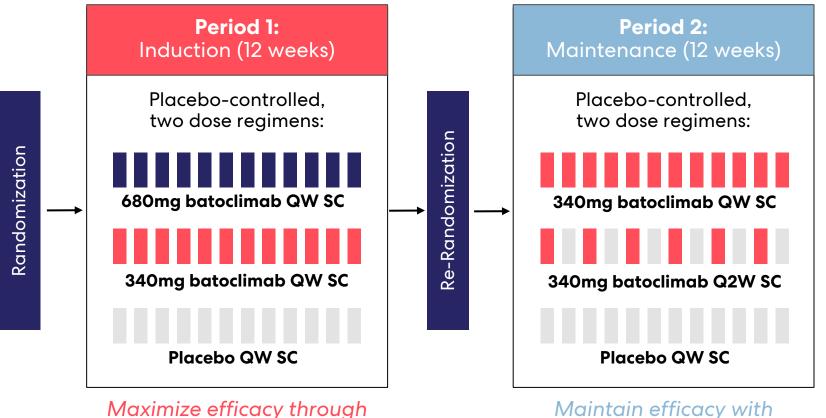
#### **Unmet Patient Needs**

- 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>

Top-line data expected in the second half of 2024



**Primary analysis population:** AChR Ab+

\*Primary endpoint: change in MG-ADL through 12 weeks

Period 2 followed by **Long-Term Extension** (LTE) study. Rescue therapy available during LTE per protocol



Maintain efficacy with anchor dose and lower dose

primary endpoint\*

# 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</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>3</sup>

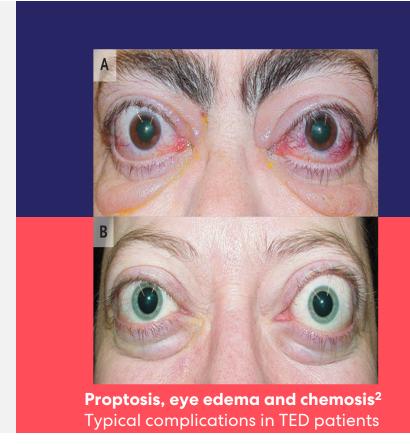
Progressive disease marked by inflammation that can lead to fibrosis and may become sight-threatening if untreated<sup>4</sup>

Caused by IgG autoantibodies that activate cell types present in tissues surrounding the eye<sup>4</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>5</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>6</sup>
- Audiological side effects of teprotumumab could enable greater market share capture by competitor

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>5,7-11</sup>





## Batoclimab TED Data Showed Higher Clinical Response with Deeper IgG Reduction

Deeper IgG reduction led to greater restoration of normal levels of pathogenic antibodies and greater proptosis response in Phase 2 trial in TED

	Placebo	Batoclimab 255 mg	Batoclimab 340 mg	Batoclimab 680 mg
Median Max % IgG Reduction at Week 5*	3%	54%	63%	79%
% Subjects with Stimulatory anti-TSHR Antibody below 140 at Week 5	0%	0%	12%	57%
Proptosis Response Rate at Week 5**	0%	11%	29%	43%

<sup>\*</sup>Week 5 data (study day 36) selected as it represents the latest time point at which the largest amount of patient data is available prior to the voluntary pause of the study. \*\*Post-hoc analysis of proptosis response at week 5. Proptosis response defined as proptosis reduction ≥2 mm in study eye, without ≥2 mm increase in non-study eye at same visit.

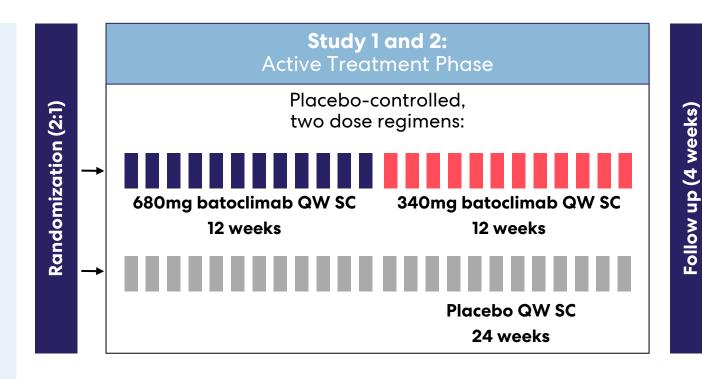


#### Two Phase 3 Clinical Trials of Batoclimab in TED Ongoing

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

#### **Inclusion**

- Subjects with clinical diagnosis of TED (active, moderate to severe TED with a CAS ≥ 4)
- Moderate to severe active TED (not sightthreatening 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 ≥ 2 mm reduction from baseline in proptosis in the study eye without deterioration (≥ 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

## 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**

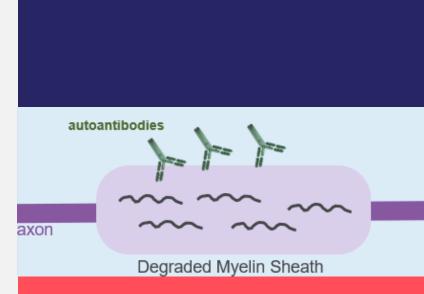
CIDP is characterized by predominant demyelination of motor and sensory nerves. Although the root cause of CIDP is unknown, significant evidence suggests that the disorder(s) are immunologically mediated<sup>3</sup>

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>
- \$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



FcRn binds to the IgG autoantibodies, inhibiting their degradation and returning them into circulation. IgGs may attack the myelin resulting in myelin degradation and neuropathy<sup>6</sup>



Broers M, et al. Incidence and prevalence of CIDP: a systematic review and meta-analysis. Neuroepidemiology 52(3-4):161-172 (2019)

Querol, L., et al. Systematic literature review of burden of illness in chronic inflammatory demyelinating polyneuropathy (CIDP). J Neurol 268, 3706–3716 (2021)

Mathey EK, Park SB, Hughes RAC, et al Chronic inflammatory demyelinating polyradiculoneuropathy: from pathology to phenotype Journal of Neurology, Neurosurgery & Psychiatry (2015)

Kuitwaard K, Bos-Eyssen ME, Blomkwist-Markens PH et al. Recurrences, vaccinations and long-term symptoms in GBS and CIDP. J Periph Nerv Syst 14(4):310–315 (2009)

CSL Behring R&D Investor Briefting, 2021.

<sup>6.</sup> Koike H, Katsun M. Pathophysiology of Chronic Inflammatory Demyelinating Polyneuropathy: Insights into Classification and Therapeutic Strategy. Neurol Ther. 2020 Dec;9(2):213-227. doi: 10.1007/s40120-020-00190-8. Epub 2020 May 14

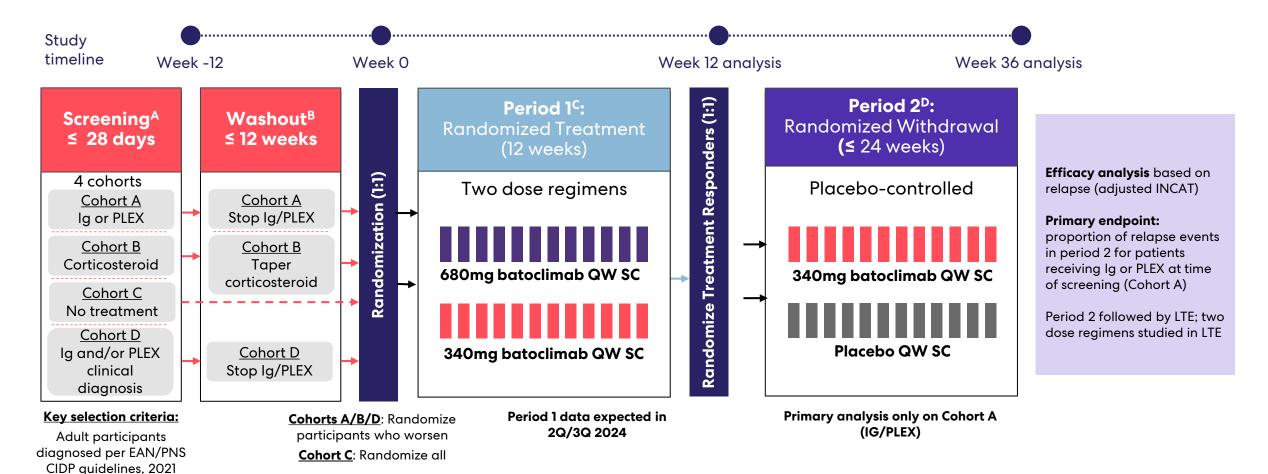
## Key Learnings from Historical and Ongoing CIDP Trials Applied to Address Challenges Unique to CIDP

Two-stage approach, to accommodate additional registration trial, if necessary, has the potential to deliver a differentiated product label with a larger effect size

Trial risks	Mitigations	Mitigation included in other anti-FcRn Trials*	Mitigation included in IMVT trial
Disease heterogeneity and challenging diagnosis	Diagnostic algorithm	X	<b>✓</b>
Mix of active and inactive disease among those enrolled creates risk of low relapse rate in the placebo arm, thereby shrinking potential effect size for the investigational product	Double enrichment:  1.Subjects must worsen after withdrawal / taper of standard of care (e.g. IVIG/SCIG, PLEX, or steroids) on study entry, AND	Not All**	<b>&gt;</b>
Patients enrolled in placebo arm of trial may not have demonstrated initial response to investigational product	2.Subjects must then improve on open label investigational product	Not All**	<b>&gt;</b>
Steroids are a common standard of care outside the US and often can't be fully tapered, weakening double enrichment	Third enrichment: Primary endpoint on IVIG/SCIG/Plex cohort only to maximize the potential effect size	X	<b>&gt;</b>
Lack of dose exploration	Data on <b>multiple doses</b> in "Period 1" of trial will inform future development strategy	X	>
Single large trial limits flexibility to optimize product label and differentiation	Smaller, initial pivotal trial that can be adjusted or complemented with a second smaller pivotal trial to optimize product label and differentiation based on new data	X	<b>&gt;</b>



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





revision

1. Two-stage approach, to accommodate additional registration trial, if necessary, has the potential to deliver a differentiated product label with a larger effect size A: Cohorts are defined by CIDP treatment at Screening. B: Participants who fail to worsen by Week 0 will be withdrawn from the study after completing Week 12 and the subsequent 4-week Follow-Up visit. Period 1 Non-Responders who require protocol-prohibited rescue therapy prior to Week 12 will discontinue IMP and may return to standard of care; these participants will be encouraged to remain in the study for Safety Follow-Up through Week 12 and the Follow-Up Visit. D: Participants that relapse in Period 2 or complete Period 2 without relapse will be eligible for participation in the Long-Term Extension study. CIDP = Chronic Inflammatory Demyelinating Polyneuropathy; EAN/PNS = European Academy of Neurology/Peripheral Nerve Society; Ig = immunoglobulin (IVIG and SCIG) therapy; IMP = investigational medicinal product; LTE = Long-term Extension; PLEX = plasma exchange; QW = every week; Wk = weekly; SC = subcutaneously; INCAT = Inflammatory Neuropathy Cause and Treatment.

#### 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 about 116,000 cases per year in the US<sup>1,2</sup>

#### **Clinical Presentation and Unmet Need**

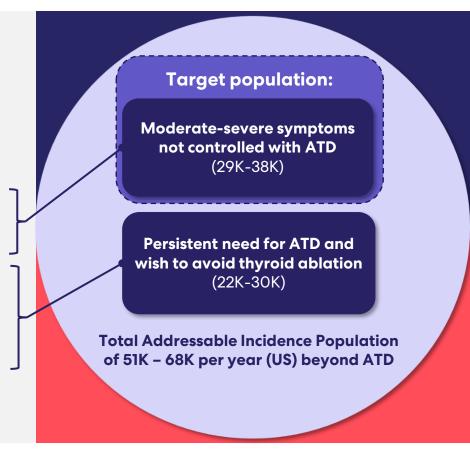
Caused by anti-TSHr autoantibodies which overstimulate the thyroid gland and cause hyperthyroidism; FcRn inhibition could foster degradation of those autoantibodies

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

- 1/4 to 1/3 of the 116K<sup>1,2</sup>US incident Graves' patients are difficult to control with ATD and remain symptomatic
- 75-100% of 30K<sup>10</sup> patients undergoing ablative procedure (radioactive iodine or surgery) may wish to avoid potential long-term risks (e.g., increased cancer, complications of thyroidectomy)





Furszyfer J, et al. Graves' disease in Olmsted County, Minnesota, 1935 through 1967. Mayo Clin Proc. 1970 Sep; 45(9):636-44

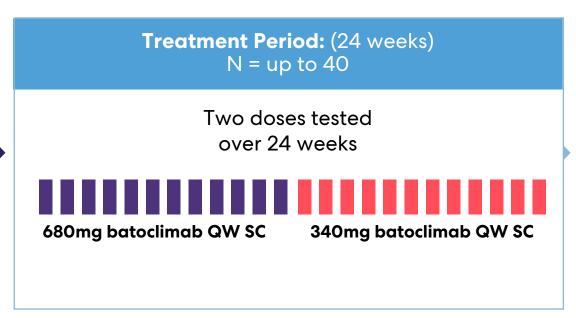
Sethi PP, Parchani A, Pathania M. Respiratory Muscle Weakness in Thyrotoxic Periodic Palsy: A Lesson to Remember. Ann Neurosci. 2021 Jul et al. Antithyroid Drugs-The Most Common Treatment for Graves' Disease in the United States: A Nationwide Population-Based Study. Thyroid. 2016 Aug; 26(8):1144-5. doi: 10.1089/thy.2016.0222. Epub 2016 Jul 5. PMID: 27267495

#### The First and Only Anti-FcRn Program Targeting Graves' Disease<sup>1,2</sup>

#### **Inclusion**<sup>A</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

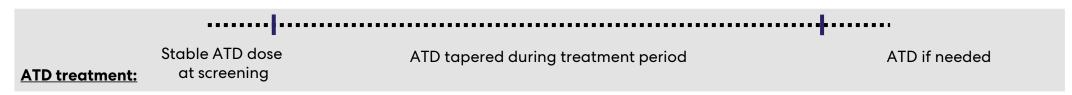
Screening (4 weeks)



Follow-up Period

#### **Primary endpoint:**

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





## Positive Initial Phase 2 Proof-of-Concept Data Enhances First-in-Class Opportunity in GD



Results from the initial cohort of patients in the ongoing 24-week clinical trial meaningfully exceeded 50% response rates



Numerically higher responses for ATD dose tapering and ATD discontinuation observed in patients receiving 680 mg batoclimab as compared with 340 mg

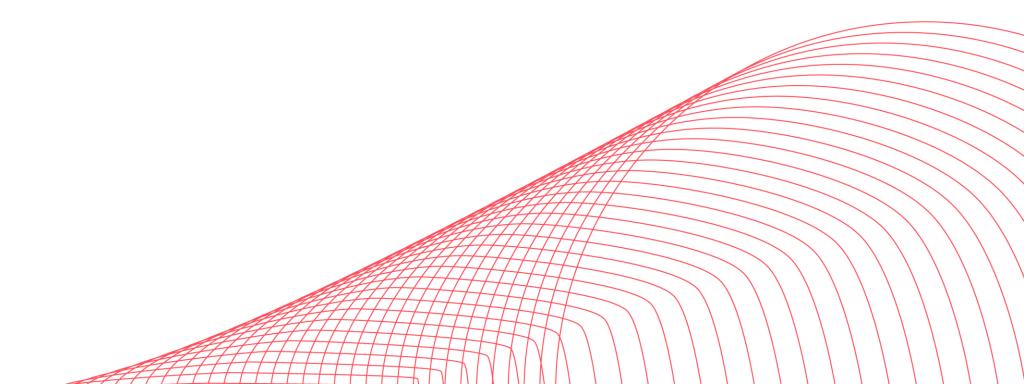


12 weeks of 680 mg batoclimab treatment demonstrated potential best-in class IgG reduction, up to 87% and a mean of 81%, greater than 340 mg IgG reduction



Future development in GD will be on IMVT-1402, with plans expected to be announced later in 2024

## Brepocitinib





#### **Oral Brepocitinib Overview**

Potential multi-billion dollar specialty autoimmune franchise with upcoming catalysts in 2024 and 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
- P3 study ongoing data expected to read out in 2025 and be sufficient for NDA filing

Initiation of Phase 3 Program in NIU Expected in 2024

- **Non-infectious uveitis:** Large orphan indication with only one approved therapy and no other oral therapies in late-stage development
- Initiation of Phase 3 program in non-infectious uveitis expected by end of 2024

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
- **Hidradenitis Suppurativa:** Phase 2 results suggest potential for better efficacy than selective JAK1 inhibitors and comparable to leading biologics

Strong Intellectual Property Position

IP protection expected until at least 2039\*



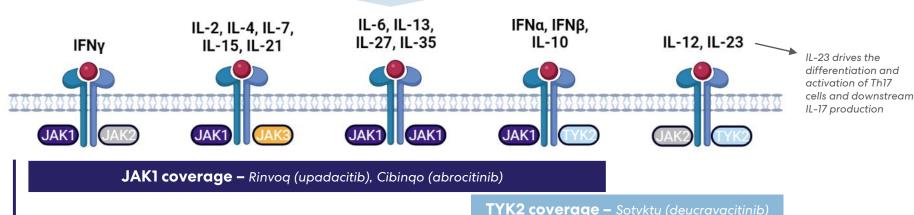
## Dual TYK2/JAK1 Inhibition is Optimized For Highly Inflammatory Heterogeneous Autoimmune Diseases With Multiple Pathogenic Cytokines

JAK inhibitors have been approved in...

**Rheumatology** RA, PsA, AS, JIA, axSpA **Immuno-Dermatology** PsO, AD, Vitiligo, Alopecia

**IBD**Ulcerative Colitis, Crohn's

Disease states are driven by different combinations of cytokines, requiring inhibition of specific JAK isoforms to treat distinct indications most effectively



Field is currently focused on single isoform inhibitors (specifically TYK2 or JAK1)

Brepocitinib was designed to target both TYK2 and JAK1

Greater coverage vs. TYK2s

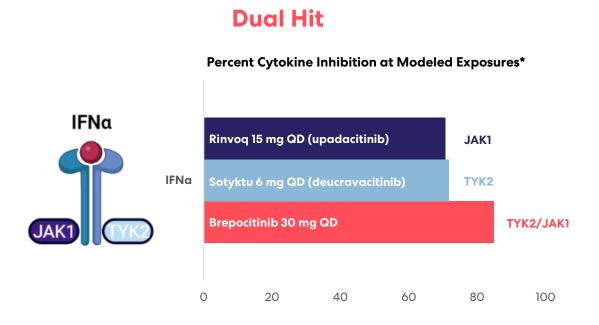
**Dual Hit** 

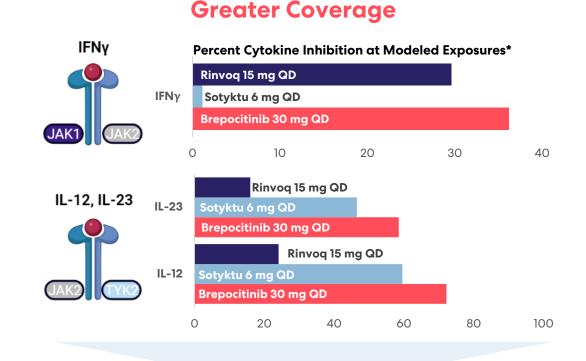
Greater coverage vs. JAK1s

Hypothesis: brepocitinib can provide best-in-class efficacy in indications mediated by the TYK2/JAK1 dimer and in diseases requiring broad cytokine coverage



## In Vitro Data Support Mechanistic Benefits of Dual Inhibition of TYK2 and JAK1





Brepocitinib may be able to achieve deeper Type I IFN suppression than is possible by targeting either TYK2 or JAK1 alone

Brepocitinib may recapitulate <u>in a single</u> <u>molecule</u> the cytokine suppression profiles of both the leading TYK2 and JAK1 agents



## 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	N¹	Brepocitinib Dose	Brepocitinib Primary Endpoi	Brepocitinib Primary Endpoint Result	
Alopecia Areata Patients with moderate-to-severe AA	942	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> Patients with active PsA	218	30 mg once daily	23.4% placebo-adjusted ACR20 RR at week 16	P = 0.0197	
Ulcerative Colitis Patients with moderate-to-severe UC	167	30 mg once daily	-2.28 placebo-adjusted CFB in Mayo Score at week 8	P = 0.0005	
Plaque Psoriasis Patients with moderate-to-severe PsO	212	30 mg once daily	-10.1 placebo-adjusted CFB in PASI Score at week 12	P < 0.0001	
<b>Hidradenitis Suppurativa</b> Patients with moderate-to-severe HS	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> Patients with moderate-to-severe CD	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>	
Non-infectious Uveitis Patients with active non-infectious intermediate-, posterior-, and panuveitis	26	45 mg once daily	29.4% Treatment Failure Rat	29.4% Treatment Failure Rate at week 24	



Overall study N represents patients randomized to all brepocitinib dose levels or placebo and excludes patients randomized to other agents

<sup>2)</sup> Includes patients from initial 24-week study period only

<sup>2)</sup> Includes patients from Initial 24-week study period only

 <sup>60</sup> mg QD for 4 weeks followed by 30 mg QD for 20 weeks
 One-sided p-value (pre-specified statistical analysis)

<sup>5)</sup> Brepocitinib 45 mg once daily was the only brepocitinib dose evaluated in this study

<sup>6)</sup> Brepocitinib 60 mg once daily was the only brepocitinib dose evaluated in the induction period of this study CFB; change from baseline; RR; response rate

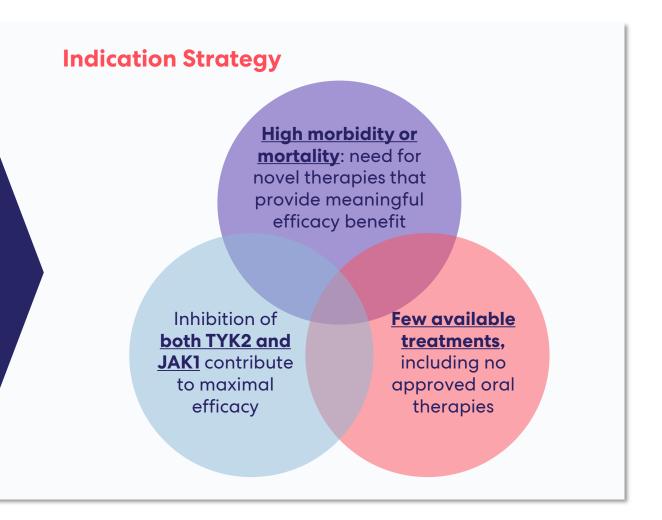
The non-infectious uveitis study was conducted by Priovant; all other studies shown here were conducted by Pfizer

#### **Brepocitinib: Potential Large Orphan Franchise**

First Phase 3 readout expected in 2025 (dermatomyositis), with NDA submission to follow

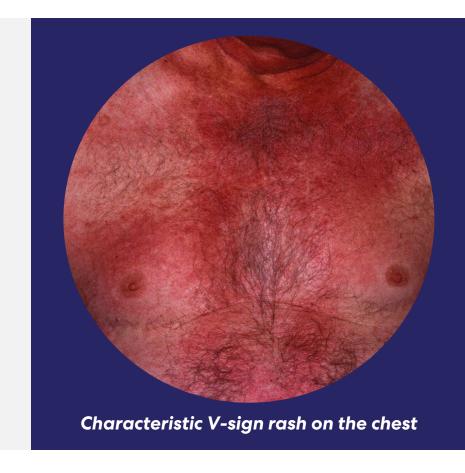
#### **Brepocitinib Background**

- Dual inhibitor of TYK2 and JAK1, optimized for highly inflammatory indications
- Clinically meaningful benefit in seven phase 2 studies (once-daily oral administration)
- Exposure in >1,400 subjects and patients suggests safety profile consistent with approved JAK inhibitors
- IP protection expected to at least 2039



## Dermatomyositis: Large Orphan Indication With Blockbuster Opportunity For An Efficacious Oral Therapy

37,000	Affected adult patients in the United States alone <sup>1</sup>
10-40%	Mortality at five years <sup>2</sup>
100%	Red, painful, itchy skin rash often disseminated across substantial body surface area
88%	Proximal muscle weakness <sup>3</sup> , limiting activities of daily living (ADL)
42%	Interstitial lung disease <sup>4</sup> , contributing to substantial morbidity
0	Other oral therapies in industry-sponsored late-stage development <sup>5</sup>
0	NCEs approved in last 60 years





<sup>1)</sup> PriovantTx estimates based on Reeder 2010, Smoyer-Tomic 2012, and claims analysis

Liu et al, Oncol Letters (2018)

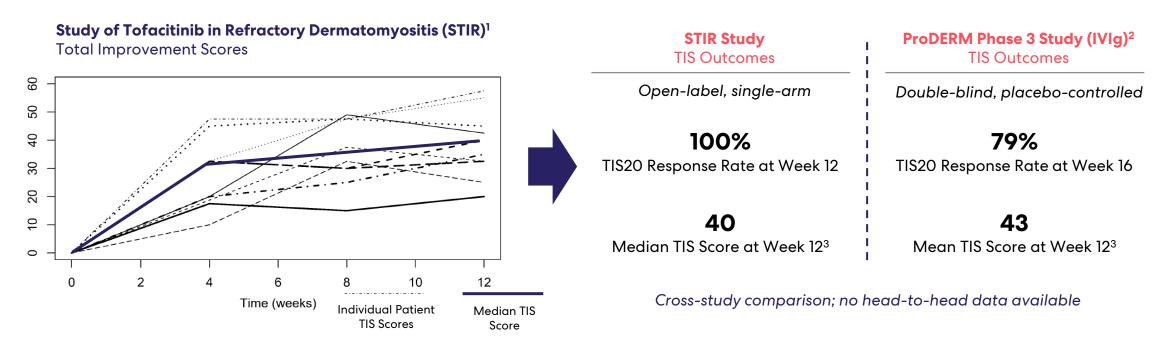
Fardet et al, Medicine (2009)

<sup>4)</sup> Sun et al, Sem Arth Rheum (2021)

<sup>5)</sup> Phase 3 trials or adaptive Phase 2/3 trials

## Clinical Proof-of-Concept with Tofacitinib Suggests High Probability of Success For Brepocitinib in Ongoing Phase 3 Study

Investigator-initiated open-label study of tofacitinib in refractory dermatomyositis demonstrated activity comparable to that of IVIg, the only approved non-corticosteroid/corticotropin therapy for dermatomyositis



Clinical PoC further validated by extensive case report literature<sup>3</sup>

DM pathobiology driven by both TYK2 and JAK1-mediated cytokines → expect brepocitinib to potentially demonstrate greater benefit



Paik et al, Arth Rheum (2020

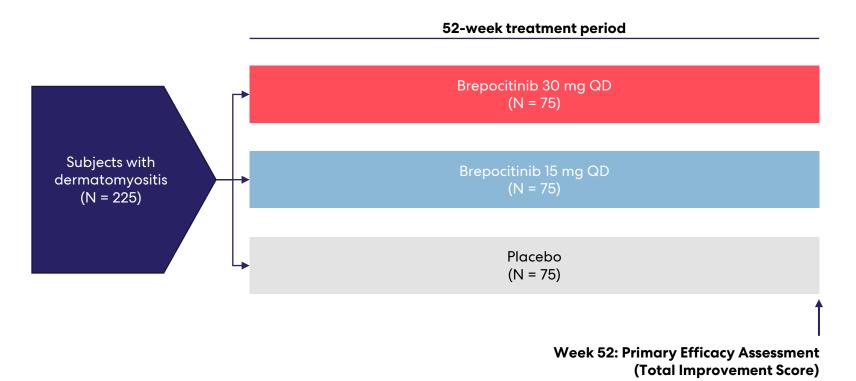
Aggarwal et al, NEJM (2022

STIR study: median is the only statistical analysis provided; ProDERM study: mean is the only statistical analysis provided

Paik et al Clin Eyn Rheum (2022)

## Single Phase 3 Study Ongoing; Expected To Generate Registrational Data Required for Approval

Primary Endpoint: Total Improvement Score (TIS), a recognized myositis improvement index that served as basis of approval for IVIg in dermatomyositis



#### **Eligible Patients**

Adult subjects with active dermatomyositis who are refractory or intolerant to at least one standard-of-care therapy

#### **Primary Endpoint**

Mean Total Improvement Score (TIS) at Week 52

#### **Secondary Endpoints**

- Proportion of patients achieving moderate response (TIS40)
- Manual Muscle Testing (MMT-8)

#### **Safety Endpoints**

Incidence of treatment-emergent AEs, SAEs, AEs of special interest, clinically significant vital signs or lab abnormalities

Data expected 2025  $\rightarrow$  potentially next approved drug of any modality

#### Non-Infectious Uveitis: A Sight-Threatening Ocular Disease

Orphan indication with potential blockbuster opportunity for brepocitinib to become the first approved oral therapy

Tens of	
<b>Thousand</b>	S

New instances of legal blindness attributable to

NIU in the United States each year<sup>1</sup>

>70,000

Patients living with non-anterior NIU in the

United States<sup>1</sup>

## Most Common Symptoms

Light sensitivity, pain, redness and floaters

#### **Etiology**

Approximately half idiopathic, half in context of

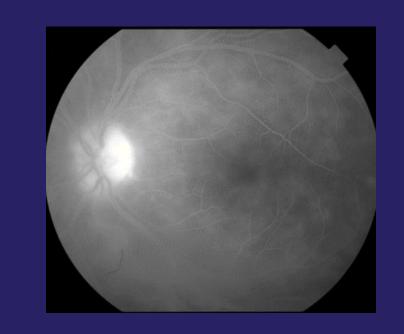
other systemic autoimmune disease<sup>2</sup>

1

Approved targeted therapy (Humira)

0

Competitors in Phase 3 development<sup>3</sup>



Posterior Segment Inflammation
Diffuse areas of capillary leakage and
disc hyperfluorescence



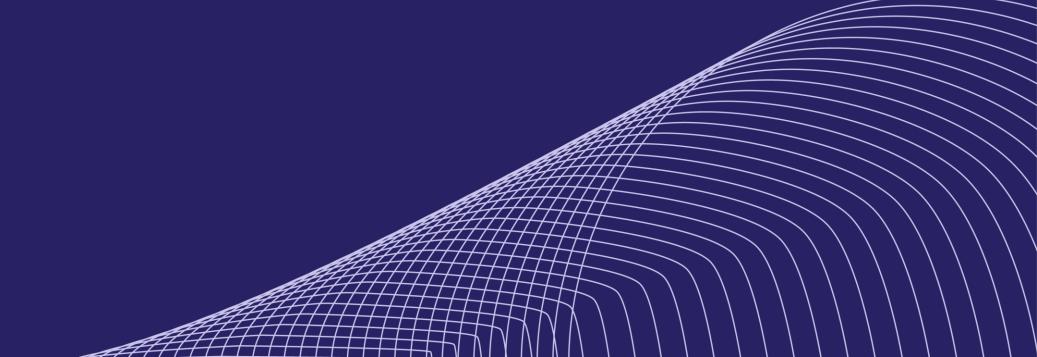
Thorne et al, JAMA Ophthalmol. (2016)

Lopalco et al. Clin Exp Rheum 2018.

One therapy in Phase 3 for uveitic macular edema, which comprises a subset of non-

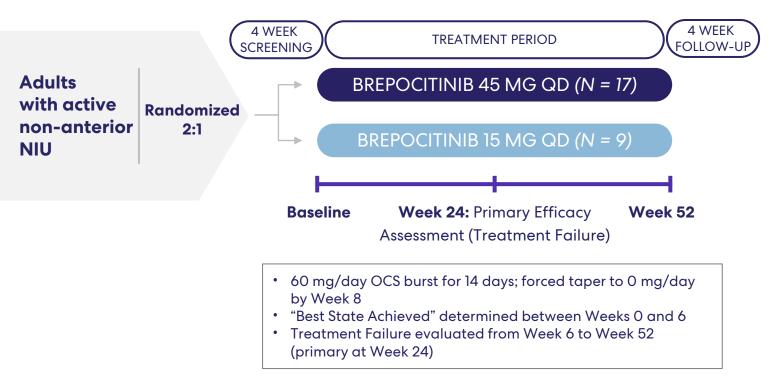
# Positive Results from Phase 2 NEPTUNE Study of Brepocitinib in NIU

roivant



#### **NEPTUNE Study Design**

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

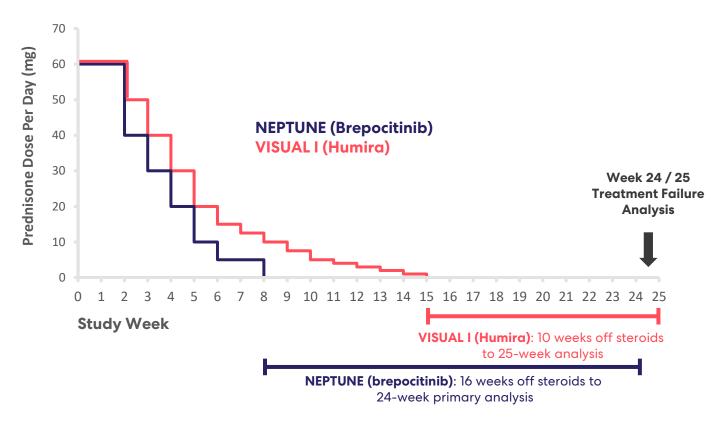


#### **Key Efficacy Endpoints**

- Treatment Failure rate at Week 24 (primary)
- Treatment Failure Sub-Components: Change on ACC grade, VH grade, inflammatory lesions, and BCVA\*
- · Change in central subfield thickness

#### 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

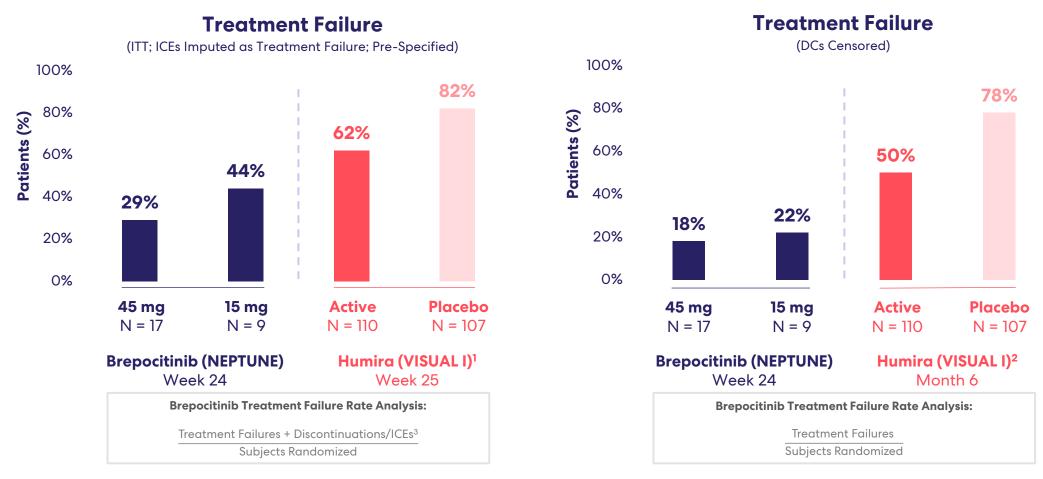
- Requires that brepocitinib act more quickly
- Requires brepocitinib meet higher efficacy bar to prevent flares

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

#### **Treatment Failure Rate at Week 24** (lower rate = greater treatment benefit)

Including Cross-Study Comparison to VISUAL I



<u>Disclaimer:</u> 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.



#### **Overview of Safety Data**

	Brepocitinib 45 mg N = 17	Brepocitinib 15 mg N = 9
Any TEAEs, n (%)	13 (76.5%)	9 (100%)
Any Treatment-Emergent SAEs	0	1 (11.1%)
Any Treatment-Related TEAEs	8 (47.1%)	2 (22.2%)
Any TEAEs Leading to Discontinuation of study drug	2 (11.8%)	2 (22.2%)

#### Brepocitinib was generally safe and well tolerated in NEPTUNE; no new safety or tolerability signals were identified

- No deaths, MACE, malignancy, or thromboembolic events in either treatment arm
- 1 SAE of Grade 2 hypersensitivity in 15 mg arm resolved following discontinuation of study drug and administration of oral diphenhydramine (Benadryl)
- TEAE severity
  - Two Grade 3 events one uveitis flare in 15 mg arm reported as an AE, one case of costochondritis (benign sternum pain) in 45 mg arm
  - All other TEAEs were mild-to-moderate in severity

#### Brepocitinib's safety database comprises >1,400 exposed subjects and patients

• Safety profile appears consistent with safety profile of approved and widely prescribed JAK inhibitors



## 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

Trial Multiple ISTs and Biologics
With Mixed Efficacy to Treat
Multiple Disease Manifestations

Large number of biologic-treated patients (~30,000) with high failure/relapse rate (~50%)

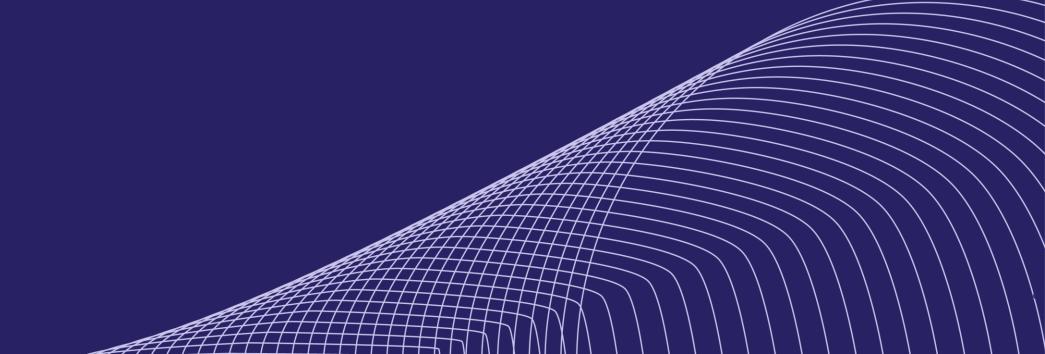
## NEPTUNE Data Supports Potential Brepocitinib Use Early In Treatment Paradigm <u>And</u> In Refractory Population

- 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



## **Expansion Opportunities**

Hidradenitis Suppurativa





#### Hidradenitis Suppurativa: A Severe and Disfiguring Skin Disease

Opportunity for brepocitinib to become leading oral therapy for treatment of exceptionally debilitating inflammatory skin disease

170,000

Patients living with HS in the United States<sup>1</sup>

**Key Symptoms** 

Nodule, abscess, and tunnel formation in intertriginous zones (skin folds)

**Comorbidities** 

Metabolic syndrome<sup>2</sup>, spondylarthritis<sup>3</sup>, inflammatory bowel disease<sup>4</sup>

>2x

Increased suicide risk for patients living with HS compared to the general population<sup>5</sup>





Estimates for moderate/severe HS only; based on Phan et al, Biomed Derm 2020

Sabat et al. PLoS One (2012)

S) Shlyankevich et al, J Am Acad Derm (2014)

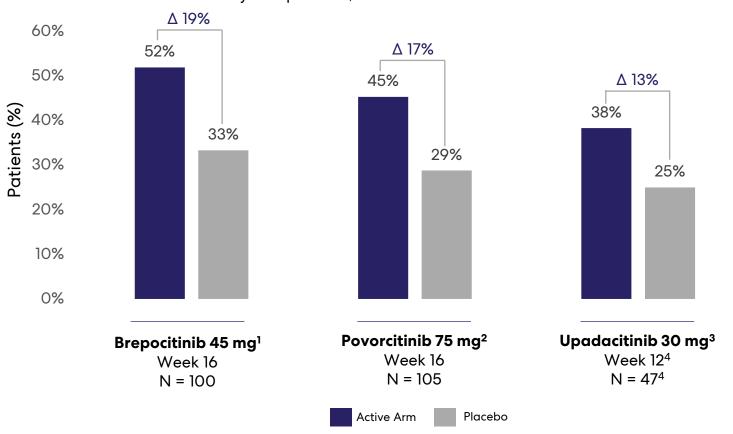
<sup>4)</sup> Deckers et al, J Am Acad Derm (2017)

E) Therlacious et al. Univert Dermatel 20

## Dual TYK2/JAK1 Inhibition May Generate Greater Efficacy than Inhibition of JAK1 Alone

#### **HiSCR50** Response

Cross-Study Comparisons; No Head-to-Head Data Available



Absolute and placebo-adjusted results numerically better than other oral agents and comparable to leading biologics

Results suggest that addition of TYK2 inhibition may contribute to better efficacy in HS; inhibition of Th17 (IL-23) axis in HS extensively validated by IL-17-targeting biologics (eg Cosentyx)



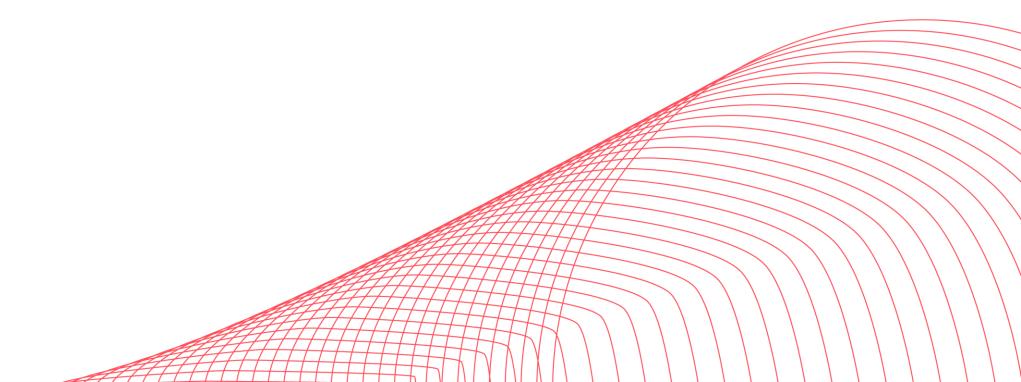
Kimball et al EADV 2022

Kirby et al. EADV 2022 Poster P0004

Kindy et al, EADV 2022 | Oster | 0004

Primary endpoint of upadactinib Phase 2 study was HiSCR at 12 weeks. N represents active arm only as primary statistical analyses were performed in reference to prespecified historical placebo control (N = 259). Active arm performance at Week 16 for UPA30 was 40%.

## Namilumab





#### Namilumab: Potential First Novel Therapy for Pulmonary Sarcoidosis, a Large, Untapped Orphan Market

#### **Pulmonary Sarcoidosis** Is A Large, Untapped **Orphan Market**

~180,000 patients in the US alone<sup>1</sup>

Characterized by the accumulation of granulomas in the lung, which cause injury and scarring

Leads to declining pulmonary function, dyspnea, fatigue, cough, pain, and death

No modern approved agents; systemic corticosteroids are the mainstay, and other immunosuppressives are used off-label

#### **GM-CSF** Inhibition Uniquely Stops the "Bad **Actor**" Cell Type

Pulmonary sarcoidosis is driven by alveolar macrophages, which form the granulomas<sup>2</sup>

Alveolar macrophages are uniquely driven by GM-CSF<sup>3</sup>

#### **Compelling Drug Properties**

Extremely potent (subnanomolar IC50)

Fully human monoclonal antibody

Dosed subcutaneously, designed for high patient convenience\*

Existing safety database of over 300 patients to date<sup>4</sup>

#### **Robust RESOLVE-LUNG Study Underway**

Robust Phase 2 is underway

Could count as a registrational study if successful

Clinical study design incorporates lessons learned from previous trials



All product candidates are investigational and subject to regulatory approval.

nab is beina developed with potentially the least frequent dosina schedule amona subcutaneous anti-GM-CSFs in Phase 2 clinical trials, with a sinale dose every four weeks after an initial loadina period 1. Denning, et al. European Respiratory Journal 2013

#### Pulmonary Sarcoidosis is a Large, Untapped Orphan Market

A well-tolerated and effective, steroid-sparing therapy for sarcoidosis has blockbuster commercial potential<sup>1</sup>

~180,000 patients in the US alone<sup>2</sup>

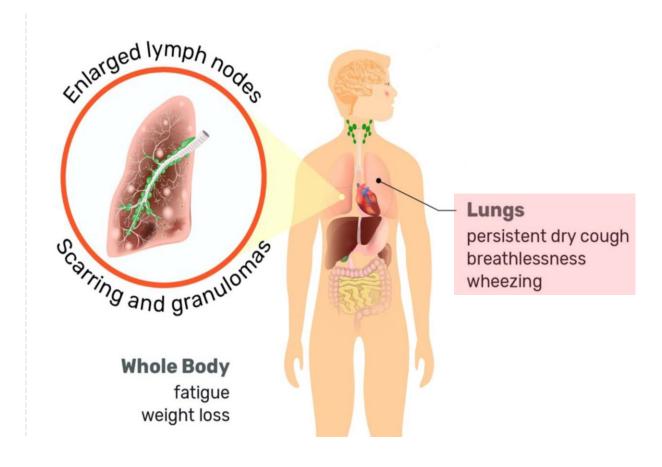


Characterized by the accumulation of granulomas - compact, centrally organized collections of macrophages and epithelioid cells encircled by lymphocytes - in the lungs, which causes injury and scarring<sup>3</sup>



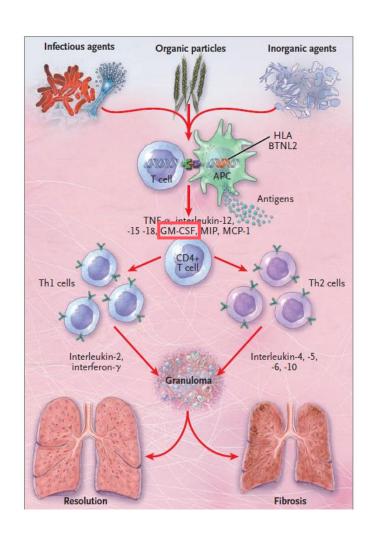
#### **Clinical consequences:**

Declining pulmonary function Dyspnea, fatigue, cough, and pain Death





## GM-CSF Inhibition Uniquely Stops the "Bad Actor" Cell Type: Alveolar Macrophages



Pulmonary sarcoidosis is an autoimmune condition driven by alveolar macrophages

Alveolar macrophages are uniquely driven by GM-CSF signaling

Alveolar
macrophages
contribute to a
cytokine feedback
loop with other
myeloid and
lymphoid cells
secreting additional
GM-CSF and other
inflammatory
cytokines

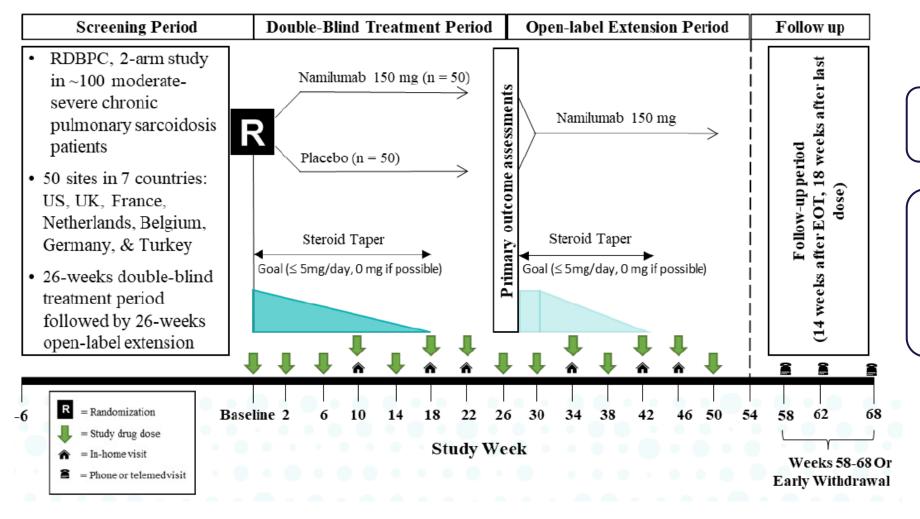
Alveolar macrophages then form noncaseating granulomas in the lungs

Granulomas and related tissue injury (e.g., lung fibrosis) are features of – and cause the disease consequences of – pulmonary sarcoidosis<sup>1</sup>



## RESOLVE-Lung: Phase 2 Pulmonary Sarcoidosis Study Could Serve as a Registrational Study if Successful





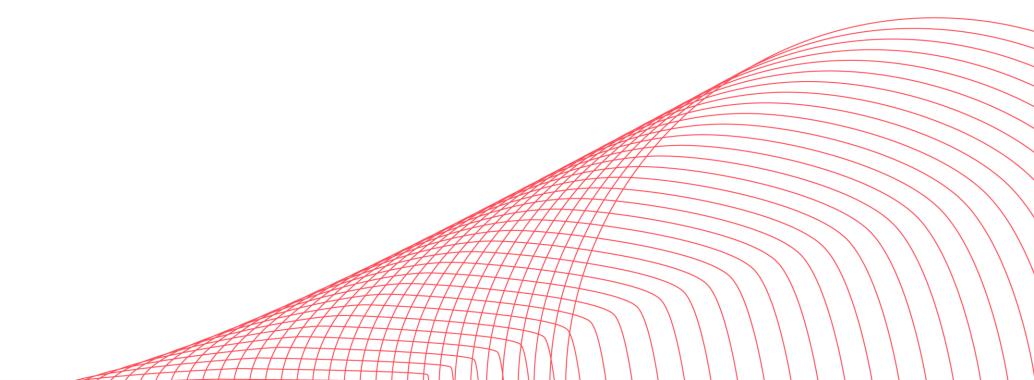
#### **Primary Endpoint**

Proportion of subjects requiring rescue<sup>1</sup> for worsening of sarcoidosis

#### **Key Secondary Endpoints**

- Change from baseline in ppFVC
- Time to rescue treatment
- Proportion of subjects successfully achieving OCS taper without rescue
- Change from baseline in the KSQ Lung domain score

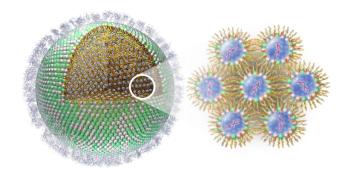
## **LNP Patent Litigation**





#### 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, Including COVID-19

Partner	LNP Collaborations Outside of COVID-19	Publicly Disclosed Financials*
SAREPTA	Gene editing therapeutics for specified neuromuscular diseases, including DMD <sup>1</sup>	Royalty rate: mid-single to low-double digits <sup>†</sup> Near-term: \$50M + significant milestones
Takeda	Nucleic acid therapeutics directed to specified targets in HSCs to treat liver fibrosis <sup>2</sup>	Royalty rate: undisclosed Upfront & milestones: \$600M
gritstone	Self-amplifying RNA (samRNA) for an unspecified indication <sup>3</sup>	Royalty rate: low to mid-single digits <sup>†</sup> Upfront & milestones: \$73M
gritstone	Self-amplifying RNA (samRNA) for various infectious disease vaccines <sup>4</sup>	Royality rate: mid to high-single digits <sup>†</sup> Option exercise fee: single-digit millions Milestones: \$136M/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®	RNA editing therapy for Alpha-1 Antitrypsin Deficiency (AATD) <sup>6</sup>	Royalty rate: mid-single digits <sup>7</sup> Upfront & milestones: \$100M
novo nordisk <sup>®</sup>	Gene editing therapy for hemophilia A <sup>8</sup>	Royalty rate: mid-single digits <sup>†</sup> Upfront & near-term option: \$10M + milestones
E Tome	Gene editing therapy for an undisclosed rare monogenic liver disorder <sup>9</sup>	Total deal value: \$114.3M Royalty rate: undisclosed
Partner	LNP Collaborations for COVID-19	Publicly Disclosed Financials*
gritstone	Self-amplifying RNA (samRNA) COVID-19 vaccine program <sup>10</sup>	Royalty rate: mid-single to mid-double digits <sup>†</sup> Upfront & milestones: \$192M/product
		D 1: 1 00/
₩ ST PHARM	mRNA COVID-19 vaccine program in specified Asian countries <sup>11</sup>	Royalty rate: 8% Upfront & milestones: \$133.75M
ST PHARM PROVIDENCE	mRNA COVID-19 vaccine program in specified Asian countries <sup>11</sup> mRNA COVID-19 vaccine program	
		Upfront & milestones: \$133.75M



<sup>\*</sup>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.

#### **Updates on Genevant IP Litigation**

#### Moderna

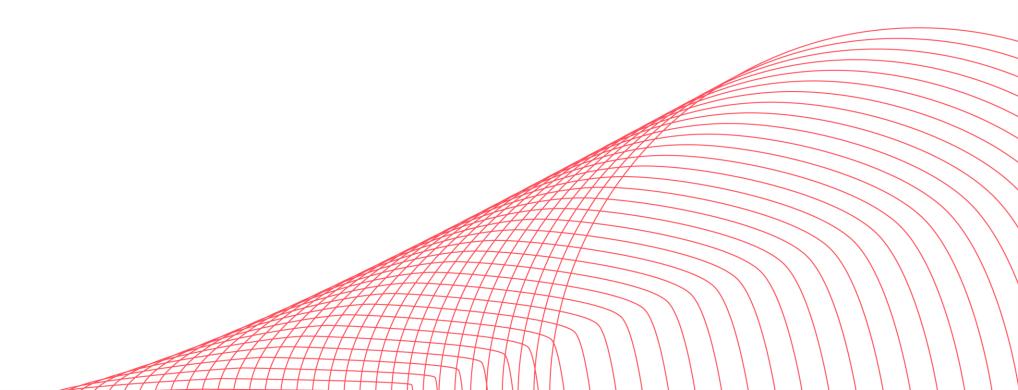
- In February 2022, Genevant and Arbutus jointly filed a complaint against Moderna in the U.S. District Court for the District of Delaware asserting infringement of six patents
- In November 2022, the Court issued an opinion and order denying Moderna's partial motion to dismiss the suit based on the 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
- Fact and expert discovery are ongoing, and the Court will entertain requests to file summary judgment motions in late 2024; a trial date has been set for April 21, 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



## VantAl

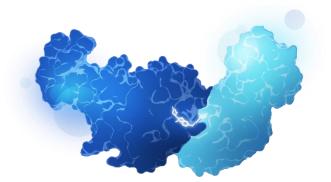




## VantAl Positioned to Unlock the Potential of Induced Proximity

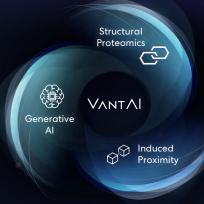
### Targeted protein degradation is just the beginning...

- Many more fields to come beyond degradation (e.g., induced phosphorylation, induced glycosylation, etc.)
- All induced proximity (current and future) relies on proteinprotein interaction
- Al is well-suited to solve the combinatorial challenges presented by three-body problems (protein-moleculeprotein)
- Challenging disease targets necessitate approaches beyond inhibition



roivant

VantAl has positioned itself at the intersection of three transformative technologies...



#### **Unique proprietary data**





Interface structure data generation at unprecedented **Speed & Scale** 

#### All star team & scientific leadership

**Including Michael Bronstein, VantAl Chief Scientist** 

#### **Trusted**



#### **Validated**





Multiple biopharma deal expansions

## Thank you.

