## Roivant Overview

## November 2023





#### **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 the pending sale of our subsidiary Telavant to Roche (the "Telavant Transaction"), our future results of operations and financial position, business strategy, research and development plans, 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 and ADORING 2 topline study results and (ii) initial data from a Phase 1 trial of IMVT-1402 and the potential for IMVT-1402 to be best-in-class with respect to IgG lowering and with respect to albumin and LDL impact, and any commercial potential of our product candidates, are forward-looking statements.

The Telavant Transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. There can be no assurance that the Telavant Transaction will close on the timelines specified in this presentation or at all.

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 and ADORING 2 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 and ADORING 2 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 <u>www.sec.gov</u> 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 VTAMA 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.

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### **Roivant: Developing and Commercializing Transformative Medicines**





Capital infusion leaves company in position of strength to **expand our pipeline**, as well as **pursuing additional investments and with the potential to return capital to shareholders** 

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#### 2023: Roivant's Biggest Year Yet



Expanded VTAMA Coverage and Reach



Coverage expanded to 83% of commercial lives in October



ADORING 1 and 2 -VTAMA Phase 3 Readouts in AD

Positive results pave the way to atopic dermatitis market, which is ~4x the size of psoriasis market



RVT-3101 (Anti-TL1A) UC Phase 2b Data

Pending sale to Roche to maximize patient opportunity and capital flexibility

Positive final data from global Phase 2b in ulcerative colitis validates best-in-class potential. Sale to Roche expected to close 4Q 2023 or 1Q 2024.



IMVT-1402 (Next-Gen Anti-FcRn) Initial Human Data



value across indications



Brepocitinib (TYK2/JAK1) Pivotal Trial Readout in SLE



Brepocitinib did not meet primary endpoint of SRI-4 at week 52 despite observing some of the highest SRI-4 responder rates in an SLE study

**FOIVADE** References are to calendar years. Other than VTAMA in psoriasis, all drugs are investigational and subject to regulatory approval. The closing of the Telavant Transaction is subject to the satisfaction of certain customary closing conditions, including certain regulatory approvals.

#### **Robust Late-Stage Pipeline**

#### Six ongoing registrational trials in multi-billion dollar markets

		Modality	Preclinical	Phase 1	Phase 2	Phase 3	Approved
۵	VTAMA (tapinardi) cream 1% Psoriasis   Dermavant	Topical					
۵	VTAMA Atopic Dermatitis   Dermavant	Topical				Completed	
Ŷ	BATOCLIMAB Myasthenia Gravis   Immunovant	Biologic				•	
Ŷ	BATOCLIMAB Thyroid Eye Disease   Immunovant	Biologic				•	
Ŷľ	BATOCLIMAB Chronic Inflammatory Demyelinating Polyneuropathy   Immunovant	Biologic			•		
Ŷ	BATOCLIMAB Graves' Disease   Immunovant	Biologic			►		
Ŷľ	IMVT-1402 Numerous Indications   Immunovant	Biologic		•			
৾৾	BREPOCITINIB Dermatomyositis   Priovant	Small Molecule				•	
৾৾	BREPOCITINIB Other Indications   Priovant	Small Molecule			►		
n	NAMILUMAB Sarcoidosis   Kinevant	Biologic					
$\widehat{}$	RVT-2001 Transfusion-Dependent Anemia in Patients with Lower-Risk MDS   Hemavant	Small Molecule		•			



Pipeline reflects both ongoing clinical trials and expected upcoming trials. VTAMA has only received FDA approval for psoriasis, not atopic dermatitis. Other than VTAMA in psoriasis, all drugs are investigational and subject to regulatory approval. RVT-3101 is subject to a definitive agreement to sell Telavant to Roche.

 Represents registrational or potentially registrational trials

### **Rich Catalyst Calendar Through 2025**

Program	Vant	Catalyst	Expected Timing
VTAMA (tapinarof) cream	۵	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	Ŷľ	Initial data from Phase 2 trial in Graves' disease	Year-end 2023
RVT-2001	$\widehat{\bullet}$	Data from RVT-2001 Phase 1/2 trial in lower-risk myelodysplastic syndrome	1Q 2024
VTAMA (tapinarof) cream	۵	Expected sNDA filing for VTAMA in atopic dermatitis	1Q 2024
Brepocitinib	ిం	Topline data from proof-of-concept trial in non-infectious uveitis	1Q 2024
Batoclimab	Ŷľ	Initial data from period 1 of Phase 2B trial in chronic inflammatory demyelinating polyneuropathy	1H 2024
Namilumab	n	Topline data from Phase 2 trial in sarcoidosis	2H 2024
Batoclimab	Ŷſ	Topline data from Phase 3 trial in myasthenia gravis	2H 2024
Batoclimab	Ŷľ	Topline data from Phase 3 trials in thyroid eye disease	1H 2025
Brepocitinib	৾৾	Topline data from Phase 3 trial in dermatomyositis	2025



## Pending Sale of Telavant



## **Roche to Acquire Telavant**

Roche to acquire Telavant for \$7.1BN upfront and a \$150M milestone, which includes:

- Development and commercial rights to RVT-3101 in US and Japan
- Option to collaborate with Pfizer on next-generation p40/TL1A directed bispecific antibody

Expected cash proceeds to Roivant of approximately \$5.2BN upon deal close plus \$110M from a onetime milestone payment upon Phase 3 initiation in UC

Roivant reported **cash, cash equivalents and restricted cash of \$1.4BN** at September 30, 2023, or **\$7.0BN** after giving effect to expected cash proceeds from the pending sale of Telavant (including one-time milestone) and the completed Immunovant follow-on offering<sup>1</sup>

Pfizer to retain commercial rights to RVT-3101 outside of US and Japan

Transaction is expected to close in 4Q 2023 or 1Q 2024. Regulatory filings completed



Dates refer to calendar quarters. The closing of the Telavant Transaction is subject to the satisfaction of certain customary closing conditions, including certain regulatory approvals.
Assumes \$150M Telavant milestone is paid; closing of the Telavant Transaction is subject to the satisfaction of certain customary closing conditions, including certain regulatory approvals.
MVT offering closed October 2, 2023, with aggregate gross proceeds of
\$492.IM, or net proceeds to Immunovant of \$466.6M.

## **Transaction Generates Significant Value for Patients and Shareholders**

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#### Maximize Patient Access

 Adds resources and expertise from a large global pharmaceutical company to maximize access for patients across multiple indications

#### Near Term Value Generation

- \$7.25BN deal value reflects large scale of TL1A opportunity
- High degree of capital efficiency for Roivant, reflecting quality of recent data and continued development progress



Capital Infusion Creates Opportunities for Growth

- We will be patient and thoughtful in decisions around allocation of capital
- Resulting significant cash capacity is sufficient to fully fund our existing programs through profitability, pursue additional deals, and potentially return capital to shareholders



The closing of the Telavant Transaction is subject to the satisfaction of certain customary closing conditions, including certain regulatory approvals

# Commercial Launch of VTAMA<sup>®</sup> Cream



#### VTAMA is Charting a Path to Become a Potential Blockbuster Topical in Both Psoriasis and Atopic Dermatitis







Powerful efficacy and rapid onset in plaque psoriasis with remittive data on label and remarkable efficacy in atopic dermatitis Favorable safety and tolerability profile that enables long term use anywhere on the body

Convenient, oncedaily product with expected single tube for psoriasis and atopic dermatitis, including for pediatric patients





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 age two (2) years old and above.

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

Over 250,000 VTAMA prescriptions written by approximately 12,800 unique prescribers since launch



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



**Net Product Revenue Since Launch** 

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

#### **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
- I 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 ~90K Weekly Topical TRx in Psoriasis to >400K Combined Weekly Topical TRx Market



1. Source: IQVIA National Prescription Audit (NPA). Market data as of week ending 1/20/2023. VTAMA TRx as of 11/3/2023. Market weekly TRx factored at the product level using ICD-10 code claim analytics. 2. 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 age two (2) years old and above.

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## VTAMA: A Paradigm Shift In Everyday Psoriasis Care

#### Physician Quotes from Investor Day KOL Panel:



"What has really struck me using this post approval in the real world is really the **fast onset of action**. I am seeing some of my patients come back into the office or message me through the portal telling me they're **clearing as early as 1 to 2 weeks into therapy**"



"In the eyes of my own patients and the rapidity of the improvement, [VTAMA] has really positioned itself as a **first-line monotherapy topical treatment** for our patients with plaque psoriasis. And that really is a **very significant change in the way we treat this disease**"



"This is really a **paradigm shift of how we're managing [psoriasis] patients.** I think that the cornerstone of topical therapy for me has radically shifted in a matter of months to using [VTAMA] as a primary treatment and thinking about the other therapies as adjuvant therapies to combine with VTAMA, if necessary"



"Patients tell me that the **feel of the cream is very elegant.** They're **not having any tolerability issues**. I've been privileged that over the last 3 months of prescribing it, I haven't seen any side effects yet"



"[One patient of mine] cleared 100% on this medication. She showed me pictures of herself in shorts, and she told me she never thought she could wear shorts again. She got teary-eyed, I got teary-eyed. But that moment just showed me that **this drug is not only impacting the disease itself. It's changing people lives**"



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

<b>VTAMA</b> (tapinarof) cream 1%	Broad Target Population and Use Cases	Mild, moderate & severe plaque psoriasis May be applied to all affected skin areas				
HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use VTAMA <sup>®</sup> cream safely and effectively. See full prescribing information for VTAMA. VTAMA (tapinarof) cream, for topical use Initial U.S. Approval: 2022	Differentiated Clinical Efficacy	Unlimited duration of treatment as demonstrated in clinical studies over 52 weeks Demonstrated median <u>REMITTIVE OFF-</u> TREATMENT FEFECT of ~4 months				
<ul> <li>VTAMA cream, 1% is an-aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults. (1)</li> <li>DOSAGE AND ADMINISTRATION</li></ul>	Safe and Well- Tolerated	No label safety warnings or precautions				
Each gram of VTAMA cream contains 10 mg of tapinarof. $(\underline{3})$		2,200+ patients treated in clinical trials				

#### **VTAMA Cream's FDA Label is Differentiated Among Competitors**

	Non-Steroid	dal Topicals		Systemics			<b>Topical Steroids</b>		Steroid Combinations			
On Label	VTAMA (tapinarof) cream 1%	ZORYVE™	OTEZLA® (Oral)	HUMIRA® (Subcutaneous)	<b>SOTYKTU™</b> (Oral)	Clobetasol	Halobetasol	Betamethasone	<b>DUOBRII™</b> (Corticosteroid/ Vitamin A)	<b>ENSTILAR®</b> (Corticosteroid/ Vitamin D)		
Remittive Off-Treatment Benefit Data <sup>,</sup>		×	~	<b>~</b>	~	×	×	×	×	~		
No Duration Limitations	<ul> <li>Image: A set of the set of the</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>	$\checkmark$		<ul> <li>Image: A second s</li></ul>	≤ 4 weeks	≤ 2 weeks	≤ 4 weeks	<ul> <li>Image: A second s</li></ul>	≤ 4 weeks		
No Body Surface Limitations (incl. Intertriginous Areas)		<ul> <li>Image: A start of the start of</li></ul>	$\checkmark$	$\checkmark$	$\checkmark$	Avoid face, groin and underarm	Avoid face, groin and underarm	Avoid face, groin and underarm	Avoid face, groin and underarm	Avoid face, groin and underarm		
No Label Safety Warnings		<ul> <li>Image: A set of the set of the</li></ul>	Gl issues, hypersensitivity weight loss, depression	Black box warning of serious infections	Hypersensitivity, serious infections, TB, malignancy, rhabdomyolysis	HPA axis suppression, Cushing's syndrome, hyperglycemia	HPA axis suppression, Cushing's syndrome, hyperglycemia	HPA axis suppression, Cushing's syndrome, hyperglycemia	Embryofetal risk, HPA axis suppression, Cushing's syndrome	HPA axis suppression, Cushing's syndrome, hyperglycemia		
No Drug Interactions		CYP3A4 or CYP3A4/CYP1A2 dual inhibitors, or oral contraceptives with gestodene and ethinyl estradiol	Strong cytochrome P450 enzyme inducers	Anakinra, live vaccines	Live vaccines, other immuno- suppressants	<ul> <li></li> </ul>	<ul> <li></li> </ul>	<ul> <li>Image: A start of the start of</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>		
No Contraindications		Moderate/severe liver impairment	Known hypersensitivity to apremilast	<ul> <li>Image: A set of the set of the</li></ul>	Known hypersensitivity to deucravacitinib	<ul> <li></li> </ul>	$\checkmark$	Known hypersensitivity to betamethasone or any other corticosteroids	Pregnancy	<ul> <li>Image: A start of the start of</li></ul>		

Comparison above is based on a review of the FDA-approved labels for the referenced products. No head-to-head studies or comparisons between the products have been conducted against other psoriasis treatments.



1. VTAMA cream demonstrated a median time of ~4 months off treatment to PGA ≥ 2. Patients on OTEZLA lost PASI-75 response after a median of ~5-weeks off treatment. Patients on SOTYKTU lost sPGA 0/1 after a median of ~8 weeks off treatment and lost PASI-75 response after a median of ~12 weeks off treatment. Patients on ENSTILAR showed a median of ~4-weeks off treatment to IGA ≥ 1.

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## 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>-3</sup>



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

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PGA, Physician Global Assessment; QD, once daily 1. Lebwohl M, et al. N Engl J Med. 2021;385:2219–2229. 2. Dermavant DOF. [DMVT-505-3001 CSR; October 2020] 3. Dermavant DOF. [DMVT-505-3002 CSR; October 2020]

### **Remittive Effect is Unprecedented, and The Hallmark of VTAMA**

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![](_page_19_Figure_1.jpeg)

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### **VTAMA Demonstrated Positive Results in Intertriginous Plaque Psoriasis**

Robust and rapid efficacy in Phase 4 open-label trial of VTAMA for the treatment of intertriginous areas after 12 weeks

![](_page_20_Figure_2.jpeg)

Overall adverse event profile was consistent with previous studies. Most TEAEs were mild or moderate, and only one patient discontinued the trial due to an AE (contact dermatitis).

![](_page_20_Picture_4.jpeg)

\*Patients with baseline PP-NRS score ≥4 who achieve ≥4-point improvement in the PP-NRS from baseline. iPGA, intertriginous Physician Global Assessment; ITT, intention-to-treat; OC, observed cases; PP-NRS, Peak Pruritus-Numerical Rating Scale; QD, once daily. 95% confidence interval calculated using Clopper Pearson method.

#### VTAMA Cream Phase 3 ADORING Program – Trial Design

813 patients down to two years of age with atopic dermatitis in two identical pivotal trials followed by long-term, open-label extension

![](_page_21_Figure_2.jpeg)

Pr	imary Endpoint:	Se	condary Endpoints:	S	afety:	PR	Os:		
•	Proportion of patients with a vIGA-AD <sup>™</sup> score of 0 (clear or 1 (almost clear) and ≥2-grade improvement from baseline at Week 8	) • • •	EASI75 from baseline at Week 8 %BSA affected from baseline at Week 8 EASI90 from baseline at Week 8 Achievement of a ≥4-point PP-NRS reduction at Week 8 <sup>¶</sup>	•	TEAEs, SAEs	•	LTS DLQI/ CDLQI/ IDQOL EQ-5D-5L/ EQ-5D-Y	•	POEM DFI PP-NRS

![](_page_21_Picture_4.jpeg)

\*A minimum of ~15% of patients will be enrolled into the following age groups: 2–6 years, 7–11 years, 12–17 years, and ≥18 years. Adults (≥18 years) will comprise a maximum of approximately 20% of enrolled patients. †Patients with a vIGA-AD<sup>TM</sup> score of 4 (severe) will represent a minimum of ~10% of the total randomized population; the remainder will have a vIGA-AD<sup>TM</sup> score of 3 (moderate). ‡Patients electing not to participate in ADORING 3 will attend a follow-up visit 1 week after completion of the treatment period in ADORING 1 or 2. ¶In patients ≥12 years with a baseline PP-NRS score ≥4. vIGA-AD is the trademark of Eli Lilly and Co.

### **ADORING 1 & 2: Baseline Demographics and Disease Characteristics**

#### 80% pediatric patients and well balanced across pediatric age cohorts

		ADORING 1		ADORING 2					
Patients, n (%)	<b>VTAMA 1% QD</b> (n=270)	Vehicle QD (n=137)	<b>Overall</b> (n=407)	<b>VTAMA 1% QD</b> (n=271)	Vehicle QD (n=135)	<b>Overall</b> (n=406)			
Age, mean (SD)	15.6 (16.62)	15.6 (16.49)	15.6 (16.56)	16.4 (16.24)	16.7 (16.05)	16.5 (16.16)			
Age group, n (%)									
2–6 years	76 (28.1)	39 (28.5)	115 (28.3)	65 (24.0)	32 (23.7)	97 (23.9)			
7–11 years	75 (27.8)	37 (27.0)	112 (27.5)	64 (23.6)	32 (23.7)	96 (23.6)			
12–17 years	67 (24.8)	34 (24.8)	101 (24.8)	89 (32.8)	44 (32.6)	133 (32.8)			
≥18 years	52 (19.3)	27 (19.7)	79 (19.4)	53 (19.6)	27 (20.0)	80 (19.7)			
<b>Male</b> , n (%)	130 (48.1)	66 (48.2)	196 (48.2)	117 (43.2)	58 (43.0)	175 (43.1)			
Weight, kg, mean (SD)	46.69 (27.251)	47.69 (27.725)	47.03 (27.381)	51.52 (29.148)	54.03 (32.005)	52.36 (30.112)			
<b>BMI</b> , kg/m², mean (SD)	21.38 (6.307)	22.06 (6.557)	21.61 (6.392)	22.65 (7.460)	23.25 (8.257)	22.85 (7.729)			
<b>vIGA-AD™,</b> n (%)									
3 – Moderate	244 (90.4)	122 (89.1)	366 (89.9)	228 (84.1)	113 (83.7)	341 (84.0)			
4 – Severe	26 (9.6)	15 (10.9)	41 (10.1)	43 (15.9)	22 (16.3)	65 (16.0)			
EASI, mean (SD)	12.24 (5.007)	12.86 (5.633)	12.45 (5.228)	13.45 (5.615)	13.09 (4.689)	13.33 (5.322)			
BSA affected (%), mean (SD)	16.45 (8.666)	17.71 (9.500)	16.87 (8.964)	17.13 (8.743)	15.84 (7.888)	16.70 (8.480)			
<b>PP-NRS (all),</b> mean (SD)	6.8 (2.33)	6.5 (2.39)	6.7 (2.35)	6.7 (2.37)	6.9 (2.09)	6.8 (2.28)			
<b>PP-NRS (≥12 years),</b> mean (SD)	6.5 (2.40)	6.3 (2.31)	6.4 (2.36)	6.3 (2.36)	6.5 (2.21)	6.4 (2.31)			
PP-NRS (<12 years), mean (SD)	7.0 (2.25)	6.6 (2.46)	6.9 (2.33)	7.1 (2.32)	7.4 (1.82)	7.2 (2.17)			

Baseline disease characteristics reflect moderate to severe patient population; age 2-81 years and mean PP-NRS of 6.7-6.8

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BMI, body mass index; BSA, body surface area; EASI, Eczema Area and Severity Index; PP-NRS, peak pruritus numeric rating scale; QD, once daily; SD, standard deviation; vIGA-AD<sup>TM</sup>, Validated Investigator Global Assessment for Atopic Dermatitis<sup>TM</sup>. Source: 14.1.2.1. Validated Investigator Global Assessment scale for Atopic Dermatitis (vIGA-AD); Eczema area and severity index score (EASI); Body surface area (BSA); Treatment emergent adverse event (TEAE); Serious adverse event (SAE); Dermatology life quality index (CDLQI); Patient Oriented Eczema Measure (POEM); Dermatitis Family Impact (DFI); Patient reported Peak Pruritus Numerical Rating Score (P-NRS); Once-daily (QD)

For investor audiences only

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

![](_page_23_Figure_1.jpeg)

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

![](_page_23_Figure_3.jpeg)

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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)

![](_page_23_Figure_5.jpeg)

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)** 

![](_page_23_Picture_7.jpeg)

\*vIGA-AD<sup>TM</sup> score of 0 or 1 and at least a ≥2-grade improvement from baseline. P-value based upon Cochran-Mantel-Haenszel analysis stratified by baseline vIGA-AD<sup>TM</sup> score and age group. ITT, intention-to-treat; QD, once daily; SE, standard error; vIGA-AD<sup>TM</sup>. Validated Investigator Global Assessment for Atopic Dermatitis<sup>TM</sup>. Source: 14.2.1.1.1. EASI75. ≥75% improvement in Eczema Area and Severity Index score: ITT, intention-to-treat; QD, once daily: SE, standard error; vIGA-AD<sup>TM</sup>, Validated Investigator Global Assessment for Atopic Dermatitis<sup>TM</sup>. Source: 14.2.2.1.1. P-value based upon Cochran-Mantel-Haenszel analysis stratified by baseline vIGA-AD<sup>TM</sup> score and age group. \*Patients with baseline PP-NRS score ≥4 who achieve ≥4-point reduction in the PP-NRS from For investor audiences only baseline. P-value based upon Cochran-Mantel-Haenszel analysis stratified by baseline vIGA-AD<sup>TM</sup>, Validated Investigator Global Assessment for Atopic Dermatitis<sup>™</sup>. Source: 14.2.2.4.1.

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24.1%

Vehicle QD

### **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

	ADOR	ING 1	ADORING 2		
Patients, n (%)	<b>VTAMA 1% QD</b> (n=270)	Vehicle QD (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

## ADORING 2: Primary Efficacy Endpoint – VTAMA Cream Regulatory Success

Rapid response to treatment with VTAMA cream in pediatric patient achieving regulatory endpoint by Week 2

![](_page_25_Figure_2.jpeg)

Example of a representative target lesion of a patient treated with VTAMA cream, 1% once daily in ADORING 2 clinical trial. Individual results may vary.

![](_page_25_Picture_4.jpeg)

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

![](_page_26_Figure_1.jpeg)

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

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

![](_page_27_Figure_1.jpeg)

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.

EASI-75 response rates shown above based on published data, company presentations, and FDA approval labels.

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#### Systemic-Like Efficacy Alongside Exceptional Product Profile as a Non-**Steroidal Once Daily Topical**

		Topical JAK Topical PDE4		Biologics		
	(tapinarof) cream 1%	Opzelura®	ZORYVE®	Eucrisa®	Dupixent®	Adbry®
Studied in Subjects with AD Down to 2 Years Old	$\checkmark$	X	X	$\checkmark$	$\checkmark$	X
Studied in Moderate to Severe AD	$\checkmark$	X	X	X	$\checkmark$	$\checkmark$
Once Daily Dosing	$\checkmark$	X	$\checkmark$	X	X	X
Little to No Systemic Absorption	$\checkmark$	X	X	$\checkmark$	X	×
>45% of Patients Achieved vIGA-AD™* Success	$\checkmark$	$\checkmark$	X	X	X	X
>55% of Patients Achieved EASI75 <sup>†</sup>	$\checkmark$	$\checkmark$	X	X	X	×
>50% 4-point Reduction in Itch <sup>†</sup>	$\checkmark$	$\checkmark$	X	X	X	X

Comparison above is based on USPI or available public information for the referenced products. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.

![](_page_28_Picture_3.jpeg)

\*Primary endpoint in ADORING 2 and INTEGUMENT-1 and 2 measured using the vIGA-ADTM; primary endpoints in other trials measured using IGA or ISGA. †As monotherapy. All data as measured at primary endpoints of vehicle-controlled studies. AD, atopic dermatitis; EASI75, ≥75% improvement in Eczema Area and Severity Index score; IGA, Investigator Global Assessment; ISGA, Investigator's Static Global Assessment; vIGA-ADTM, Validated Investigator Global Assessment for Atopic DermatitisTM. 1. Dermavant, Data on File, March 2023. 2. VTAMA (tapinarof) cream, 1%. Prescribing Information. Dermavant; 2022. 3. Arcutis Biotherapeutics. Press release. Available at: https://www.globenewswire.com/en/newsrelease/2022/12/12/2571826/0/en/Arcutis-Announces-Positive-Topline-Results-from-Second-Atopic-Dermatitis-Pivotal-Phase-3-Trial-of-Roflumilast-Cream-in-Adults-and-Children-Aaed-6-and-Older.html. Accessed March 14. 2023. 4. Zorvye (roflumilast) cream. Prescribing Information. Arcutis Biotherapeutics; 2022. 5. Paller AS, et al. J Am Acad Dermatol. 2016;75:494–503. 6. Eucrisa (crisabole) ointment, 2%. Prescribing Information. Pfizer, Inc.; 2020. 7. Dupixent (dupilumab) injection. Prescribing Information Regeneron Sanofi; 2022. 8. Opzelura (ruxolitinib) cream. Prescribing Information. Incyte; 2022. 9. Papp K, et al. J Am Acad Dermatol. 2021;85:863-72. 10. Adbry (tralokinumab ldrm) injection. Prescribing Information. LEO Pharma; 2022.

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

![](_page_29_Picture_1.jpeg)

#### Differentiated Assets to Address a Range of Patient Needs Are the Goals of Our Development

#### **Batoclimab**

![](_page_30_Picture_2.jpeg)

![](_page_30_Picture_3.jpeg)

**Tailored dosing** to address varying symptom severity across indications and stage of disease

- Short term maximal IgG suppression
- Lower chronic doses where less IgG suppression needed
- Simple subcutaneous delivery with commercially attractive format Multiple pivotal trials ongoing in MG, TED and CIDP

#### **IMVT-1402**

![](_page_30_Picture_9.jpeg)

![](_page_30_Picture_10.jpeg)

**Tailored and chronic dosing** to address symptom severity and duration for extended periods of time (>12 weeks)

- Sustained maximal IgG suppression where needed
- Chronic delivery with simple subcutaneous delivery in seconds
- Simple subcutaneous delivery with commercially attractive format

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

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

![](_page_31_Picture_2.jpeg)

#### NEUROLOGY

Myasthenia gravis (MG) Chronic inflammatory demyelinating polyneuropathy (CIDP) Myositis

Myelin oligodendrocyte glycoprotein antibody disorders

; C t

#### RHEUMATOLOGY

Primary Sjogrens syndrome Systemic lupus erythematosus Rheumatoid arthritis Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis Severe fibromyalgia syndrome

![](_page_31_Picture_8.jpeg)

#### HEMATOLOGY

Autoimmune encephalitis

(MOG-antibody disorder)

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

![](_page_31_Picture_11.jpeg)

#### DERMATOLOGY

Bullous pemphigoid Pemphigus foliaceus Pemphigus vulgaris Cutaneous lupus erythematosus

![](_page_31_Picture_14.jpeg)

## ENDOCRINOLOGY

Thyroid eye disease (TED) Graves' disease

![](_page_31_Picture_17.jpeg)

#### RENAL

Membranous nephropathy Lupus nephritis Antibody-mediated rejection

![](_page_31_Picture_20.jpeg)

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

	Company	Evidence of Greater IgG Reductions Translating to Clinical Benefit
Ю М	argenx ?	Patient-level scatter plot showed that greater IgG declines -> greater MG-ADL improvements
TED	<b>M</b> IMMUNOVANT	Greater IgG reduction across arms $\rightarrow$ higher rates of anti-TSHR antibody reduction and greater clinical response rates
Ъ	argenx	Greater sustained IgG reduction across arms -> higher complete clinical response and lower relapse rates
Ē		Greater IgG reduction across arms $ ightarrow$ greater platelet responses
RA	Janssen	In those patients with greater IgG reduction $\rightarrow$ correlation with greater autoAb reduction $\rightarrow$ correlation with greater clinical response

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\*Many of the analyses above were post-hoc and not all were statistically significant. Cross trial and post-hoc analyses are inherently limited and are presented for hypothesis generating purposes only, nevertheless consistent and numerically positive increases in efficacy were observed as noted above. MG: Myasthenia gravis, TED: Thyroid eye disease, PV: Pemphigus vulgaris, ITP: Immune thrombocytopenic purpura, RA: Rheumatoid arthritis

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#### **Best-in-Class Potential for IMVT-1402 – Why it Matters**

FcRn inhibition is a proven mechanism with broad potential applicability based on targeted reduction of IgG as an improved and more targeted modality

Evidence across broad range of auto-antibody conditions that deeper IgG reduction correlates with greater efficacy

IMVT-1402 demonstrates potentially best-in-class IgG reduction, similar to batoclimab, delivered via a simple subcutaneous injection and with minimal to no impact on albumin and LDL, similar to placebo

Immunovant has the potential to create a unique and class-leading portfolio of indications with IMVT-1402

![](_page_33_Picture_5.jpeg)

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

![](_page_34_Picture_1.jpeg)

#### IMVT-1402 600mg MAD Data Consistent with 300mg MAD Data

Albumin % change over time LDL % change over time IgG % change over time IMVT-1402: Multiple-ascending SC Dose IMVT-1402: Multiple-ascending SC Dose IMVT-1402: Multiple-ascending SC Dose 40% 20% 50% 40% 20% 10% 30% 0% 20% 0% 10% -20% -10% 0% -40% -10% -20% -20% -60% -30% -30% -80% -40% -100% -40% -50% 30 30 ഗ് 20 5 Dav Day Day ----- IMVT-1402: MAD SC 600mg Group Mean ----- IMVT-1402: MAD SC 600mg Group Mean ----- IMVT-1402: MAD SC 300mg Group Mean ----- IMVT-1402: MAD SC 300mg Group Mean ----- IMVT-1402: MAD SC 300mg Group Mean ----- IMVT-1402: MAD SC Placebo (600mg) Group Mean ----- IMVT-1402: MAD SC Placebo (600mg) Group Mean ----- IMVT-1402: MAD SC Placebo (600mg) Group Mean ------ IMVT-1402: MAD SC Placebo (300mg) Group Mean – IMVT-1402: MAD SC Placebo (300mg) Group Mean - IMVT-1402: MAD SC Placebo (300mg) Group Mean

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## IMVT-1402 MAD Data Suggests Potential Best-in-Class IgG Reduction



IgG % change over time



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# IMVT-1402 MAD Data Suggests Potential Best-in-Class IgG Reduction Similar to Batoclimab\*

IgG % change over time



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Dose administration \* Data presented are from separate clinical trials, not a head-to-head study, conducted by
 Immunovant

## IMVT-1402 MAD Data: Minimal to No Albumin Reduction, Similar to Placebo, **After Four Weeks of Dosing**



#### Albumin % change over time

0

5

2

---- IMVT-1402: MAD SC 300mg Group Mean

Day

- IMVT-1402: MAD SC Placebo (300mg) Group Mean

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# IMVT-1402 MAD Data: Minimal to No LDL Increase, Similar to Placebo, After Four Weeks of Dosing



#### LDL % change over time

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## 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 bruise <sup>2</sup>	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

 Participant who discontinued experienced a Mild TEAE. The event was considered not related to study treatment.
 A catheter was used for frequent blood draws TEAE = treatment emergent adverse event; TESAE = treatment emergent serious adverse event

# Portfolio Development for IMVT-1402



# **Creating the Best Portfolio of Indications for IMVT-1402**

Guided by IgG biomarker in proven mechanism with well-characterized safety profile

Addressable population

Unmet patient need

Competitive differentiation

Technical success probability

**Regulatory Pathway** 

Potential to address multiple indications in an exciting class



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

First-in-Class	<ul> <li>Assuming differentiated benefit/risk and simple SC delivery, opportunity to leverage potency of 1402 to further expand applicable patient types for anti-FcRn development</li> <li>Example – Graves' disease</li> </ul>	High unmet need, biologic plausibility
Best-in-Class	<ul> <li>IgG autoantibodies part of disease pathophysiology</li> <li>Insights from later-stage anti-FcRn programs may be leveraged together with 1402 potency to optimize development approach for IMVT-1402</li> <li>Examples – MG, CIDP</li> </ul>	Classic autoAb, class data positive
Best-in-Class	<ul> <li>Other underserved patient populations</li> <li>Potential to enhance PTS via focus on subset of patients with autoantibodies of interest and leverage 1402 potency</li> <li>Examples – Refractory rheumatoid arthritis</li> </ul>	Other auto- immune, class data suggestive

## **Examples of Potential First-in-Class and/or Best-in-Class Indications\***

2

## **Graves' Disease**

Large unmet need between oral anti-thyroid medications (ATD) that work for many & definitive therapies that many others require

Ablative 2L therapy (30K/yr in the US) carries radiation or surgical risks and commits the patient to lifelong thyroid replacement therapy

Remaining euthyroid off ATD, for those who achieve it without definitive therapy, is associated with normalizing stimulating anti-TSHR antibodies

High absolute anti-TSHR antibody titers found in many Graves' patients are likely to require deeper IgG reduction for a durable response

## **Rheumatoid Arthritis**

Large unmet need in refractory rheumatoid arthritis (RA) for patients who fail to respond to more than 1 biologic therapy

Recently presented data for nipocalimab showed a correlation between depth of auto-antibody reduction and clinical response

In the same study, nipocalimab achieved a 58% mean total IgG reduction at trough

Taken together, we believe these points could translate to greater – and meaningful – efficacy in refractory RA with deeper IgG reduction

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

## **IMVT-1402**



Novel, fully human, monoclonal antibody inhibiting FcRnmediated 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\*

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# 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

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





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



Data at Week 7, End of Controlled Portion of Study



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# **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



#### **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

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## Registrational Phase 3 Trial of Batoclimab Designed to Offer MG Patients Tailored Dosing

Top-line data expected in the second half of 2024

primary endpoint\*



Maintain efficacy with anchor dose and lower dose

**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

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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</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 sightthreatening 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>



**Proptosis, eye edema and chemosis**<sup>2</sup> Typical complications in TED patients



1. Horizon Therapeutics estimate on moderate-to-severe TED population based on triangulating data from clinician interactions, surgical procedures, epidemiological publications, and U.S. steroid utilization claims data. 2. Bahn R. Graves' ophthalmopathy. New England Journal of Medicine, 2010. 3. Davies T. and Burch H.B. Clinical features and diagnosis of Graves' orbitopathy (ophthalmopathy), UpToDate, 2018. 4. McAlinden C. An overview of thyroid eye disease. Eye and Vision, 2014. 5. Horizon Therapeutics Investor Presentations. 6. Horizon Therapeutics press release, 2020. 7. Lazarus JH et al. Best Practice & Research Clinical Endocrinology & Metabolism. v26 (2012) 273-279. 8. HCP Qualitative Research, Immunovant, 2020. 9. 2021 Cowen equity Research, March 2022 – surveyed 25 clinicians who treat 3,000+ patients with TED annually. 10. Teprotumumab's US Prescribing Information. 11. Douglas R et al. American Academy of Ophthalmology, No. 4.

# 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%

\*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  $\geq 2$  mm in study eye, without  $\geq 2$  mm increase in non-study eye at same visit.

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# **Two Phase 3 Clinical Trials of Batoclimab in TED Initiated**

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  $\geq$  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

## 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>

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

2. 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-Evssen ME, Blomkwist-Markens PH et al. Recurrences, vaccinations and lona-term symptoms in GBS and CIDP, J Periph Nerv Syst 14(4):310–315 (2009)

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# 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>v</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	<b>Double enrichment:</b> 1.Subjects must worsen after withdrawal / taper of standard of care (e.g. IVIG/SCIG, PLEX, or steroids) on study entry, AND	Not All**	~
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**	~
Steroids are a common standard of care outside the US and often can't be fully tapered, weakening double enrichment	<b>Third enrichment:</b> Primary endpoint on IVIG/SCIG/Plex cohort only to <b>maximize the potential effect size</b>	X	~
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	~



Notes: \*Other anti-FcRn trials in CIDP include efgartigimod, nipocalimab, and rozanolixizumab. \*\*clinical trial designs for efgartigimod in CIDP and nipocalimab in CIDP include double enrichment in trial design. Rozanolixizumab ph2 trial in CIDP did not include double enrichment.

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



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A: Cohorts are defined by CIDP treatment at Screening., B: Participants who fail to worsen by Week 0 will be withdrawn from the study at Week 0., C: Period 1 Non-Responders who complete Period 1 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. Acronyms: 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 57

## 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 U.S.<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
  - 1/4 to 1/3 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)



Moderate-severe symptoms not controlled with ATD (29K-38K)

Persistent need for ATD and wish to avoid thyroid ablation (8K-10K)

Total Addressable Incidence Population of 37K – 48K per year (US) beyond ATD



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







Based on clinicaltrial.gov database, last accessed on 3/24/2023. 2. Lane LC, et al. Endocr Rev. 2020 Dec 1;41(6):873-84
 Additional inclusion and exclusion criteria not listed on slide
 GD = Graves' Disease; ATD = anti-thyroid medications; QW = weekly; SC = subcutaneous injection

# 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	<ul> <li>Clinically meaningful efficacy demonstrated in Psoriasis, Alopecia, Psoriatic Arthritis, Ulcerative Colitis, Hidradenitis Suppurativa, and Crohn's disease</li> <li>Did not meet primary endpoint in Systemic Lupus Erythematosus</li> <li>Safety in line with other JAKs</li> </ul>
Registrational Data in DM Expected in 2025	<ul> <li>Dermatomyositis: Large orphan indication with no NCEs approved in past 60 years and no other oral therapies in late-stage development</li> <li>P3 study ongoing – data expected to read out in 2025 and be sufficient for NDA filing</li> </ul>
Potential for Multiple Additional Large Market Orphan Indications with Rapid Path to Market	<ul> <li>Hidradenitis Suppurativa: Phase 2 results suggest potential for better efficacy than selective JAK1 inhibitors and comparable to leading biologics</li> <li>Non-infectious uveitis: PoC data expected Q1 2024</li> <li>Potential 2024 initiation of a registrational study (e.g., in NIU or HS) and additional POC studies</li> </ul>
Strong Intellectual Property Position	<ul> <li>IP protection expected until at least 2039*</li> </ul>

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



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



#### **Dual Hit**



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

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## Clinical Experience Confirms Oral Brepocitinib is Highly Active and Able to Generate Consistent, Reproducible Clinical Benefit in TYK2- and JAK1-Driven Indications

Statistically Significant and Clinically Meaningful Results in Six Placebo-Controlled Phase 2 Studies

Study Population	N <sup>1</sup>	Brepocitinib Dose	Brepocitinib Primary Endpo	Brepocitinib Primary Endpoint Result	
<b>Alopecia Areata</b> Patients with moderate-to-severe AA	<b>94</b> <sup>2</sup>	30 mg once daily <sup>3</sup>	49.18 placebo-adjusted CFB in SALT Score at week 24	<b>P &lt; 0.0001</b> ⁴	
<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	
<b>Ulcerative Colitis</b> 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	
<b>Plaque Psoriasis</b> 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 daily⁵	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>	



 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)

Brepocitinib 45 mg once daily was the only brepocitinib dose evaluated in this study
 Brepocitinib 60 mg QD was the only brepocitinib dose evaluated in the induction period of this study
 CFB: change from baseline; RR: response rate
 All studies shown here were conducted by Pfizer

## Priovant Strategy: Indications with <u>High Unmet Need</u> and <u>Tailored to Novel</u> <u>Mechanism</u> of dual TYK2 / JAK1 Inhibition



#### Opportunity for brepocitinib to become a **leading treatment option** in **large, uncrowded markets**

	Lead Indication
	DM
Biologically exquisitely suited for dual TYK2/JAK1 inhibition	$\checkmark$
Large unmet medical need with favorable benefit/risk	$\checkmark$
TYK2 and/or JAK1 clinical proof-of-concept	$\checkmark$
NCEs approved in the last 60 years*	0
Approved branded oral drugs*	0
OVERALL OPPORTUNITY	HIGH



## 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>
0-40%	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







4) Sun et al, Sem Arth Rheum (2021)

5) 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



# 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



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

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**Expansion Opportunities** 

**Non-Infectious Uveitis** 

Hidradenitis Suppurativa



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

Opportunity for brepocitinib to become the first approved oral therapy for the treatment of a leading cause of blindness

**30,000** New cases of legal blindness attributable to NIU in the US each year<sup>1</sup>

**>75,000** Patients living with non-anterior NIU in the United States<sup>1</sup>

Light sensitivity, pain, redness and floaters

Idiopathic, or secondary to systemic autoimmune diseases<sup>2</sup>

Approved targeted therapy (Humira)



**Posterior Segment Inflammation** Diffuse areas of capillary leakage and disc hyperfluorescence

 Thorne et al, JAMA Ophthalmol. (2016)

 2)
 De Smet et al, Prog in Ret and Eye Res (2011)

Most Common

Symptoms

Etiology

# Phase 2 POC Study Designed to Provide Rapid Validation of TYK2/JAK1 Approach in NIU

Enrollment complete; topline data expected in Q1 2024



- Phase 2 study of filgotinib confirmed therapeutic relevance of JAK1 inhibition in NIU; TYK2-mediated cytokines (IL-12/23) are also involved in pathobiology
- Success criteria for brepocitinib study: 45mg treatment failure rate of no greater than 70%\*



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# 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

**Comorbidities** 

>2x

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

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

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



Extensive skin involvement with tunnel formation and scarring in a Hurley Stage III (severe) patient



Estimates for moderate/severe HS only; based on Phan et al, Biomed Derm 2020
 Sabat et al, PLoS One (2012)
 Shlyankevich et al, J Am Acad Derm (2014)

Deckers et al, J Am Acad Derm (2017)
 Thorlacious et al, J Invest Dermatol 2018
### 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
- Kimball et al, AAD 2023 Poster 43799

Primary endpoint of upadacitinib 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%.

## **Clear Path To Multi-Billion Dollar Specialty Autoimmune Franchise**

Multiple Catalysts Over the Near and Long Term







### RVT-2001: Potential First-in-Class Small Molecule SF3B1 Modulator for the Treatment of Transfusion-Dependent Anemia in Patients with Lower-Risk MDS

Lower-Risk MDS is a Commercially Validated Market	Encouraging Proof-of-Concept Data	Multipronged Strategy to Optimize RVT-2001's Clinical Impact	Expect Fast, Well-Established Path to Potential Approval	Strong Intellectual Property Position
Transfusion-dependent anemia in MDS has limited treatment options	First-in-class potential as the only known SF3B1 modulator currently in clinical development	Development strategy optimizing dosing, utilizing precision medicine enrollment, and excluding certain	Conducting a robust open-label expansion of an ongoing Phase 1/2 trial	Composition of matter IP protection expected until 2035, before any potential patent term extensions
Luspatercept (Reblozyl), approved for ESA- experienced RS+ MDS in 2020 and ESA-naïve MDS in 2023, with current run rate sales >\$900M; BMS projected potential peak >\$4B <sup>1</sup>	Compelling data in a highly refractory population 80+ subjects treated in Phase 1/2 study; generally well- tolerated <sup>2</sup>	refractory patients Precedent suggests minimal data decay between Phase 2 and Phase 3 <sup>3</sup>	Precedent in the space is a single pivotal study with approximately 200-250 patients <sup>4</sup>	



All product candidates are investigational and subject to regulatory approval. 1. Bristol Myers Squibb filings, July 27, 2023 Earnings Release. 2. Steensma et al., 2021. Data as of January 10, 2022. 3. Platzbecker et al., 2017; Fenaux et al., 2020; List et al., 2006; Fenaux et al., 2011 4. Fenaux et al., 2017; Fenaux et al. 2011; Santini et al. 2016

# High Unmet Need for an Oral Therapy in Transfusion-Dependent Anemia in Lower-Risk MDS

Current treatment options leave significant unmet need in multiple treatment segments



- Lower-risk MDS is a chronic condition; therapy is focused on management of symptoms
- Erythropoiesis-stimulating agents (ESA) or luspatercept used in first line
  - ESA ineffective in >50% of patients, primarily used in patients with low transfusion burden and EPO levels<sup>2</sup>
- Luspatercept and lenalidomide are currently approved for subsets of MDS patients and can have challenging toxicity profiles
  - Luspatercept is ineffective in >50% of second line patients<sup>3</sup>
  - Lenalidomide is approved in patients with del(5q) lower-risk MDS, who make up roughly 10%<sup>4</sup> of the population<sup>4</sup>

#### Initial plan to target second line in SF3B1-mutated patients, with potential to expand to other spliceosome mutations and first line



All product candidates are investigational and subject to regulatory approval. 1. Cogle et al., 2015, prevalence based on midpoint, incidence based on lower end of range using 2021 US population. 2. Carraway et al., 2020, overall response rates of 20% to 40% and an 18- to 24-month duration of response. 3. Cazzola et al. 2020 4. Solé F, Espinet B, Sanz GF, et al. Incidence, characterization and prognostic significance of chromosomal abnormalities in 640 patients with primary myelodysplastic syndromes. 2000

## SF3B1: A Target Uniquely Suited to Improving Anemia in MDS

RVT-2001 is an oral therapy for the treatment of anemia associated with lower-risk MDS that utilizes a novel mechanism to correct aberrant splicing caused by SF3B1 mutations



Genetic knock-in of mutant SF3B1 in mice show progressive anemia (left figure), and recapitulates the impaired erythroid differentiation observed in humans with SF3B1-mutant MDS (right figure)



## **Encouraging Early Data Demonstrate RVT-2001's Clinical Potential**

#### Meaningful Clinical Impact in Refractory Patient Population to Date<sup>1</sup>

- RVT-2001: RBC-TI rate of >30% in Phase 1/2 study in subset of 19 patients with lower-risk, transfusiondependent MDS, 15 of whom had documented prior treatment with lenalidomide and/or HMAs<sup>1</sup>
  - Median duration of treatment for responders of approximately 2 years<sup>1,2</sup>
  - Luspatercept: 13% RBC-TI among patients with prior lenalidomide exposure in Phase 2 trial<sup>3</sup>
  - Lenalidomide: 12% HI-E among patients with prior HMA exposure in investigator-sponsored trial<sup>4</sup>
- RVT-2001 was generally well-tolerated in Phase 1/2 study (n=84 in patients with MDS, AML, and CMML), with the majority of events classified as Grade 1<sup>1</sup>

#### Note: No head-to-head studies of RVT-2001 have been conducted

#### Potential for Improved Therapeutic Effect in Earlier-Line Patients

- Hemavant enrolling earlier-line patients in RVT-2001 trials, who have been more responsive in trials for other therapies to treat anemia associated with lower-risk MDS
  - Luspatercept's ESA-experienced Phase 3 trial excluded prior lenalidomide exposure following reduced RBC-TI responses in Phase 2<sup>3</sup>
    - In a Phase 2 trial, luspatercept showed 44% RBC-TI in patients without prior lenalidomide exposure vs. 13% with prior lenalidomide exposure<sup>3</sup>
  - In an investigator-sponsored trial of patients with lower-risk, non-del(5q) MDS, lenalidomide showed HI-E of 38% prior to HMAs vs. 12% post-HMAs<sup>5</sup>

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All product candidates are investigational and subject to regulatory RBC-TI: Red blood cell-transfusion independence. HMA: Hypomethylating agents. AML: Acute myeloid leukemia. CMML: Chronic myelomonocytic leukemia. Hi-E: Erythroid hematologic improvement

## **Trial Design Intended to Target Improved and Extended Responses**

Robust signal-enhancing design can provide multiple paths to demonstrate value through potential high response rates and/or long duration either in the overall population or in genetically defined subsets

#### **Target Genetically Defined Subpopulations**



- Selectively enrolling lower-risk MDS patients with SF3B1 mutations (~30% of MDS patients)<sup>1</sup>
- Expand dataset in high TMEM14C ratio subset
  - **RBC-TI of 71% (5/7)** among patients in RVT-2001 Phase 1/2 study with the highest levels of aberrant TMEM14C transcripts (as measured by elevated AJ/CJ ratios)<sup>2</sup>
  - High ratios of aberrantly spliced TMEM14C transcripts were associated with SF3B1 mutations<sup>2</sup>

#### **Improve Dosing**

 Strengthen pharmacodynamic effect by optimizing dose and schedule of RVT-2001

#### **Minimal Data Decay**

 Minimal data decay observed historically from Phase 2 to Phase 3 in precedent trials for other therapies in MDS



## Phase 1/2 Ongoing with Recently Added Dose-Optimization Cohort



Primary Efficacy Data: RBC transfusion independence

**Study Objectives:** Determine the recommended Phase 3 dose and frequency, assess safety and tolerability, inform patient selection

## 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

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All product candidates are investigational and subject to regulatory approval.
\* Namilumab is being developed with potentially the least frequent dosing schedule among subcutaneous anti-GM-CSFs in Phase 2 clinical trials, with a single dose every four weeks after an initial loading period
1. Denning, et al. European Respiratory Journal 2013
2. Ishioka S, et al. Sarcoidosis, Vasculitis, and Diffuse Lung Diseases 1996.
3. Itoh A, et al. Respirology 1998
4. Taylor P, et al. Arthritis Res Therapy 2019; Tanaka S et al. International J Pharmacol Therapy 2018; Papp KA et al. J Dermatol 2019; Huizinga TW et al. Arthritis Res Ther. 2017; Unpublished Ph 2 results ankylosing spondylitis; Fisher et al. The Lancet Respiratory Medicine

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## 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>



<u>Clinical consequences:</u> 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





## **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
- Today, LNPs have emerged as 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

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## Genevant Collaborates with Leading Companies for Access to its LNP Technology to Develop Medicines for a Variety of Diseases and Disorders, Including COVID-19

Collaboration 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 and milestones: \$600M	
Takeda	Nonviral gene therapies for up to two rare liver diseases <sup>3</sup>	Royalty rate: undisclosed Upfront and milestones: \$303M	
2seventybio?	Gene editing therapies for hemophilia A <sup>4</sup>	Royalty rate: mid-single digits <sup>†</sup> Upfront and near-term option: \$10M + milestones	
gritstone	Self-amplifying RNA (samRNA) for an unspecified indication <sup>5</sup>	Royalty rate: low to mid-single digits <sup>†</sup> Upfront and milestones: \$73M	
gritstone	Self-amplifying RNA (samRNA) for various infectious disease vaccines <sup>6</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>7</sup>	Milestones and royalties (amounts undisclosed); 50:50 on co-development programs	
Collaboration Partner	LNP Collaborations for COVID-19	Publicly Disclosed Financials*	
<b>g</b> ritstone	Self-amplifying RNA (samRNA) COVID-19 vaccine program <sup>8</sup>	Royalty rate: mid-single to mid-double digits <sup>†</sup> Upfront and milestones: \$192M/product	
ST PHARM	mRNA COVID-19 vaccine program in specified Asian countries <sup>9</sup>	Royalty rate: 8% Upfront and milestones: \$133.75M	
PROVIDENCE	mRNA COVID-19 vaccine program	Undisclosed	
Chalalongidorn University	mRNA COVID-19 vaccine program in specified Asian countries	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.

All trademarks are property of their respective owners. 1. Genevant and Sarepta joint press release, January 13, 2021. 2. Genevant press release, March 15, 2021. 3. Genevant press release, August 23, 2021. 4. 2seventy bio press release, January 6, 2022. 5. Gritstone Oncology 8-K, October 20, 2020. 6. Gritstone press release, August 15, 2023. 7. BioNTech Form F-1, July 21, 2020. 8. Genevant and Gritstone joint press release, January 20, 2021. 9. ST Pharm Korean disclosure document, April 8, 2021.

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## **Updates on Genevant IP Litigation**

- In February 2022, Genevant and Arbutus jointly filed a complaint against Moderna in the US District Court for the District of Delaware asserting infringement of six patents
- On November 2, the federal district court in Delaware 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, which was an attempt by Moderna to shift liability for an unspecified portion of its alleged infringement to the US government and taxpayers
- On February 14, the United States Government filed a Statement of Interest in which it urged the court to rule that
  the government-contractor defense applied to shield Moderna from liability for patent infringement related to the
  first vaccine contract with the Government and force Genevant and Arbutus to assert infringement claims based on
  that contract against the Government in the Court of Claims
- On March 10, the court issued a memorandum opinion in which it reaffirmed the analysis and conclusions in its November 2 opinion and order and refused to grant Moderna's partial motion to dismiss
- On March 21, the court entered a formal scheduling order for pre-trial activities but did not set a trial date and discovery is now ongoing
- On April 4, 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

## 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 ٠ beyond inhibition



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

Ć ναντλί Generative P Induced

Structural Proteomics

#### **Unique proprietary data**



Largest known protein interface structure database

Interface structure data generation at unprecedented speed & scale

AI

#### All star team & scientific leadership

**Including Michael Bronstein, VantAl Chief Scientist** 

#### Validated



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**Trusted** 

partnerships

Multiple preclinical milestones hit

x J x o x Multiple biopharma deal expansions

# Thank you.

