

# Targeted Science, Tailored Solutions



Corporate Presentation March 2023



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### **Our Vision:**

### Normal Lives for People with Autoimmune Disease

Love Trailblazing



Bolder, Faster





All Voices







#### **Our Mission:**

## Build a Leading Anti-FcRn Franchise Targeting Multiple Underserved Autoimmune Disease Indications



- Approximately 100 years of combined experience in drug development and commercialization across C-suite
- Composition of matter patent protection for batoclimab to 2035<sup>1</sup>
- Pending patent protection expected for IMVT-1402 to 2043<sup>1</sup>
- Approximately \$433M cash balance as of 12/31/2022
- Cash runway expected to fund operations into second half of 2025<sup>2</sup>
- FcRn is a validated target following the regulatory approval of efgartigimod
- Differentiated product candidates may offer patients tailored dosing and ease of administration
- 22 indications currently announced or in development across the anti-FcRn class<sup>3</sup>

- 1. Not including any potential patent term extension
- The assumptions upon which we have based our estimates, including expenditures relating to planned or potential clinical trials, are routinely evaluated and may be subject to change
- 3. Indications announced or in development with anti-FcRn assets by Immunovant, argenx, Johnson & Johnson, and UCB



### **Our Leadership Team:**

### A Tight-knit Group of Experienced Executives



Peter Salzmann, MD MBA
Chief Executive Officer



Eva Renee Barnett, MBA
Chief Financial Officer



William L. Macias, MD PhD Chief Medical Officer



Julia G. Butchko, PhD Chief Development and Technology Officer



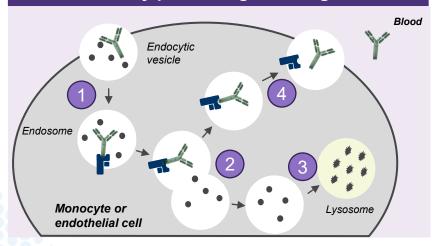
Mark S. Levine
Chief Legal Officer and Corporate Secretary



#### **Our Focus:**

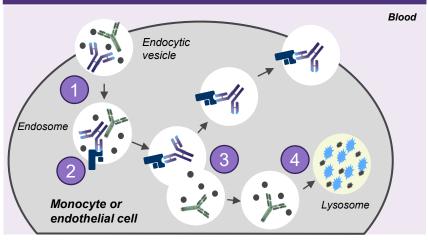
### The Neonatal Fc Receptor (FcRn)

## FcRn maintains levels of antibodies (IgG) in circulation by preventing their degradation



- 1. IgG is taken up into cells in endocytic vesicle
- 2. FcRn-IgG complexes are sorted from unbound proteins
- 3. Unbound proteins are trafficked to lysosome for degradation
- 4. IgG is recycled back into circulation

### FcRn inhibitor blocks binding of IgG to FcRn and promotes their removal and degradation



- 1. IgG and FcRn inhibitor are taken up into cells in endocytic vesicles
- 2. FcRn inhibitor binds to FcRn in endosomes
- 3. IgGs are blocked from forming complexes with FcRn
- 4. Non-receptor bound IgGs are degraded in lysosomes





### **Our Opportunity:**

### Autoimmune Diseases Driven by Pathogenic IgG

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



#### **NEUROLOGY**

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

Myositis

Autoimmune encephalitis

Myelin oligodendrocyte glycoprotein antibody disorders (MOG-antibody disorder)



#### **HEMATOLOGY**

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



#### **ENDOCRINOLOGY**

Thyroid eye disease (TED)
Graves' disease



#### RHEUMATOLOGY

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



#### **DERMATOLOGY**

Bullous pemphigoid Pemphigus foliaceus Pemphigus vulgaris Cutaneous lupus erythematosus



#### RENAL

Membranous nephropathy Lupus nephritis Antibody-mediated rejection

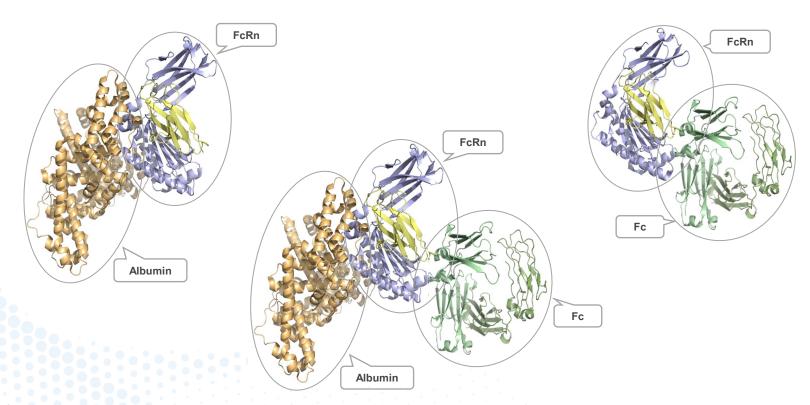


### Anti-FcRn Inhibitors Have Unique Characteristics

		Batoclimab (IMVT-1401) <sup>1</sup>	IMVT-1402 <sup>1</sup>	Efgartigimod <sup>2</sup>	Nipocalimab (M281)³	Rozanolixizumab (UCB7665) <sup>4</sup>	ALXN1830/ SYNT001 <sup>5</sup>
Company	,	Immunovant	Immunovant	Argenx	Janssen	UCB	Alexion/ AstraZeneca
Structure		Human IgG1	Human IgG1	Human IgG1 frag, Fc mutations	Human IgG1	Humanized IgG4	Humanized IgG4
Fc Effecto Potential	or	No	No	No	No	Low	Low
FcRN-lgG Binding- pH 7.4	Affinity (KD)	3.2 nM +++	0.28 nM +++	320 nM +	0.029 nM ++++	0.023 nM ++++	0.87 nM +++
FcRN-lgG Binding- pH 6.0	Affinity (KD)	1.4 nM +++	0.35 nM +++	14.2 nM ++	0.044 nM ++++	0.034 nM ++++	1.19 nM +++
Human Half-life		10-38 hours	Ph1 study planned for 2023	85-104 hours for 2-50 mg/kg	7.82-33.7 hours		0.636-7.779 hours

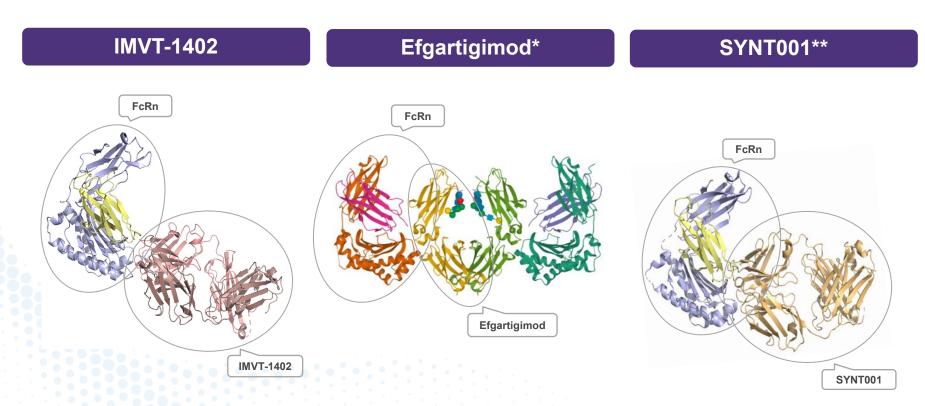


## Fc Portion of Endogenous IgG (Fc) and Albumin Have Different Binding Sites on FcRn



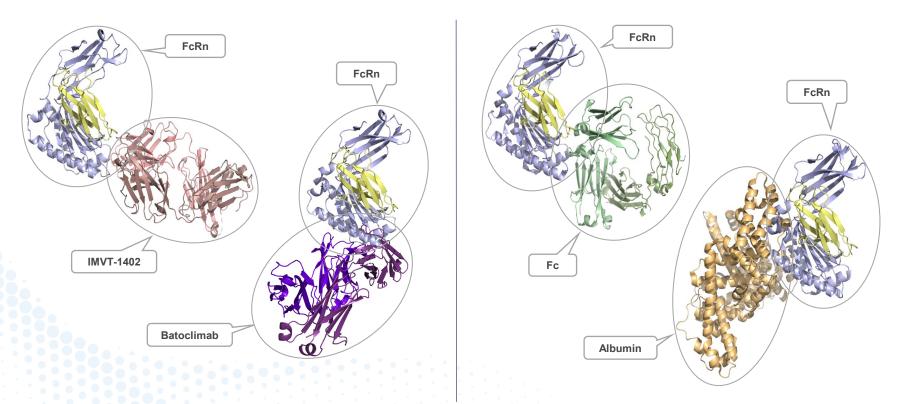


## Co-crystal Structures for FcRn Complexes of IMVT-1402, Efgartigimod and SYNT001





## Co-crystallization Shows IMVT-1402-FcRn Complex Orients Differently from Batoclimab-FcRn Complex

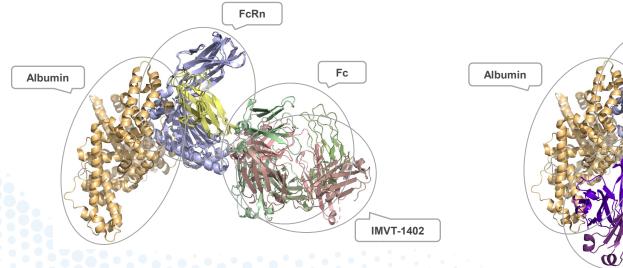


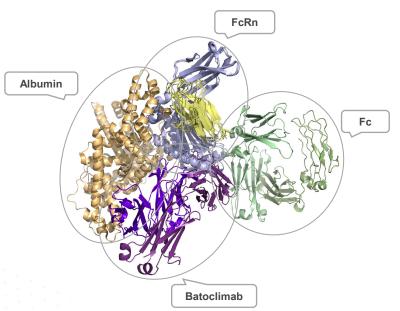


## IMVT-1402 Selected to Deliver Maximum IgG Reduction While Minimizing Interference with Albumin Recycling

IMVT-1402: overlay with albumin and Fc

Batoclimab: overlay with albumin and Fc

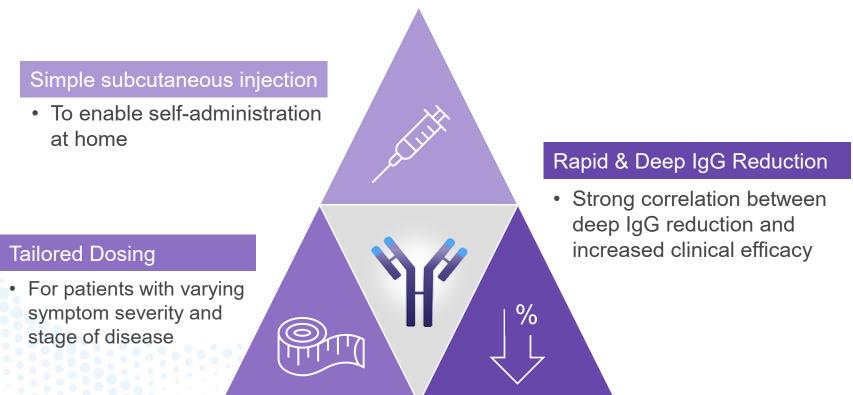






### **Our Value Proposition:**

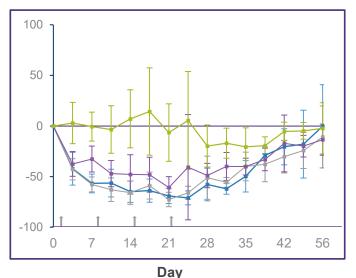
Three Potentially Unique Attributes to Address Unmet Patient Needs

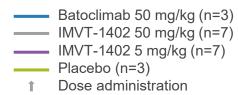




## IMVT-1402 and Batoclimab Each Demonstrated Rapid and Deep IgG Reduction in a Head-to-Head Monkey Study

IgG concentration (mg/mL), mean percent change from baseline ± SD





- 20 monkeys, dosed IV in head-to-head study across four groups
- At comparable doses, IgG lowering is similar for both batoclimab and IMVT-1402
- Cynomolgus monkeys observed to be reliable pharmacodynamic proxy for anti-FcRn mediated impacts on IgG<sup>1,2</sup>

We believe that deeper IgG suppression correlates with the clinical benefits across several anti-FcRn data sets

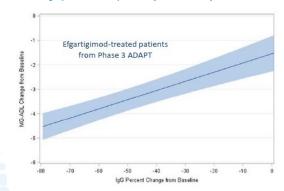


Source: Lledo-Garcia, et al, Pharmacokinetic-pharmacodynamic modelling of the anti-FcRn monoclonal antibody rozanolixizumab: Translation from preclinical stages to the clinic, UCB Pharma, 2022.

2 Data on file at Immunovant

## Strong Correlation Between Deep IgG Reduction and Increased Clinical Efficacy in MG Across Anti-FcRn Assets

The ADAPT Phase 3 trial of IV efgartigimod demonstrated that patients with deeper IgG reductions saw greater improvements in their disease activity (MG-ADL) compared to patients with lesser IgG suppression



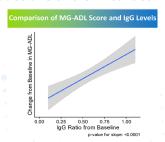
Patient-level data from Efgartigimod (n=84) arm in P3 study

In Batoclimab's (IMVT) Phase 2 trial in MG, we observed deeper IgG and AChR autoantibody reductions correlated with bigger MG-ADL changes

Data at week 7	Placebo (N=6)	Batoclimab 340 mg / week (N=5)	Batoclimab 680 mg / week (N=6)
% Change in total IgG from baseline	-3%	-59%	-76%
% Change in Anti-AChR-lgG from baseline	2%	-54%	-87%
% Change in MG-ADL from baseline	3%	-23%	-38%

While a small n, deeper IgG and anti-AChR autoantibody reductions achieved greater % improvements in MG-ADL

### Nipocalimab Phase 2 trial in MG showed a correlation between IgG reductions and clinical activity





## Multiple Other Autoantibody-Driven Indications Also Suggest Strong Correlation Between IgG Reduction and Clinical Efficacy

Immunovant's Phase 2 trial in TED indicated that reduction in IgG led to greater restoration of normal levels of pathogenic Abs and greater proptosis response rates

	Placebo	Batoclimab 255 mg	Batoclimab 340 mg	Batoclimab 680 mg
Median Max % lgG Reduction Through Week 6*	3%	54%	63%	79%
% Subjects with Stimulatory anti-TSHR Antibody below 140 at Week 6	0%	0%	12%	57%
Proptosis Response Rate at week 6**	0%	11%	29%	43%

\*Week 6 data selected as it represents the latest time point at which the largest amount of patient data is available prior to the voluntary pause. \*\*Post-hoc analysis of proptosis response at week 6. Proptosis response defined as proptosis reduction ≥2 mm in study eye, without ≥2 mm increase in non-study eye at same visit.

In UCB's Phase 2 trial in ITP, higher doses and greater IgG reductions were associated with better platelet responses

Single Dose of Rozanolixizumab	Est. IgG Reduction	Mean platelet count (x10º/L)	% change platelet count (x10º/L)
Day 8			
4 mg/kg	27%*	27	53%
7 mg/kg	27%*	21	53%
10 mg/kg	47%*	41	122%
15 mg/kg	52%	108	409%
20 mg/kg	60%	145	706%

<sup>\*</sup>IgG reduction at day 8 estimated by WebPlotDigitizer for 4mg/kg, 7mg/kg and 10mg/kg doses

#### In efgartigimod Phase 2 in Pemphigus Vulgaris (PV), more intensive dosing regimens led to deeper skin responses

Note: No clinical head-to-head comparisons of Immunovant product candidates and third party anti-FcRn assets has been conducted.

W	IMMUNOVANT

	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Dosing				
Dose	10mg/kg	10mg/kg	10mg/kg	25mg/kg
Induction Dose Regimen	QW, 4 weeks	QW, 4 weeks	QW, 4 weeks	QW, until EoC
Maintenance Dose Regimen	Week 2, Week 6	Q2W, 8 weeks	Q2W, 12 weeks	Q2W, up to 34 weeks
IgG Reduction*				
Est. Max IgG Reduction (Day 28)	-56%	-69%	-62%	-67%
Est. IgG Reduction Day 120	11%	-33%	-52%	-54%
Efficacy <sup>†</sup>				
Complete Response	0%	0%	71%	60%
Relapse	50%	67%	43%	29%

lesions per month that do not heal spontaneously in 1 week, or extension of established lesions, evaluated after DC

Highest doses → highest sustained IgG reduction → higher CRs & lower relapse rates

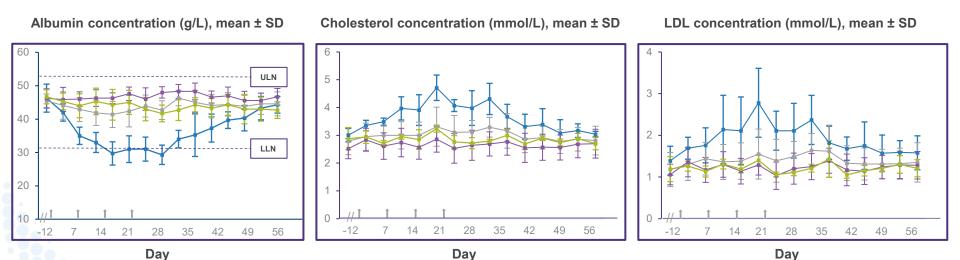
Argenx phase 2 PV/PF publication, Br J Dermatol. 2022 Mar;186(3):429-439; \* Estimated by WebPlotDigitizer † End of Consolidation (EoC): the time at which no new lesions had developed for min. 2 weeks and ~80% of lesions had healed; Disease control (DC): no new lesions and established lesions starting to heal; Complete response (CR): no new lesions and established lesions completely healed; Relapse: Appearance of three or more new

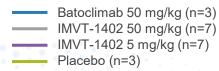
## Consistent Evidence Across All Programs and All Indicators that Greater IgG Reduction Leads to Greater Efficacy

	Company	Evidence of Greater IgG Reductions Translating to Clinical Benefit
<b>(D</b>	**IMMUNOVANT	Greater IgG reductions across arms → greater anti-AChR autoantibody reductions and greater MG-ADL improvements
WG	argenx Janssen J	Patient-level scatter plot showed that greater IgG declines → greater MG-ADL improvements
TED	<b>IMMUNOVANT</b>	Greater IgG reduction across arms → higher rates of anti-TSHR antibody reduction and higher proptosis response rates
A	argenx	Greater sustained IgG reduction across arms → higher complete response and lower relapse rates
Ē		Greater IgG reduction across arms → greater platelet responses



## In a Head-to-Head Monkey Study, We Observed That IMVT-1402 and Placebo Produced Similar Albumin and LDL Effects

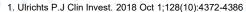






## Albumin Impact in Non-human Primates Translatable to Humans Translatability Observed Across Multiple Anti-FcRn Inhibitors

Product	Impact on Albumin Levels from Baseline				
(Company)	Cynomolgus Monkeys	Clinical Data			
Efgartigimod (argenx)	<ul> <li>Reported no impact on albumin homeostasis<sup>1</sup></li> <li>EMA public assessment report indicates that there was no impact on albumin levels across doses<sup>2</sup></li> </ul>	<ul> <li>Phase 1 reported multiple doses had no impact on albumin levels in humans<sup>1</sup></li> <li>Phase 3 pivotal trials did not identify a safety signal of hypoalbuminemia<sup>3</sup></li> </ul>			
SYNT-001 (Syntimmune)	<ul> <li>Reported no difference in albumin levels from baseline for vehicle, 10, 30, or 100mg/kg<sup>4</sup></li> </ul>	<ul> <li>Phase 1 data showed no difference in albumin levels from baseline following a single dose of vehicle, 1, 3, 10, or 30mg/kg<sup>4</sup></li> </ul>			
Nipocalimab (Momenta / J&J)	<ul> <li>Data not published</li> <li>Momenta management's public commentary indicated that albumin reductions were seen in MAD studies in cynomolgus monkeys<sup>5</sup></li> </ul>	<ul> <li>Phase 1 reported reductions in albumin levels from baseline at 15 and 30mg/kg doses<sup>6</sup></li> <li>Phase 2 showed reductions in albumin levels from baseline at 30 and 60mg/kg<sup>7</sup></li> </ul>			
Rozanolixizumab (UCB)	Reported small reductions (1-13%) in albumin levels from baseline <sup>8</sup>	<ul> <li>Phase 1 reported a small decrease in albumin levels from baseline for both IV and SC (1-5%)<sup>9</sup></li> </ul>			
Batoclimab (Immunovant)	Observed consistent reduction in albumin levels from baseline	Observed dose dependent decreases in albumin levels from baseline			
IMVT-1402 (Immunovant)	No or minimal impact on albumin levels observed from baseline (variability like placebo)	<ul> <li>Initial Phase 1 data (SAD) expected in mid-2023 (Aug/Sept), MAD data expected in Oct/Nov 2023<sup>10</sup></li> </ul>			



<sup>2.</sup> Efgartigimod EMA assessment report - EMA/641081/2022

Eligartigimod Elina assessment report - Elina/04/108/72022
 Efgartigimod FDA integrated review - 7611950rig1s000

<sup>4.</sup> Blumberg LJ. Sci Adv. 2019 Dec 18;5(12):eaax9586

<sup>5.</sup> Stifel research note - Momenta Pharmaceuticals, December 18, 2018

<sup>6.</sup> Ling et.al, Clin Pharmacol Ther. 2019 Apr;105(4):1031-1039.

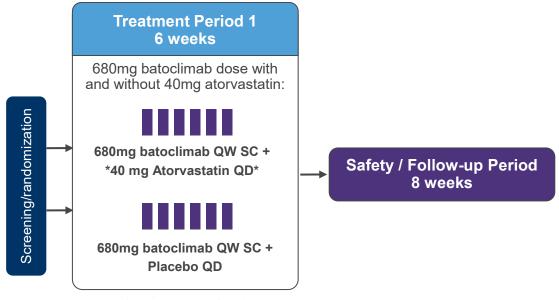
<sup>7.</sup> Momenta Investor Presentation - June 15, 2020

<sup>8.</sup> Smith B, MAbs. 2018 Oct;10(7):1111-1130

<sup>9.</sup> Kiessling P. Sci Transl Med. 2017 Nov 1;9(414):eaan1208

## Cholesterol Elevations Observed with Batoclimab Predictable, Well-understood, and Manageable

Healthy volunteer study initiated to measure LDL impact of concomitant statin therapy with batoclimab

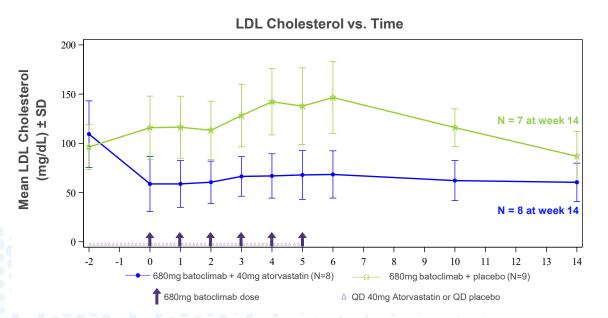


\*40mg atorvastatin dosing initiated 14 days prior to initiation of 680mg batoclimab dosing



## Healthy Volunteer Study Shows Robust LDL Reduction with Co-Administration of Batoclimab and Atorvastatin

Mean LDL cholesterol for first two cohorts of patients reflects impact of statin treatment on LDL cholesterol when co-administered with 680mg batoclimab



#### Distribution of Atorvastatin in US (2019)\*

Diotribution of 7 ttor v	aotatiii iii 00 (2010)		
Strength	% of dispensed products		
80 mg	13.8		
40 mg	36.0		
20 mg	29.1		
10 mg	20.6		
Other, unspecified, or misc.	0.5		

Nominal Time (weeks post first batoclimab dose)



### Key Takeaways on Impact of Batoclimab on LDL Cholesterol

1

### Mechanism is not unique to batoclimab

LDL changes correlated with on target changes in albumin

2

### Cholesterol changes are reversible

Dose dependent changes in LDL returned to normal with cessation of dosing

3

### Cholesterol changes expected to be manageable

Batoclimab dose titration and use of statins or other cholesterol-lowering therapies provide levers for maximizing benefit-risk



### **Our Investigational Product Pipeline**

Anti-FcRn	Target Indication / Therapeutic Area	Stage of Development
	Myasthenia Gravis	Pivotal Phase 3
Dataskasah	Thyroid Eye Disease	Pivotal Phase 3
Batoclimab	Chronic Inflammatory Demyelinating Polyneuropathy	Pivotal Phase 2b*
	Graves' Disease	Phase 2
IMVT-1402	Rheumatology, Hematology, and potentially Graves' Disease	Phase 1



## Myasthenia Gravis



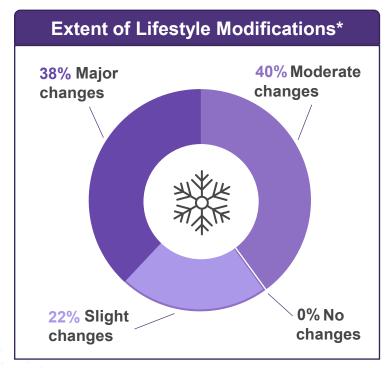


### Myasthenia Gravis (MG)

### An IgG-mediated Autoimmune Disease that Typically Requires Lifestyle Changes

#### **Myasthenia Gravis – Key Takeaways**

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



<sup>\*</sup> Source: MG Patient Quantitative Survey (n=50). Q: What is the extent of lifestyle modifications you make around your myasthenia gravis?





## Current and Emerging Therapies for Myasthenia Gravis Do Not Fully Address Patient Needs

Drug Name	Manufacturer	Mechanism of Action	Phase of Development	Route of Administration	Note
Efgartigimod	argenx	FcRn inhibitor	Approved (12/2021)	Intravenous	Halozyme-enhanced SC pending FDA review
Nipocalimab	Janssen   Johnson-Johnson	FcRn inhibitor	Phase 3	Intravenous	Albumin reduction reported <sup>1</sup>
Rozanolixizumab	ись	FcRn inhibitor	BLA submitted	Subcutaneous infusion	Headaches reported in treated patients <sup>2</sup>
Eculizumab	AstraZeneca 🕏	C5 complement inhibitor	Approved (10/2017)	Intravenous	Has a black box warning for meningococcal infections <sup>3</sup>
Ravulizumab	AstraZeneca 2	C5 complement inhibitor	Approved (4/2022)	Intravenous	Has a black box warning for meningococcal infections <sup>4</sup>
Zilucoplan		C5 complement inhibitor	NDA submitted	Subcutaneous injection	



<sup>1.</sup> Ling LE et al. Clin Pharmacol Ther. 2019 Apr; 105(4): 1031-1039

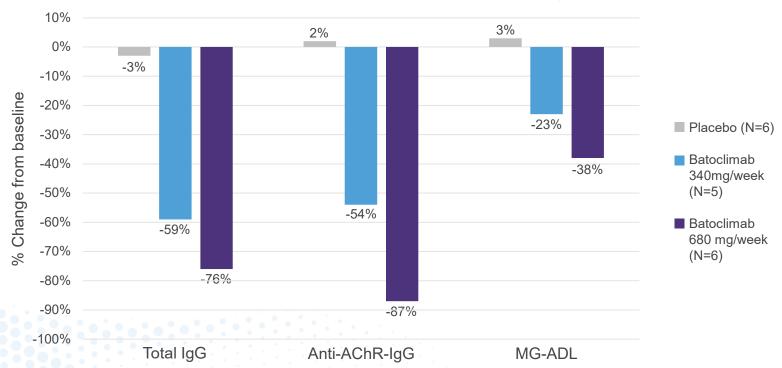
<sup>2.</sup> Bril V, et al. Neurology. 2021 Feb 9;96(6):e853-e865

<sup>3.</sup> https://www.accessdata.fda.gov/drugsatfda\_docs/label/2011/125166s172lbl.pdf

<sup>4.</sup> https://www.accessdata.fda.gov/drugsatfda\_docs/label/2018/761108s000lbl.pdf

## We Observed Encouraging Efficacy Signals in a Phase 2 Trial of Batoclimab in Myasthenia Gravis







## Batoclimab Phase 3 Trial Designed to Address Unmet Patient Needs Flexible Design First for a Myasthenia Gravis Trial but Common in Immunology



### INDUCTION PHASE

Gain control

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



#### MAINTENANCE PHASE

Keep control

 Lower dose designed to maintain efficacy with potentially fewer side effects

#### **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



### LONG-TERM EXTENSION

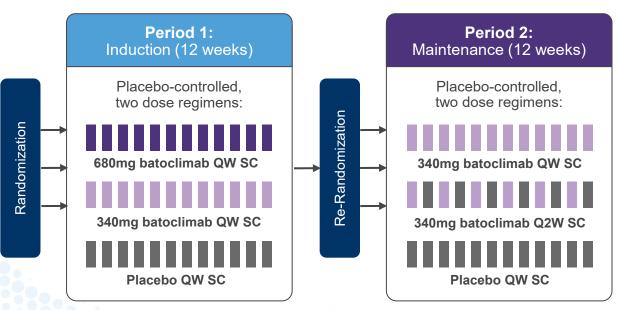
Optimize control

Rescue therapy available



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

Top-line data expected in the second half of 2024



Maximize efficacy through 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.



## Batoclimab Potentially Well Positioned to Compete in Myasthenia Gravis Market



#### **Efgartigimod**

IV administration, bridging to Halozyme-enhanced SC administration

4 infusions, 10 mg/kg QW additional cycles based on loss of response

Symptomatic exacerbations treated with additional intravenous cycle



#### **Batoclimab**

Simple SC administration

Continuous dosing via induction, maintenance (3 different doses)

Dose increase and dose decrease allowed in LTE based on symptoms



#### **Nipocalimab**

IV administration

15 mg/kg Q2W for 22 weeks, after single loading dose of 30 mg/kg

Dose decrease allowed in LTE



## Thyroid Eye Disease

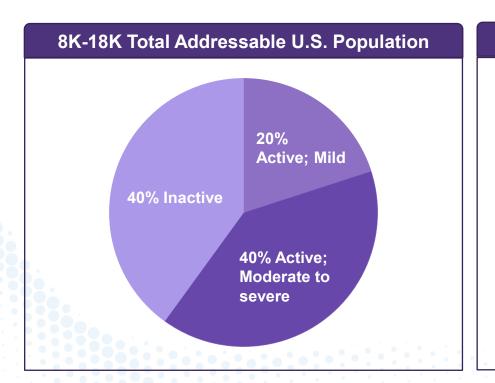






### Thyroid Eye Disease (TED)

A Heterogeneous Condition that Presents with a Variety of Clinical Symptoms



#### Thyroid Eye Disease - Key Takeaways

- Teprotumumab is the only approved treatment specifically for TED
  - Treatment period is relatively short (~24 weeks)
     and disease recurrence is common
- 14% of TED patients, and a far higher proportion among active moderate or worse disease, are on teprotumumab and/or immunosuppressants
  - Audiological side effects of teprotumumab could enable greater market share capture by competitor



## Unique Dynamics of TED Market Create Potentially Favorable Commercial Opportunity for New Therapeutic Approaches



Reimbursement is often strictly to label for specialty products TED products will likely continue to be labeled for a fixed duration equal to the controlled period of the registration trials



In the OPTIC 48-week off-treatment follow-up period<sup>1</sup>, 44% of teprotumumab patients who were proptosis responders at Week 24 in OPTIC were not proptosis responders at Week 72 illustrating the opportunity for additional treatment



We anticipate that patients who do not maintain their proptosis response will be candidates for a new mechanism of action

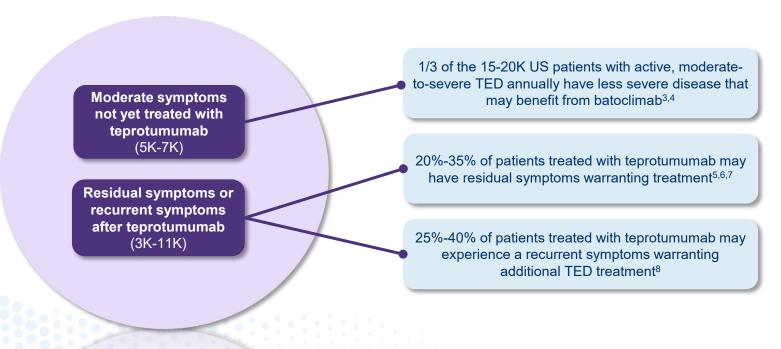


We believe that a simple subcutaneous route of administration is also important to patients, and perhaps more so during retreatment due to total duration



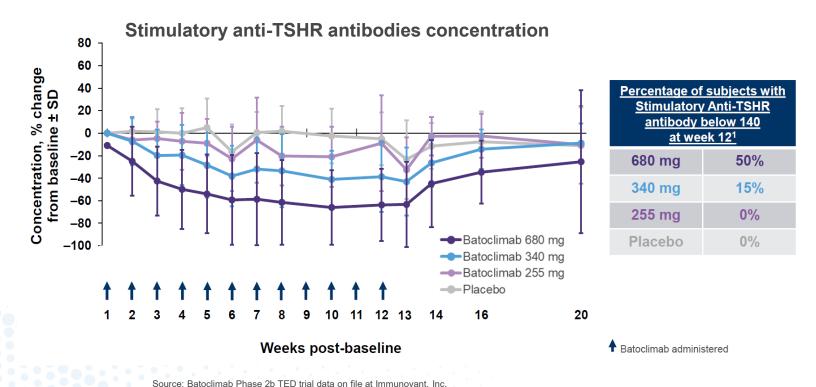
## We Believe Batoclimab is Well Positioned to Capture Significant Thyroid Eye Disease Market Share

#### Batoclimab is the first FcRn inhibitor targeting TED<sup>1,2</sup>





### Encouraging Pharmacodynamic Signals Observed from Phase 2b Trial of Batoclimab in Thyroid Eye Disease

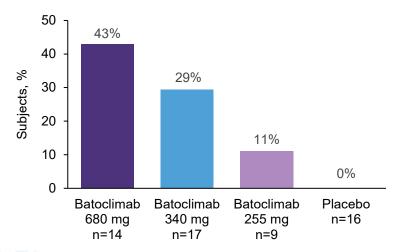




1SRR is the "Sample to Reference Ratio". This cell-based assay readout is the ratio of the sample signal to that of a reference control, expressed as %. A value less than 140 is considered negative for stimulatory antibody; a value greater than or equal, positive for stimulatory antibody. The efficacy of batoclimab and clinical outcomes were deemed inconclusive, in part, because the study was terminated early.

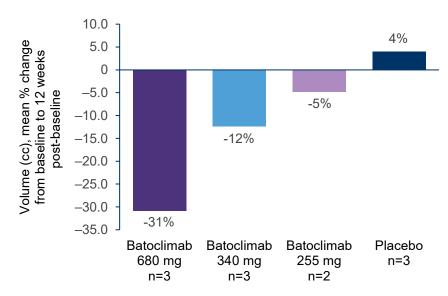
## Additional Early Efficacy Signals Observed from Phase 2b Trial of Batoclimab in Thyroid Eye Disease

#### Post-hoc analysis of proptosis response at week 61



Effect size similar at week 12 though confidence intervals wide

Total muscle volume at 12 weeks post-baseline in all subjects with baseline and end of treatment CT scans



CT: computed tomography.

Represents all patients who had a baseline and week 12 CT scan, a subset of all study participants.

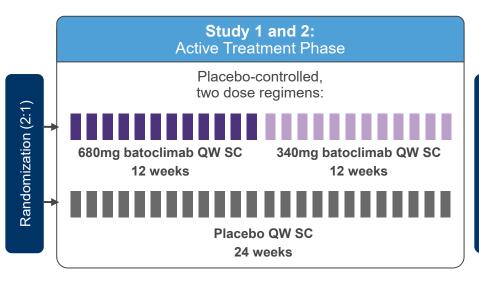


<sup>1</sup> Proptosis response defined as proptosis reduction ≥2 mm in study eye, without ≥2 mm increase in nonstudy eye at same visit. Week 6 data selected as it represents the latest time point at which the largest amount of patient data is available prior to the voluntary pause

#### Two Phase 3 Clinical Trials of Batoclimab in Thyroid Eye Disease Initiated



- 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



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

(4 weeks)

Follow up

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

**Primary endpoint:** 

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

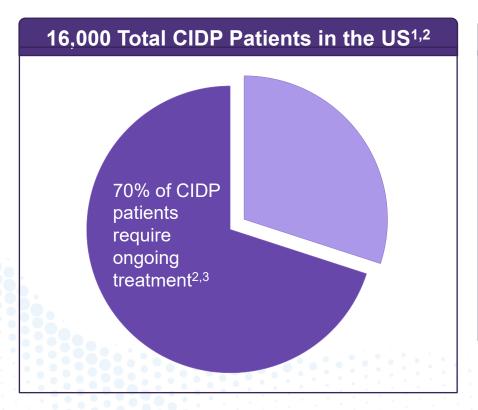


# Chronic Inflammatory Demyelinating Polyneuropathy





### Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) An Important Disease in Neurology & Exciting Opportunity for the Anti-FcRn Class



#### **CIDP - Key Takeaways**

- Current therapies (IVIg, plasma exchange, and steroids) are effective, but have significant side effects and logistical limitations (IVIg & plasma exchange).
- CIDP represents 22% of total IVIg market by volume
  - ~\$3B in global annual sales for IVIg in CIDP<sup>4</sup>
- Target population patients with active CIDP

Sources: 1. Broers M, et al (2019) Incidence and prevalence of CIDP: a systematic review and meta-analysis. Neuroepidemiology 52(3–4):161–172; 2. Querol, L., et al. Systematic literature review of burden of illness in chronic inflammatory demyelinating polyneuropathy (CIDP). J Neurol 268, 3706–3716 (2021).; 3. Kuitwaard K, Bos-Eyssen ME, Blomkwist-Markens PH et al (2009) Recurrences, vaccinations and long-term symptoms in GBS and CIDP. J Periph Nerv Syst 14(4):310–315. <a href="https://doi.org/10.1111/j.1529-8027.2009.00243">https://doi.org/10.1111/j.1529-8027.2009.00243</a>; 4. CSL Behring R&D Investor Briefting, 2021.



### A Differentiated Approach to Developing an Anti-FcRn as a Chronic Treatment for CIDP

1

### CIDP is an exciting indication that is ripe for disruption

• Given disease complexity, trial design is critical

2

# Pivotal study optimized versus historical and current studies

 To improve probability of success and effect size, and include multiple doses for optimal differentiation 3

## Potential best-in-class efficacy and simple subcutaneous administration

 Representing meaningful innovation for patients with this chronic disease



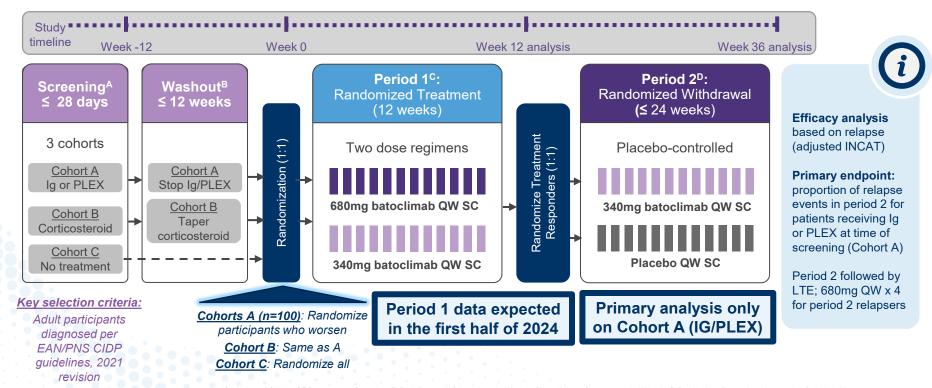
### Key Learnings from Historical and Ongoing CIDP Trials Applied to Address Challenges Unique to CIDP

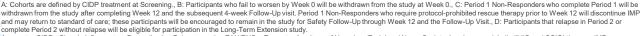
Trial risks	Mitigations	Mitigation included in other anti-FcRn Trials*	Mitigation included in IMVT trial
Disease heterogeneity and challenging diagnosis	Diagnostic algorithm	X	<b>✓</b>
Mix of active and inactive disease among those enrolled creates risk of low relapse rate in the placebo arm, thereby shrinking potential effect size for the investigational product	care (e.g. IVIG/SCIG, PLEX, or steroids) on study entry, AND	Not All**	<b>~</b>
Patients enrolled in placebo arm of trial may not have demonstrated initial response to investigational product	Subjects must then improve on open label investigational product	Not All**	<b>~</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>~</b>
Lack of dose exploration	Data on <b>multiple doses</b> in "Period 1" of trial will inform future development strategy	X	<b>~</b>
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>~</b>

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



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





#### Batoclimab and IMVT-1402 Provide Strategic Options in CIDP

Open-label period from batoclimab Phase 2b trial in CIDP to potentially inform IgG reduction and clinical efficacy



Planned Phase 1 trial of IMVT-1402 to provide dosage and dosing schedule for IMVT-1402 in future trials



Learnings from both trials combined to determine which asset(s) to develop in CIDP



### Graves' Disease

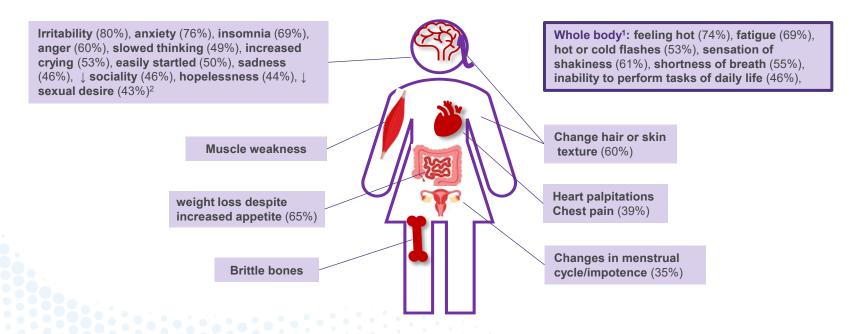
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### Systemic Graves' Disease Impacts Multiple Organ Systems Leaving Many Patients with Substantial Symptoms

#### Graves' disease incidence 116K / year 3,4





### Current Standards-of-care for Graves' Disease Have Well-documented, Potentially Serious Safety and Tolerability Concerns

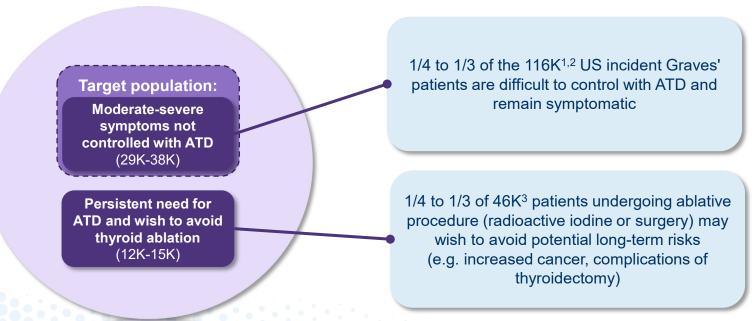
	Safety			Tolerability		
SoC Treatments	Risk of liver damage	Risk of secondary cancers	Risk of low blood cell counts	Invasive	Rash/Itching	Hypothyroidism risk and fatigue
Anti-Thyroid Medicines	<b>✓</b>	х	<b>✓</b>	X	<b>✓</b>	<b>✓</b>
Radioiodine	X	<b>✓</b>	X	X	x	<b>✓</b>
Surgery	X	х	X	<b>*</b>	x	✓

<sup>\*</sup>Surgical risks include laryngeal nerve damage, hypoparathyroidism and bleeding



#### Large Population of Underserved Patients with Graves' Disease

Total addressable <u>incidence</u> population of 41K – 53K <u>per year</u> (U.S.) beyond anti-thyroid drug (ATD)





### Graves' Disease Represents Potential First-in-class Opportunity for Anti-FcRns and Meaningful Expansion in Endocrinology

1

Graves' disease represents first-in-class opportunity for anti-FcRns in an indication with substantial need beyond 1L therapy with ATD

2

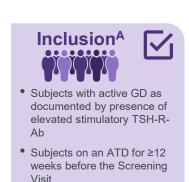
Poor QOL in Graves' disease patients who do not respond to ATD is primarily related to hyperthyroidism that is directly linked to autoantibodies

3

Potent FcRn inhibition has the potential to lower stimulating anti-TSHR antibodies and may thereby improve hyperthyroidism in ATD insufficient responders

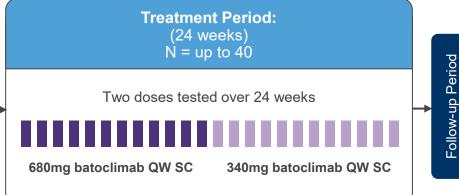


#### The First and Only Anti-FcRn Program Targeting Graves' Disease<sup>1,2</sup>



 Subjects hyperthyroid despite ATD







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

Period

Stable ATD dose ATD tapered during treatment period ATD if needed at screening **ATD treatment:** 



#### A Potential Targeted Therapy for Graves' Disease

Large unmet need in Graves' disease

Our Phase 2 trial will enroll patients who have elevated thyroid hormone levels despite treatment with ATDs

High scientific rationale and encouraging initial data\*

Graves' disease is a classic autoantibody condition and interesting anecdotal data from TED 2b trial

Phase 2 significantly derisking for development program in Graves' disease

Phase 2 trial designed to further define dose-response and time course to inform potential Phase 3; patient population and trial endpoints likely the same

Initial Phase 2 data expected in the second half of 2023



### Building a Leading Anti-FcRn Franchise







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

#### **Batoclimab**





**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
- Fixed duration dosing in certain conditions

#### **IMVT-1402**





Tailored and chronic dosing to address symptom severity and duration for extended periods of time (>12 weeks)<sup>1</sup>

- Sustained maximal IgG suppression where needed
- Chronic delivery with simple subcutaneous delivery in seconds
- No or minimal impact to albumin / LDL



#### Potential Synergy in Clinical Development

Learnings from Batoclimab Potentially Leverageable to Accelerate IMVT-1402 Development

#### Potential synergy for IMVT-1402 development in Graves' disease

Batoclimab Phase 2 trial in Graves' disease to potentially inform future pivotal trial design and effect size



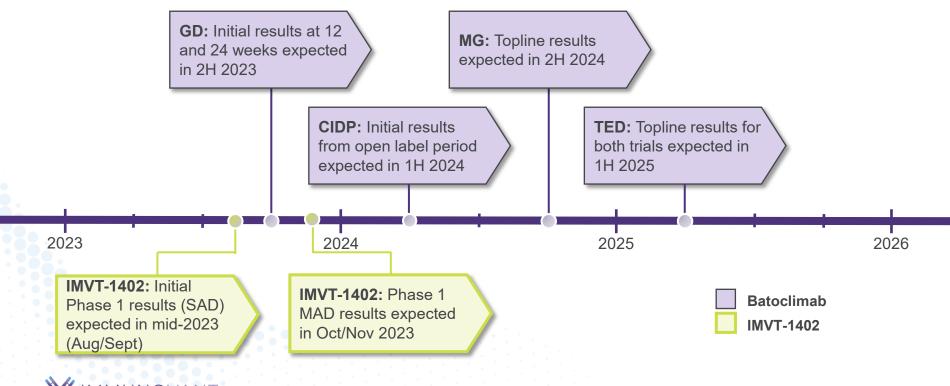
Planned Phase 1 trial of IMVT-1402 to provide dosage and dosing schedule for IMVT-1402 in future trials



Learnings from both trials combined to potentially accelerate IMVT-1402 to pivotal trial in Graves' disease



### Expected Cadence of Key Catalysts Every 6 Months for Potential Sustained Value Creation



#### **Our Vision:**

#### Normal Lives for People with Autoimmune Disease

Love Trailblazing

Potentially first to develop subcutaneous anti-FcRn that can be administered in seconds



Bolder, Faster

Complementary anti-FcRns potentially enable accelerated development pathways



All Voices

Cultivating broad network of experts to optimize multiindication development plan





# Thank you

**M**IMMUNOVANT