



# Targeted science, Tailored solutions

*for people with autoimmune disease*



Portfolio Update  
November 28, 2023



# Forward-Looking Statements

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# Our Vision:

## Normal Lives for People with Autoimmune Disease

### What we do:

We are developing targeted therapies that are designed to address the complex and variable needs of people with autoimmune diseases.



**Love  
Trailblazing**



**Bolder,  
Faster**



**All  
Voices**



# Goals for the Phase 1 Program

**Demonstrate potential best-in-class IgG reductions similar to batoclimab**



**Demonstrate minimal to no impact on albumin**



**Demonstrate minimal to no impact on LDL**



**Achieve all of the above with a simple, commercially attractive subcutaneous injection**



# 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



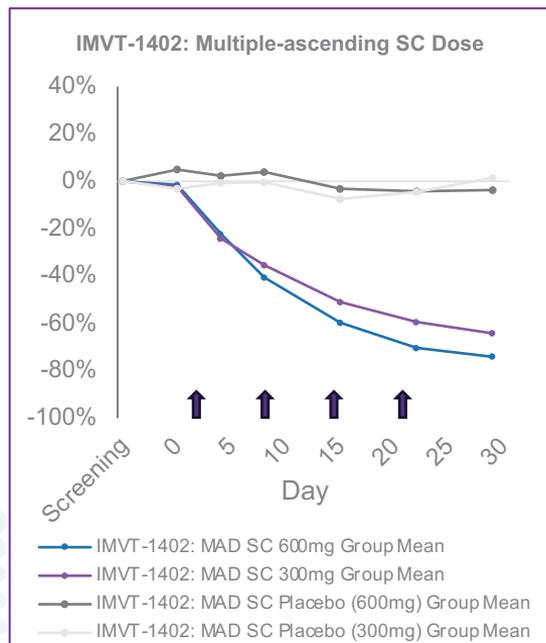
Immunovant has the potential to create a unique and class-leading portfolio of indications with IMVT-1402

# Multiple-Ascending Subcutaneous Doses

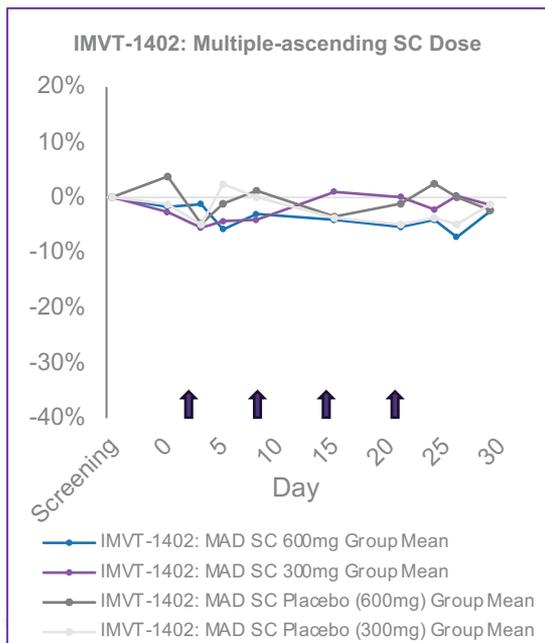
(Once-weekly dosing x 4 weeks)

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

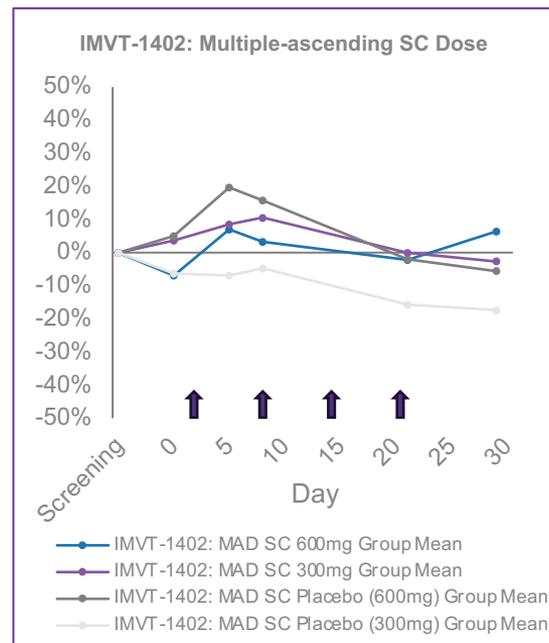
## IgG % change over time



## Albumin % change over time

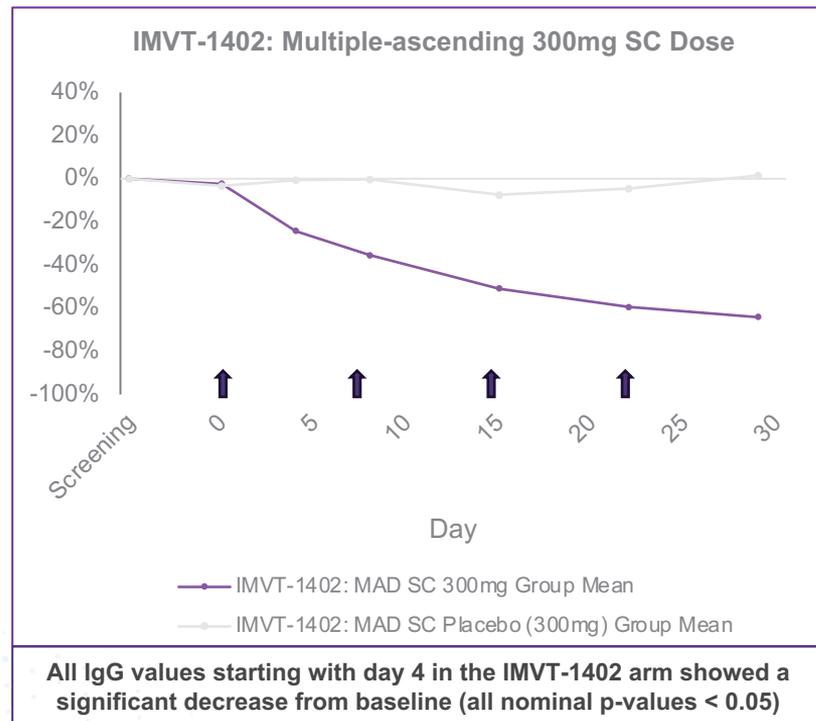
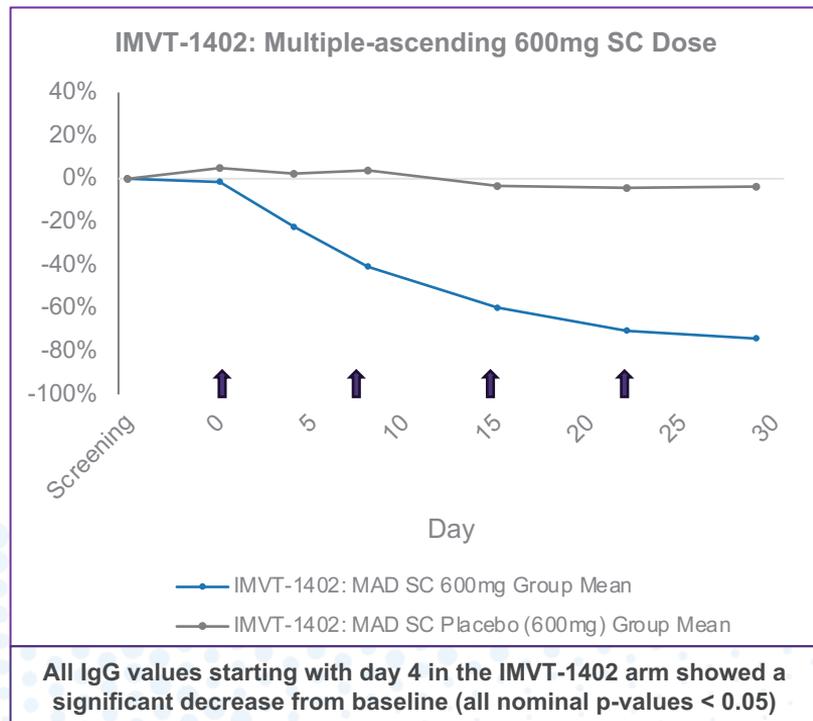


## LDL % change over time



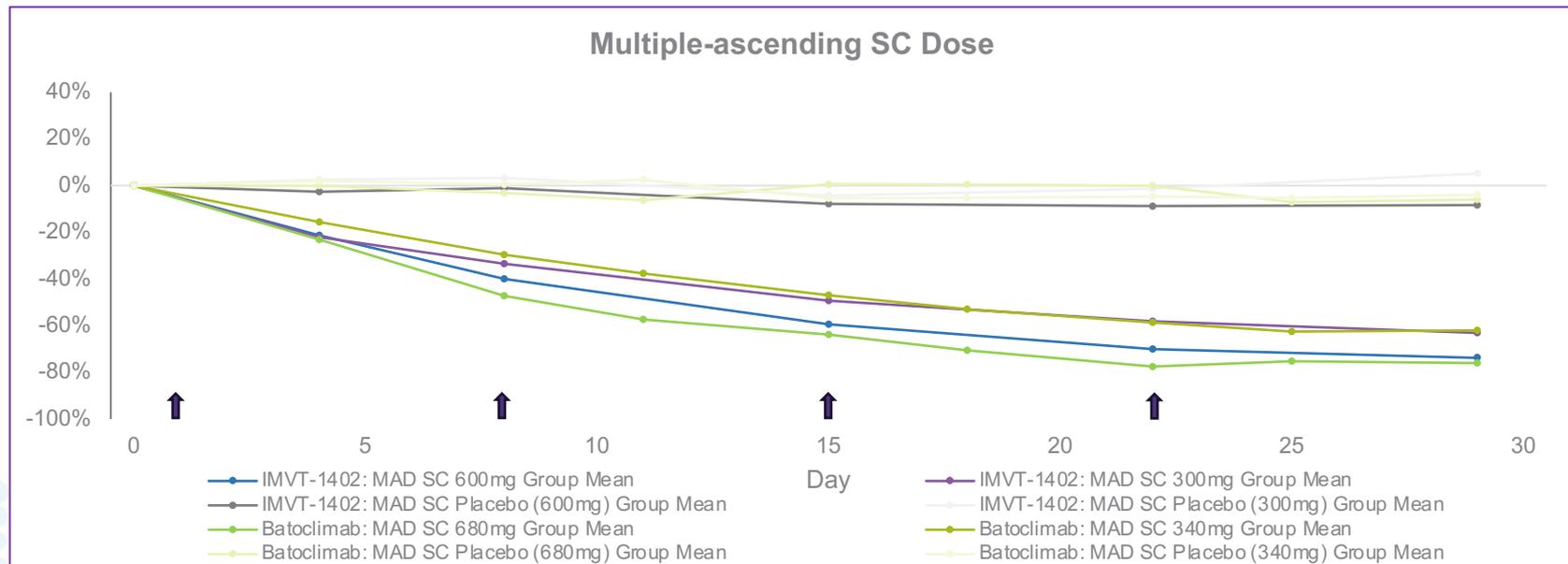
# IMVT-1402 MAD Data Suggests Potential Best-in-Class IgG Reduction

IgG % change over time



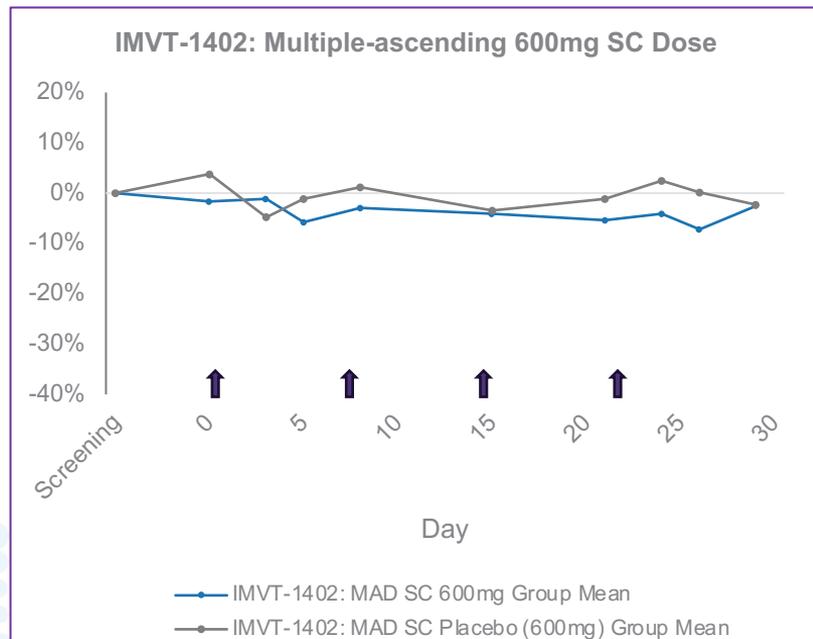
# IMVT-1402 MAD Data Suggests Potential Best-in-Class IgG Reduction Similar to Batoclimab\*

IgG % change over time

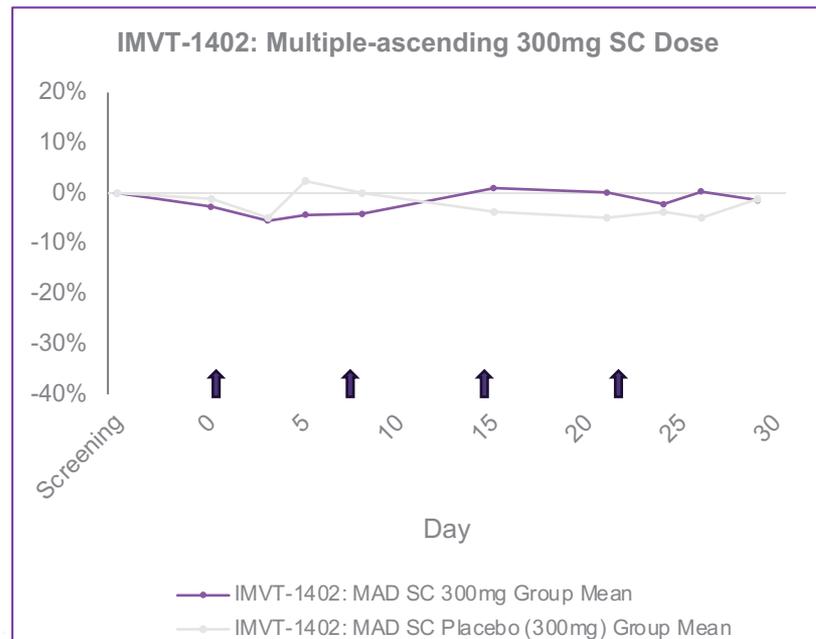


# IMVT-1402 MAD Data: Minimal to No Albumin Reduction, Similar to Placebo, After Four Weeks of Dosing

## Albumin % change over time



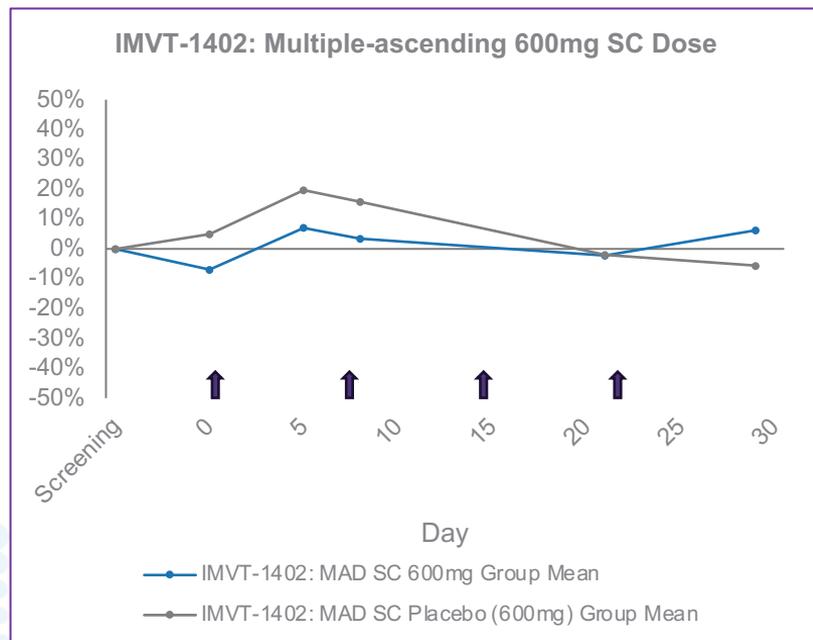
Albumin value at Day 29 (peak pharmacodynamic impact) did not show a significant decrease from baseline (nominal p-values > 0.05)



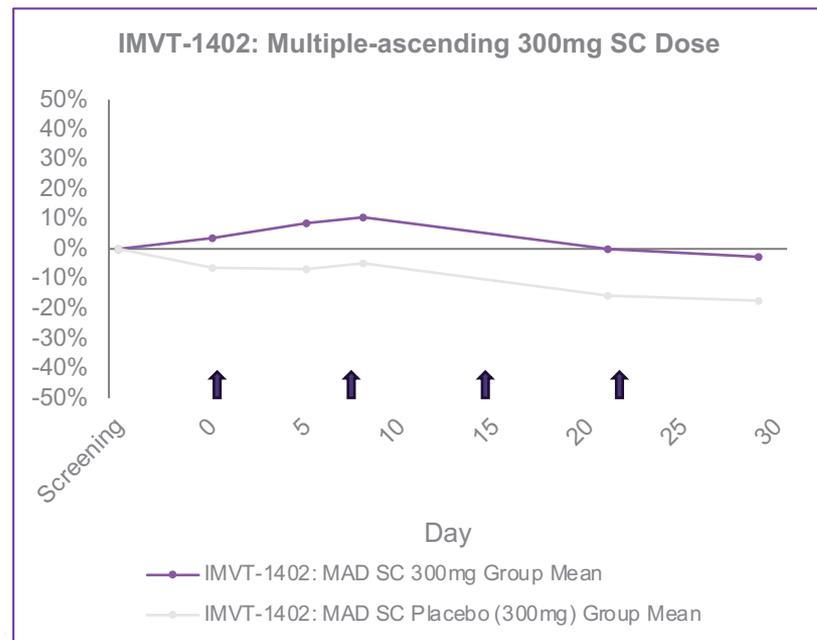
Albumin value at Day 29 (peak pharmacodynamic impact) did not show a significant decrease from baseline (nominal p-values > 0.05)

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

LDL % change over time



**LDL value at Day 29 (peak pharmacodynamic impact) did not show a significant increase from baseline (nominal p-values > 0.05)**



**LDL value at Day 29 (peak pharmacodynamic impact) did not show a significant increase from baseline (nominal p-values > 0.05)**

# 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
<b>TEAE (≥ 2 Participants in any 1402 treated cohort)</b>						
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**

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

2. A catheter was used for frequent blood draws

TEAE = treatment emergent adverse event; TESAE = treatment emergent serious adverse event

# IgG Reduction and Clinical Efficacy Correlation

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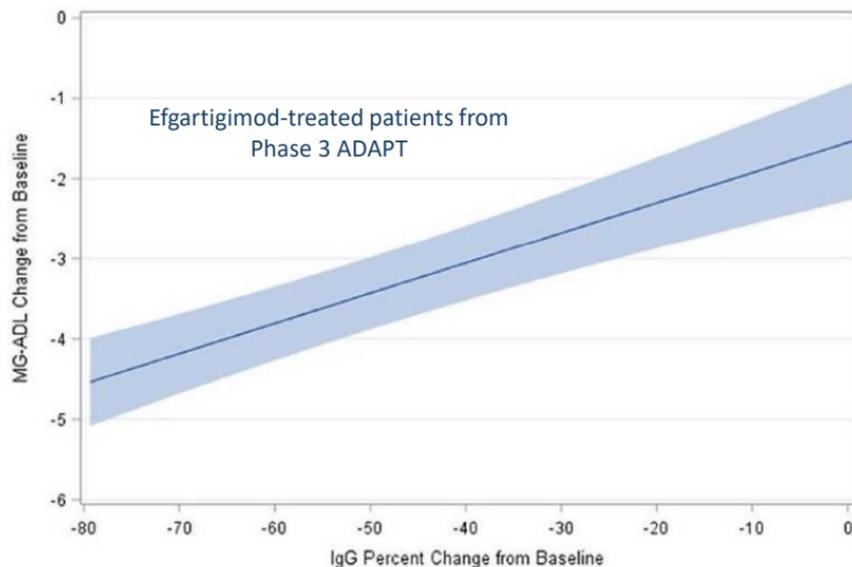
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# Consistent Evidence Across Programs and Indications that Greater IgG Reduction Leads to Greater Efficacy\*

	Company	Evidence of Greater IgG Reductions Translating to Clinical Benefit
MG	 	Patient-level scatter plot showed that greater IgG declines → greater MG-ADL improvements
TED		Greater IgG reduction across arms → higher rates of anti-TSHR antibody reduction and greater clinical response rates
PV		Greater sustained IgG reduction across arms → higher complete clinical response and lower relapse rates
ITP		Greater IgG reduction across arms → greater platelet responses
RA		In those patients with greater IgG reduction → correlation with greater autoAb reduction → correlation with greater clinical response

# Efgartigimod MG and PV Data Showed Higher Clinical Response with Deeper IgG Reduction

ADAPT Phase 3 trial of IV efgartigimod in MG showed a correlation between IgG reductions and clinical response



Source: argenx JP Morgan Healthcare Conference Presentation January 2021

In efgartigimod Phase 2 in PV, more intensive dosing regimens led to deeper skin responses

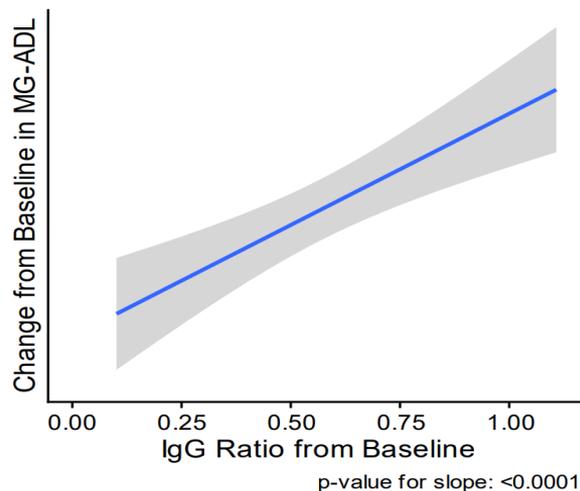
Dosing	Cohort 1	Cohort 2	Cohort 3	Cohort 4
<i>Dosing</i>				
Dose	10mg/kg	10mg/kg	10mg/kg	25mg/kg
Induction Dose Regimen	QW, 4 weeks	QW, 4 weeks	QW, 4 weeks	QW, until EoC
Maintenance Dose Regimen	Week 2, Week 6	Q2W, 8 weeks	Q2W, 12 weeks	Q2W, up to 34 weeks
<i>IgG Reduction*</i>				
Est. Max IgG Reduction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

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

# Nipocalimab MG and RA Data Showed Higher Clinical Response with Deeper IgG Reduction

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

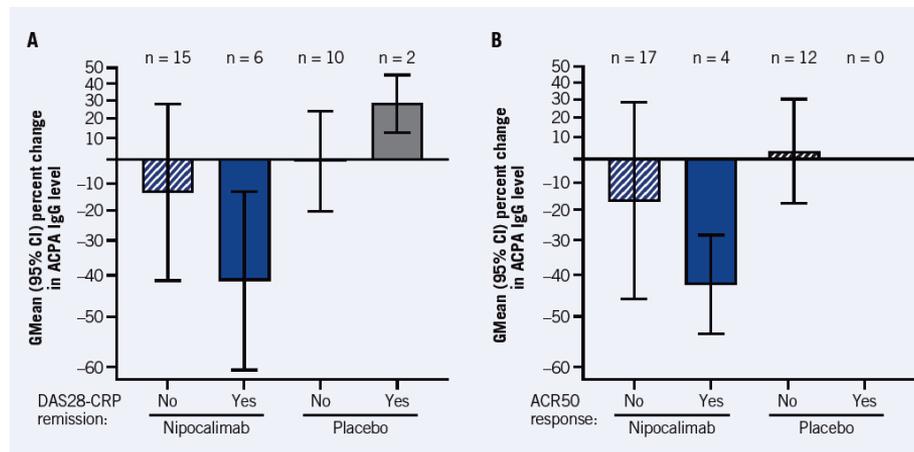
## Comparison of MG-ADL Score and IgG Levels



Source: Momenta Vivacity-MG Interim Phase 2 Investor Presentation, 2020

Nipocalimab Phase 2 trial in RA showed a correlation between auto-Ab reductions and clinical response

Figure 4. Percent Changes From Baseline at Trough in ACPA IgG (Anti-CCP2) Levels Versus (A) DAS28-CRP Remission and (B) ACR50 Response at Week 12



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

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

# 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.

# Rozanolixizumab ITP Data Showed Higher Clinical Response with Deeper IgG Reduction

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

Single Dose of Rozanolixizumab	Data at Day 8		
	Estimated IgG Reduction	Mean platelet count (x109/L)	% change platelet count (x109/L)
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%

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



# Portfolio Development for IMVT-1402

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



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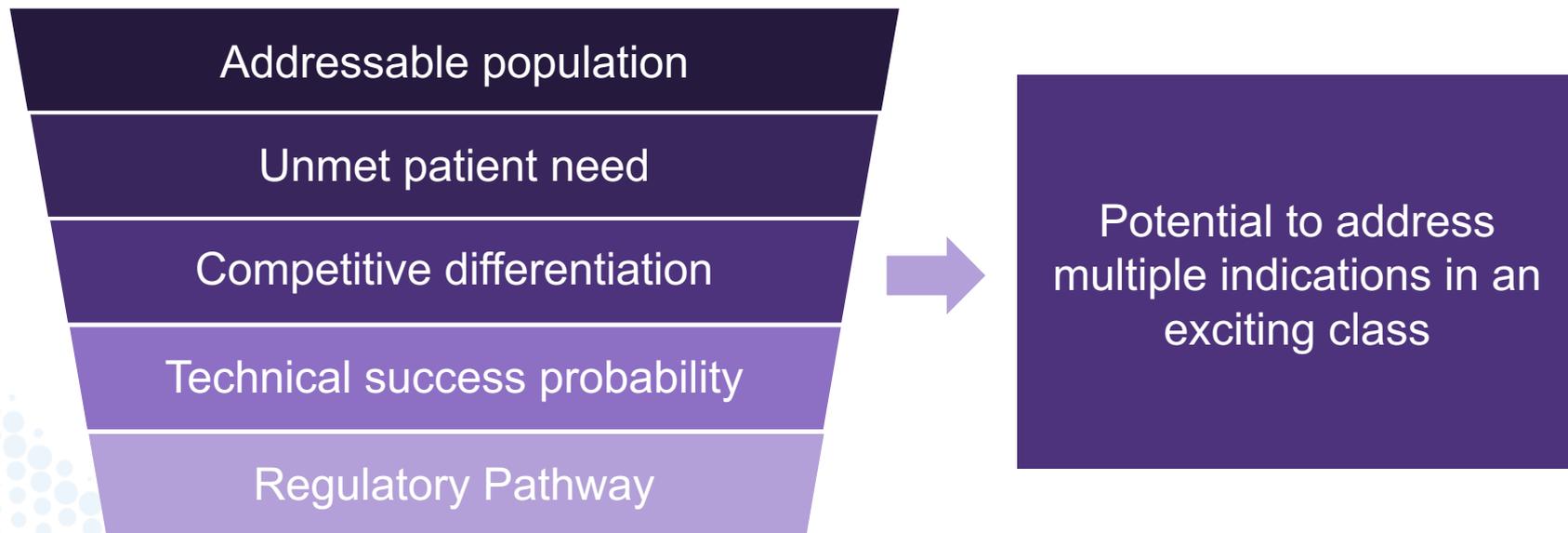
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# Creating the Best Portfolio of Indications for IMVT-1402

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



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

## First-in-Class

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

**High unmet need, biologic plausibility**

## Best-in-Class

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

**Classic autoAb, class data positive**

## Best-in-Class

- Other underserved patient populations
- Potential to enhance PTS via focus on subset of patients with autoantibodies of interest and leverage 1402 potency
- Examples – Refractory rheumatoid arthritis

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

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

## Graves' Disease

- 1 Large unmet need between oral anti-thyroid medications (ATD) that work for many & definitive therapies that many others require
- 2 Ablative 2L therapy (30K/yr in the US) carries radiation or surgical risks and commits the patient to lifelong thyroid replacement therapy
- 3 Remaining euthyroid off ATD, for those who achieve it without definitive therapy, is associated with normalizing stimulating anti-TSHR antibodies
- 4 **High absolute anti-TSHR antibody titers found in many Graves' patients are likely to require deeper IgG reduction for a durable response**

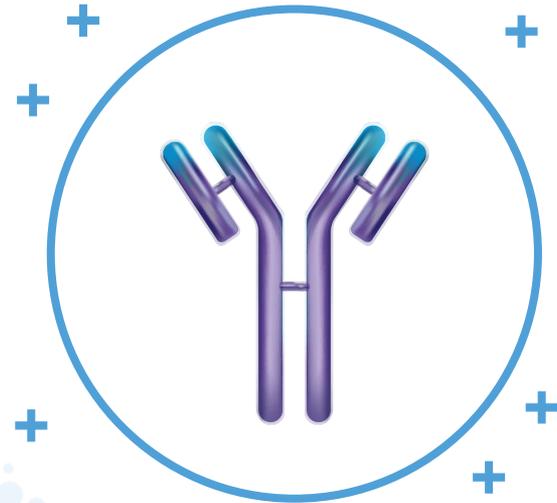
## Rheumatoid Arthritis

- 1 Large unmet need in refractory rheumatoid arthritis (RA) for patients who fail to respond to more than 1 biologic therapy
- 2 Recently presented data for nipocalimab showed a correlation between depth of auto-antibody reduction and clinical response
- 3 In the same study, nipocalimab achieved a 58% mean total IgG reduction at trough
- 4 **Taken together, we believe these points could translate to greater – and meaningful – efficacy in refractory RA with deeper IgG reduction**

# Concluding Thoughts

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

## IMVT-1402



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



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



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



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



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

# Concluding Thoughts



**The proven anti-FcRn class keeps getting more exciting**



**IMIVT-1402's profile and potency creates an exciting range of potential indications**



**2024 will be a big year for IMVT-1402 as we announce a broad portfolio of pivotal trials and POCs**