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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 9, 2023**

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**IMMUNOVANT, INC.**  
(Exact name of Registrant as specified in its Charter)

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**Delaware**  
(State or other jurisdiction of incorporation or organization)

**001-38906**  
(Commission File Number)

**83-2771572**  
(IRS Employer Identification No.)

**320 West 37th Street**  
**New York, NY**  
(Address of principal executive offices)

**10018**  
(Zip Code)

**Registrant's telephone number, including area code: (917) 580-3099**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock, \$0.0001 par value per share</b>	<b>IMVT</b>	<b>The Nasdaq Stock Market LLC</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 8.01 Other Events.**

During the week of the 41st Annual J.P. Morgan Healthcare Conference that begins on January 9, 2023, Immunovant, Inc. will provide business updates for investors with a new corporate presentation. A copy of the presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Presentation dated January 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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Exhibit 99.1

Corporate Presentation  
January 2023



# Forward-looking Statements

This presentation contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "can," "may," "might," "will," "would," "should," "expect," "believe," "estimate," "design," "plan," "intend," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant's expectations regarding patient enrollment, timing, design, and results of clinical trials of its product candidates and indication selections; Immunovant's plan to develop batoclimab and IMVT-1402 across a broad range of autoimmune indications; expectations with respect to the safety and monitoring plan and size of the safety database for these planned clinical trials; the timing of discussions with regulatory agencies; the size and growth of the potential markets for Immunovant's product candidates and indication selections; Immunovant's plan to explore in subsequent study periods follow-on treatment with alternative dosing regimens; Immunovant's expectations regarding its cash runway; Immunovant's beliefs regarding the potential benefits of batoclimab's and IMVT-1402's unique product attributes; and Immunovant's expectations regarding the issuance and term of any pending patents. All forward-looking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others: initial results or other preliminary analyses or results of early clinical trials may not be predictive of final trial results or of the results of later clinical trials; results of animal studies may not be predictive of results in humans; the timing and availability of data from clinical trials; the timing of discussions with regulatory agencies, as well as regulatory submissions and potential approvals; the continued development of Immunovant's product candidates, including the timing of the commencement of additional clinical trials and resumption of current trials; Immunovant's scientific approach, clinical trial design, indication selection, and general development progress; future clinical trials may not confirm any safety, potency, or other product characteristics described or assumed in this presentation; any product candidate that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; Immunovant's pending composition of matter patent for IMVT-1402 may not be issued; Immunovant's product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic, geopolitical tensions, and adverse macroeconomic conditions on Immunovant's clinical development plans and timelines; Immunovant's business is heavily dependent on the successful development, regulatory approval and commercialization of batoclimab and IMVT-1402; Immunovant is at an early stage in development for IMVT-1402 and in various stages of clinical development for batoclimab; and Immunovant will require additional capital to fund its operations and advance batoclimab and IMVT-1402 through clinical development. These and other risks and uncertainties are more fully described in Immunovant's periodic and other reports filed with the Securities and Exchange Commission (SEC), including in the section titled "Risk Factors" in Immunovant's most recent Annual Report on Form 10-K, its Form 10-Q filed with the SEC on November 4, 2022, and Immunovant's subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

All trademarks, trade names, service marks, and copyrights appearing in this presentation are the property of their respective owners. Dates used in this presentation refer to the applicable calendar year unless otherwise noted.



# 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 \$476M pro forma cash balance as of 9/30/2022<sup>2</sup>
- Cash runway expected to fund operations into second half of 2025<sup>3</sup>
- FcRn is a validated target following the regulatory approval of efgartigimod
- Differentiated product candidates may offer patients tailored dosing and ease of administration
- 19 indications currently announced or in development across the anti-FcRn class<sup>4</sup>



1. Not including any potential patent term extension
2. The pro forma cash balance includes net proceeds from our October 2022 follow-on offering
3. 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
4. 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

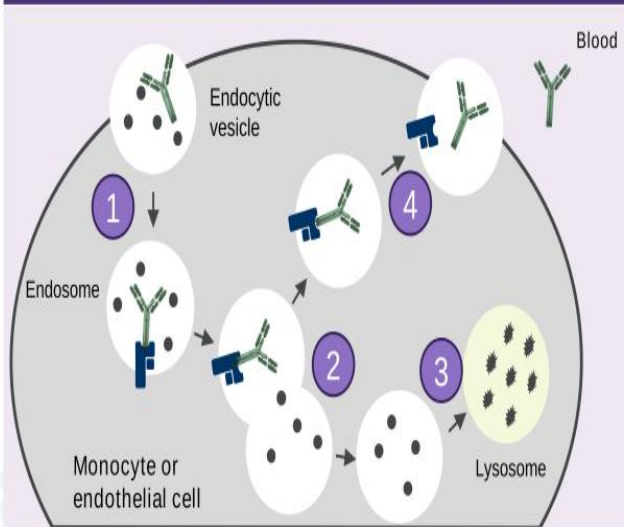


Mark S. Levine  
Chief Legal Officer and Corporate Secretary



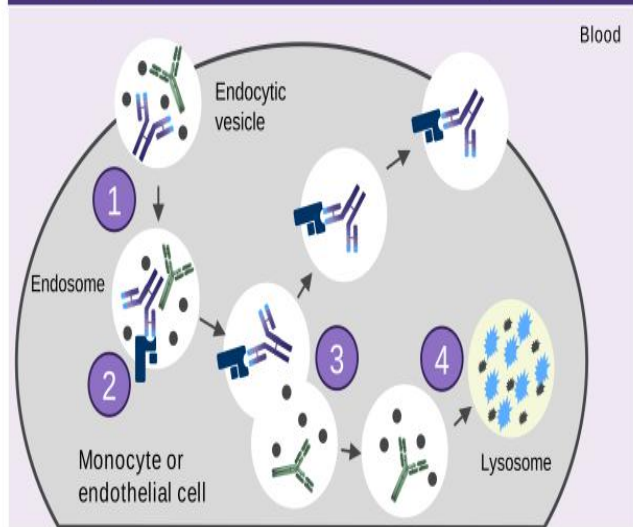
# Our Focus: The Neonatal Fc Receptor (FcRn)

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



Key: IgG FcRn FcRn inhibitor Serum protein

# Our Opportunity: Autoimmune Diseases Driven by Pathogenic IgG

19 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)



## ENDOCRINOLOGY

Thyroid eye disease (TED)  
Graves' disease



## RENAL

Membranous nephropathy  
Lupus nephritis



## HEMATOLOGY

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



## RHEUMATOLOGY

Primary Sjogrens syndrome  
Systemic lupus erythematosus  
Rheumatoid arthritis



## DERMATOLOGY

Bullous pemphigoid  
Pemphigus foliaceus  
Pemphigus vulgaris  
Cutaneous lupus erythematosus

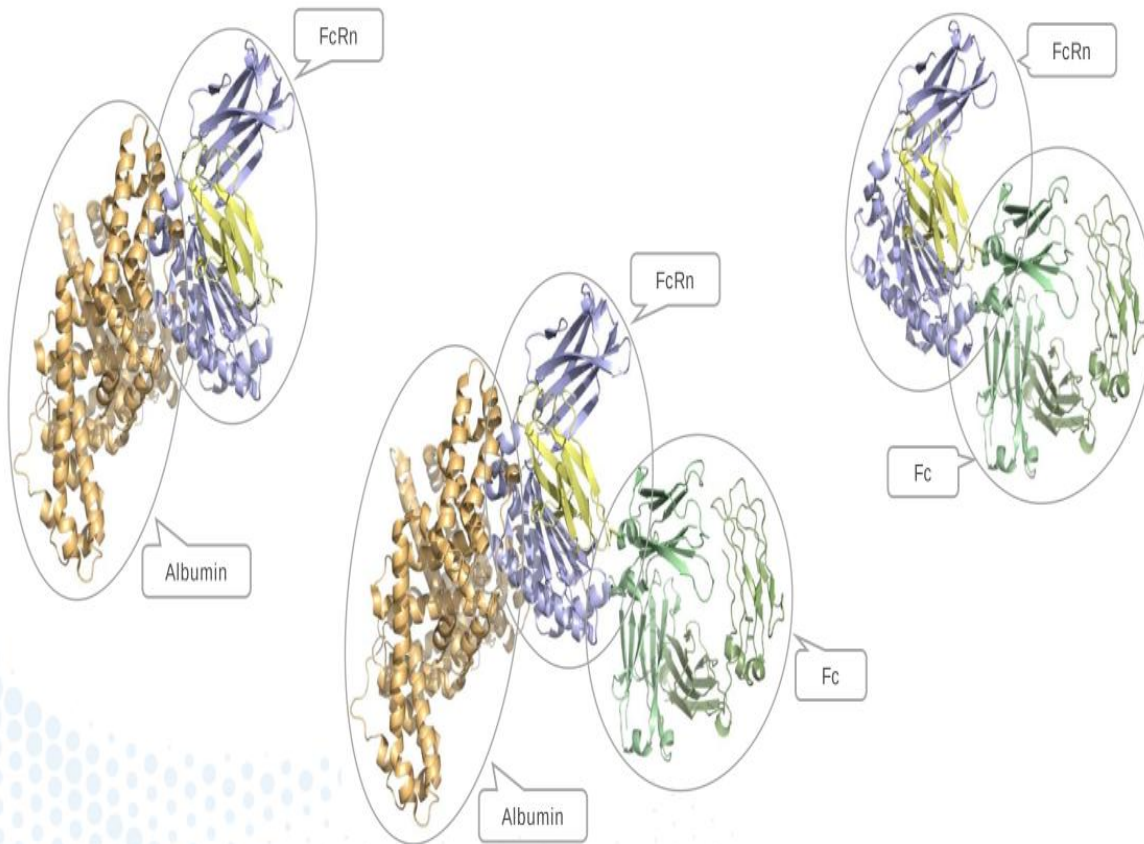
## Anti-FcRn Inhibitors Have Unique Characteristics

	Batoclimab (IMVT-1401) <sup>1</sup>	IMVT-1402 <sup>1</sup>	Efgartigimod <sup>2</sup>	Nipocalimab (M281) <sup>3</sup>	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 Effector Potential	No	No	No	No	Low	Low	
FcRN-IgG Binding- pH 7.4	Affinity (KD) +++	3.09-3.26 nM +++	0.27-0.29 nM +++	320 nM +	0.029 nM ++++	0.023 nM ++++	0.87 nM +++
FcRN-IgG Binding- pH 6.0-6.3	Affinity (KD) +++	1.42-1.45 nM +++	0.35-0.36 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	



No clinical head-to-head comparisons of Immunovant product candidates and third party anti-FcRn assets has been conducted. Binding affinities are determined by surface plasmon resonance.  
Sources: 1. On file at Immunovant; 2. Ulrichts 2018; 3.Ling, 2019 (ASH 2015 poster); 4.Smith, 2018; Kiessling, 2017; 5. Blumberg, 2017 (ASH 2017 poster)

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

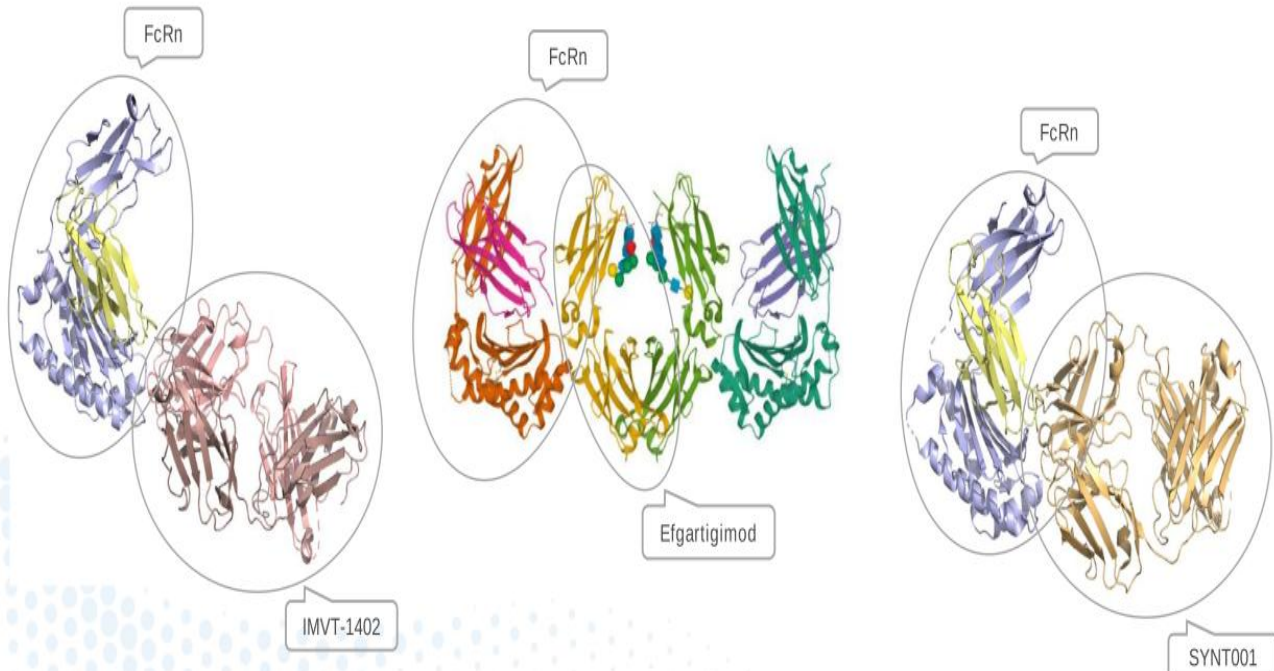


# Co-crystal Structures for FcRn Complexes of IMVT-1402, Efgartigimod\* and SYNT001\*\*

IMVT-1402

Efgartigimod\*

SYNT001\*\*

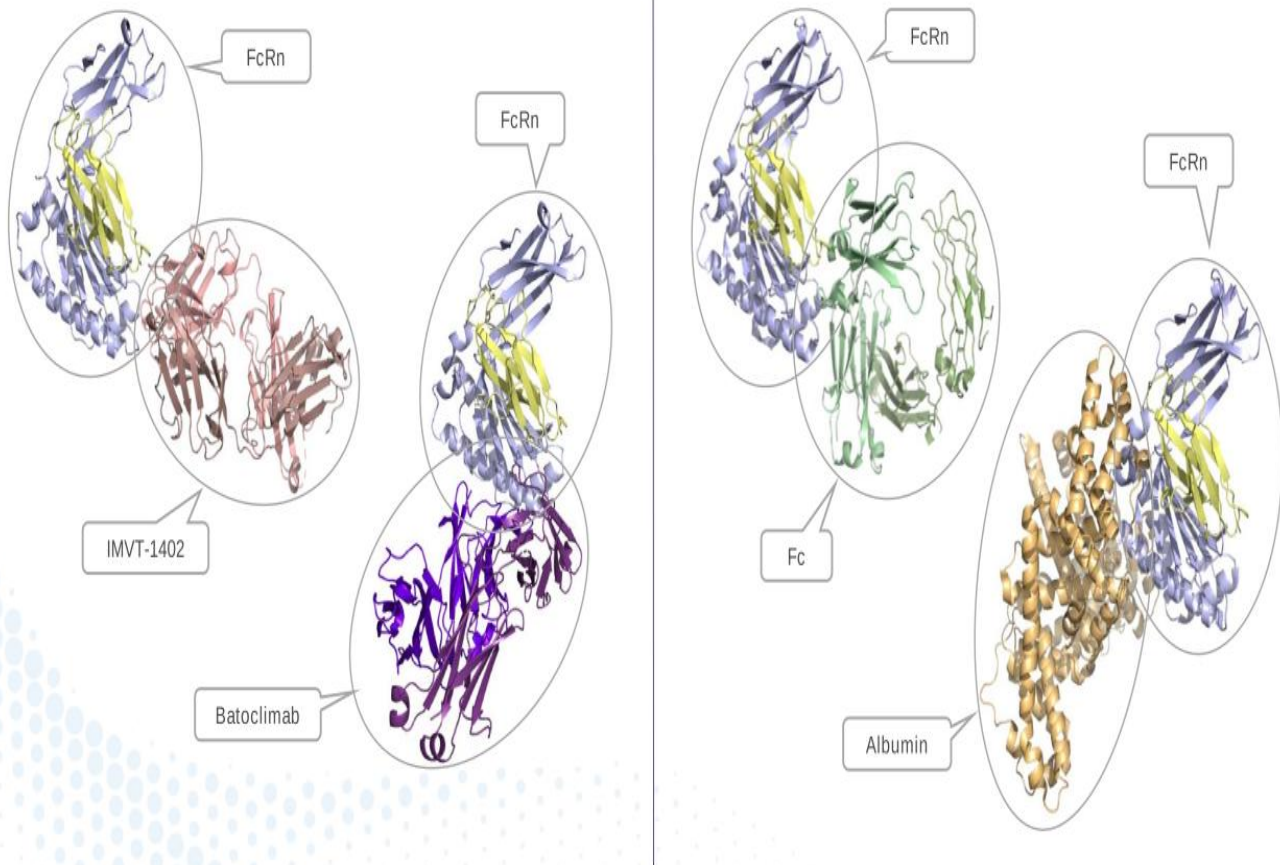


\*<https://www.rcsb.org/structure/7Q15>; \*\*Blumberg et al., Sci. Adv. 2019 Dec 18;5(12):eaax9586

Note: Ribbon representations generated from X-Ray co-crystal structure.

Orientation of FcRn is shown a bit differently (based on publicly available data) for efgartigimod vs 1402 and SYNT001.

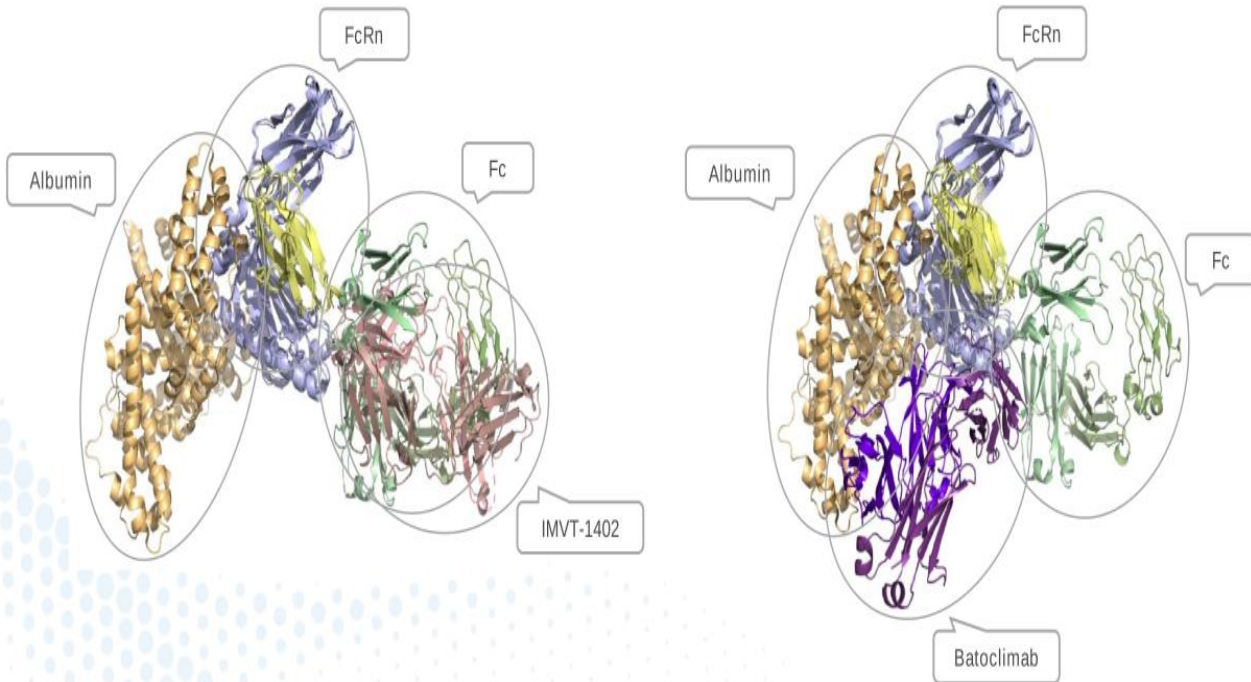
# Co-crystallization Shows IMVT-1402-FcRn Complex Orients Differently from Batoclimab-FcRn Complex



# 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

## Simple subcutaneous injection

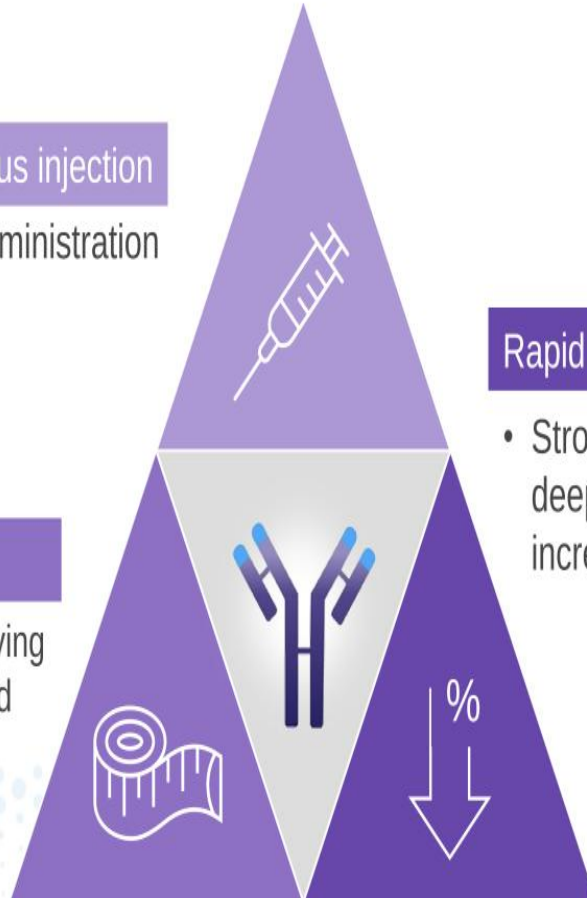
- To enable self-administration at home

## Tailored Dosing

- For patients with varying symptom severity and stage of disease

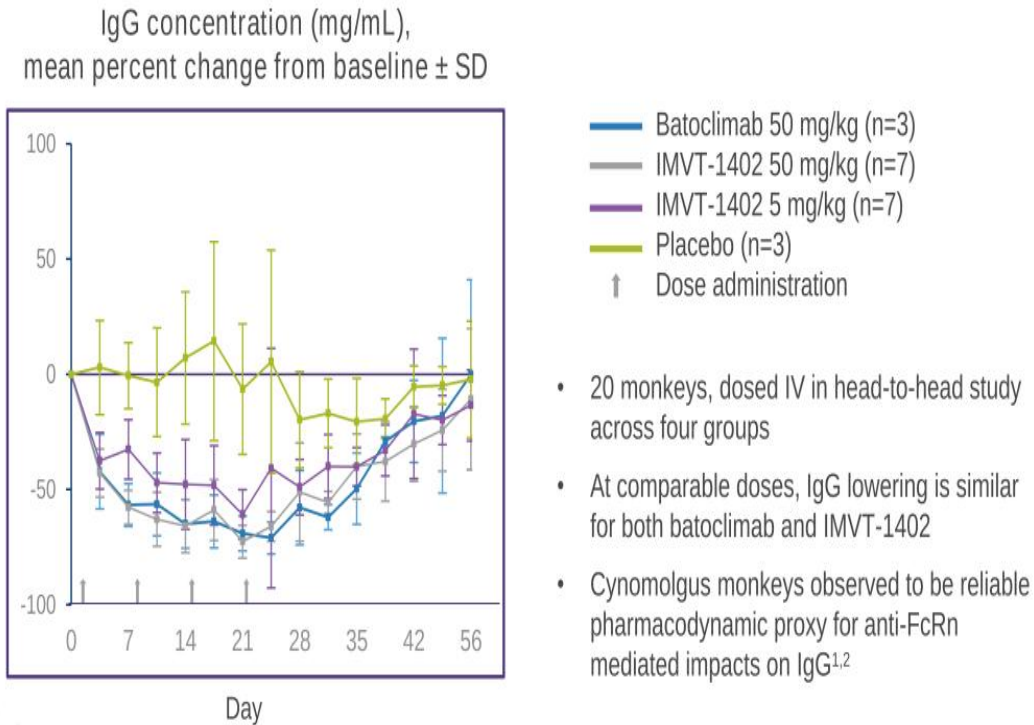
## Rapid & Deep IgG Reduction

- Strong correlation between deep IgG reduction and increased clinical efficacy





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



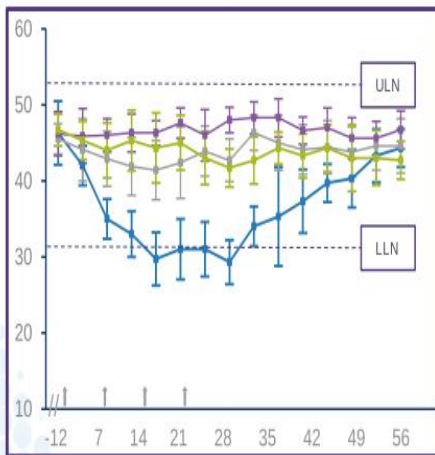
We believe that deeper IgG suppression correlates with the clinical benefits across several anti-FcRn data sets



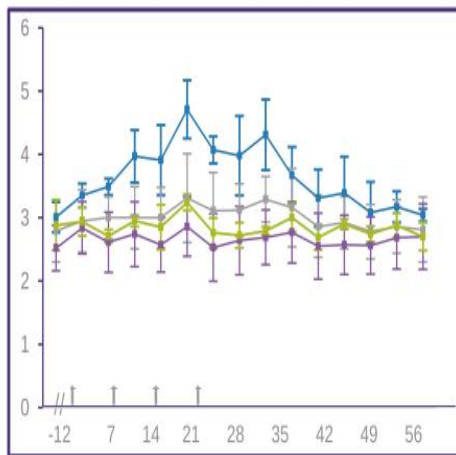
1. Source: Lledo-Garcia, et al, Pharmacokinetic-pharmacodynamic modelling of the anti-FcRn monoclonal antibody rozanolixizumab: Translation from preclinical stages to the clinic, UCB Pharma, 2022.  
2. Data on file at Immunovant

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

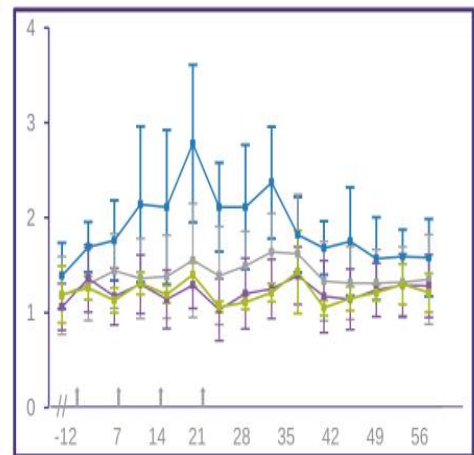
Albumin concentration (g/L), mean  $\pm$  SD



Cholesterol concentration (mmol/L), mean  $\pm$  SD



LDL concentration (mmol/L), mean  $\pm$  SD



Day

Day

Day

- Batoclimab 50 mg/kg (n=3)
- IMVT-1402 50 mg/kg (n=7)
- IMVT-1402 5 mg/kg (n=7)
- Placebo (n=3)



SD, standard deviation; ULN, upper limit of normal; LLN, lower limit of normal; Arrows indicate time of dosing.  
Data on file at Immunovant

# Albumin Impact in Non-human Primates Translatable to Humans

## Translatability Observed Across Multiple Anti-FcRn Inhibitors

Product (Company)	Impact on Albumin Levels from Baseline	
	Cynomolgus Monkeys	Clinical Data
Efgartigimod (argenx)	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <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 style="list-style-type: none"> <li>Reported no difference in albumin levels from baseline for vehicle, 10, 30, or 100mg/kg<sup>4</sup></li> </ul>	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <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 style="list-style-type: none"> <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)	<ul style="list-style-type: none"> <li>Reported small reductions (1-13%) in albumin levels from baseline<sup>8</sup></li> </ul>	<ul style="list-style-type: none"> <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)	<ul style="list-style-type: none"> <li>Observed consistent reduction in albumin levels from baseline</li> </ul>	<ul style="list-style-type: none"> <li>Observed dose dependent decreases in albumin levels from baseline</li> </ul>
IMVT-1402 (Immunovant)	<ul style="list-style-type: none"> <li>No or minimal impact on albumin levels observed from baseline (variability like placebo)</li> </ul>	<ul style="list-style-type: none"> <li>Initial Phase 1 data available in mid-2023</li> </ul>



1. Ulrichs P.J Clin Invest. 2018 Oct 1;128(10):4372-4386  
 2. Efgartigimod EMA assessment report - EMA/641081/2022  
 3. Efgartigimod FDA integrated review - 761195Orig1s000  
 4. Blumberg L.J. Sci Adv. 2019 Dec 18;5(12):eaax9586  
 5. Stifel research note – Momenta Pharmaceuticals, December 18, 2018

6. Ling et.al, Clin Pharmacol Ther. 2019 Apr;105(4):1031-1039.  
 7. Momenta Investor Presentation – June 15, 2020  
 8. Smith B, MAbs. 2018 Oct;10(7):1111-1130  
 9. Kiessling P. Sci Transl Med. 2017 Nov 1;9(414):eaan1208

# Our Investigational Product Pipeline:

## Only Company with 2 Anti-FcRns Targeting 5 Autoimmune Diseases

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



\*Registrational package for CIDP may include 1 or 2 pivotal trials depending on a variety of factors

\*\*WAIHA design to be finalized based on recent FDA interaction

\*\*\*including potentially WAIHA

# Myasthenia Gravis



# Myasthenia Gravis (MG)

An IgG-mediated Autoimmune Disease that Typically Requires Lifestyle Changes

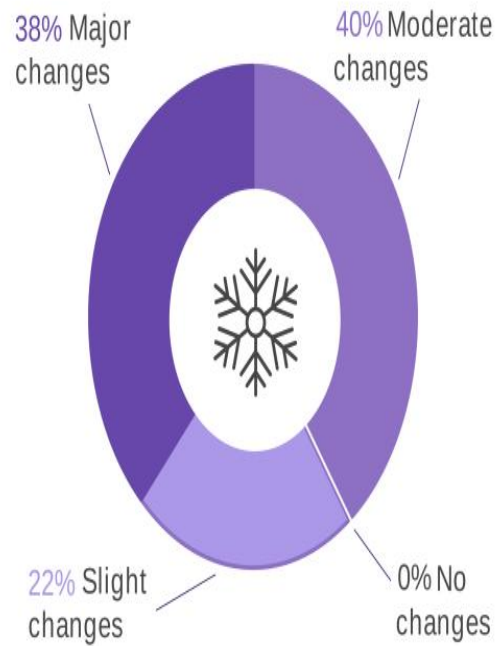
## Myasthenia Gravis – Key Takeaways

- 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

Source: KOL Interviews: Data on file at Immunovant









## Extent of Lifestyle Modifications\*



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

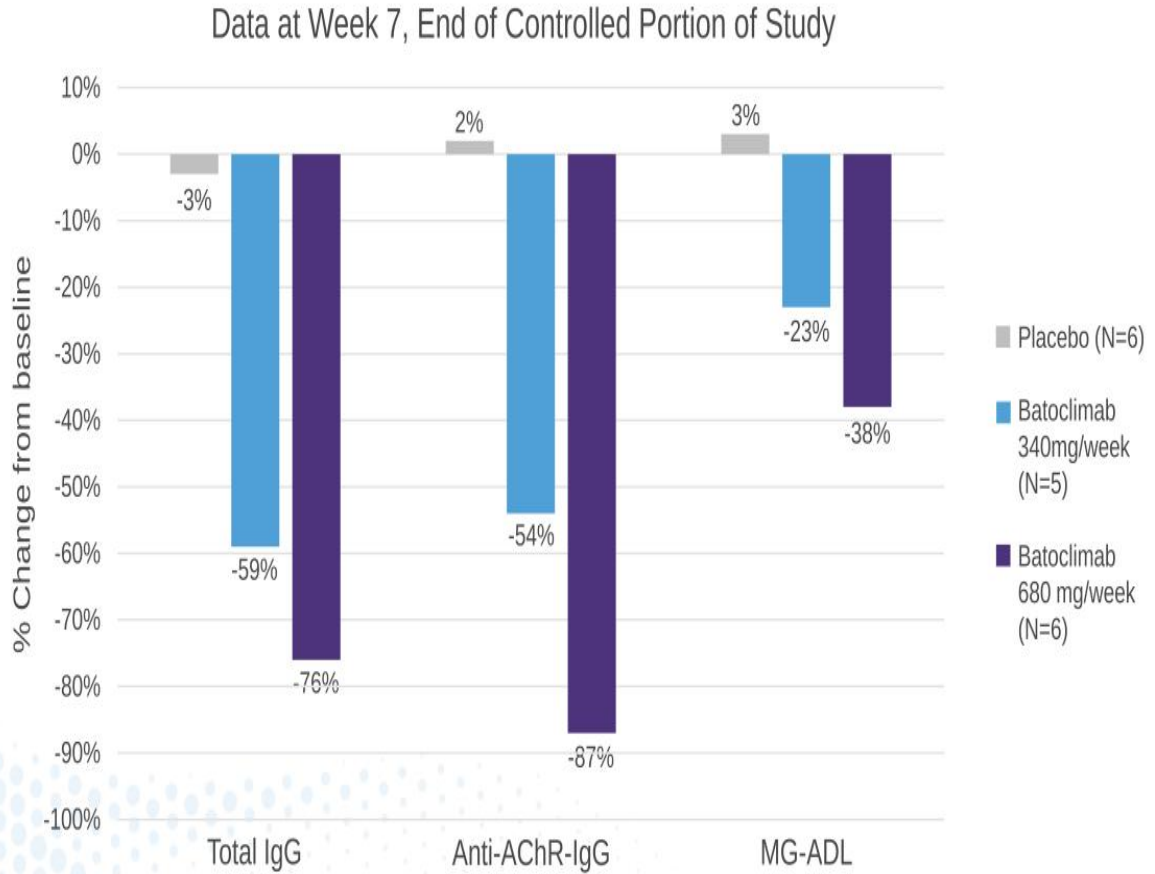
# Current and Emerging Therapies for Myasthenia Gravis Do Not Fully Address Patient Needs

Drug Name	Manufacturer	Mechanism of Action	Phase of Development	Route of Administration	Note
Efgartigimod		FcRn inhibitor	Approved (12/2021)	Intravenous	Halozyne-enhanced SC pending FDA review
Nipocalimab	 <small>PHARMACEUTICALS A DIVISION OF JANSSEN-Cilag</small>	FcRn inhibitor	Phase 3	Intravenous	Albumin reduction reported <sup>1</sup>
Rozanolixizumab		FcRn inhibitor	BLA submitted	Subcutaneous infusion	Headaches reported in treated patients <sup>2</sup>
Eculizumab		C5 complement inhibitor	Approved (10/2017)	Intravenous	Has a black box warning for meningococcal infections <sup>3</sup>
Ravulizumab		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	



1. Ling LE et al. Clin Pharmacol Ther. 2019 Apr; 105(4): 1031–1039
2. Bril V, et al. Neurology. 2021 Feb 9;96(6):e853-e865
3. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/125166s172lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125166s172lbl.pdf)
4. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/761108s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761108s000lbl.pdf)

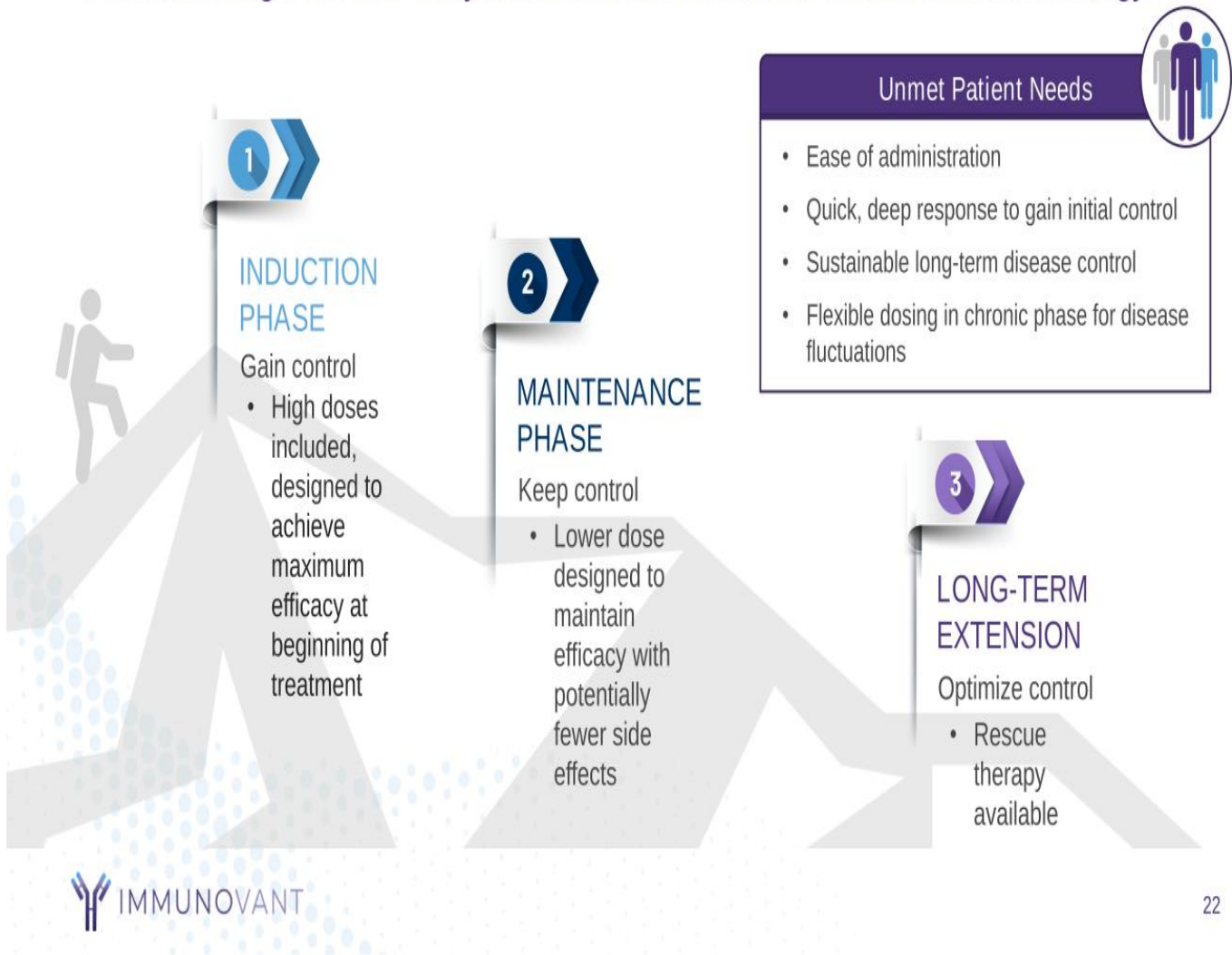
# We Observed Encouraging Efficacy Signals in a Phase 2 Trial of Batoclimab in Myasthenia Gravis





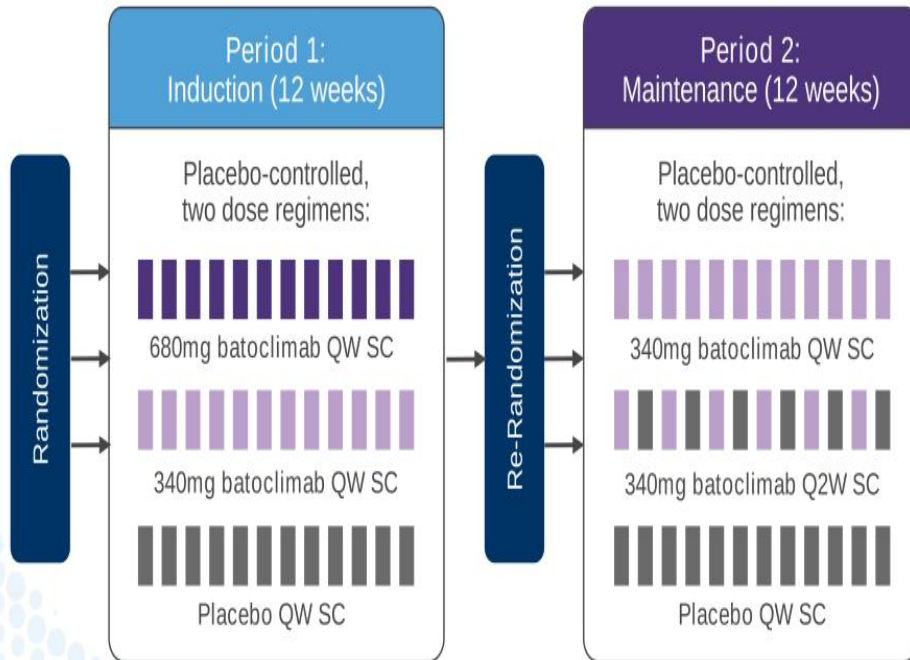
# Batoclimab Phase 3 Trial Designed to Address Unmet Patient Needs

## Flexible Design First for a Myasthenia Gravis Trial but Common in Immunology



# 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+

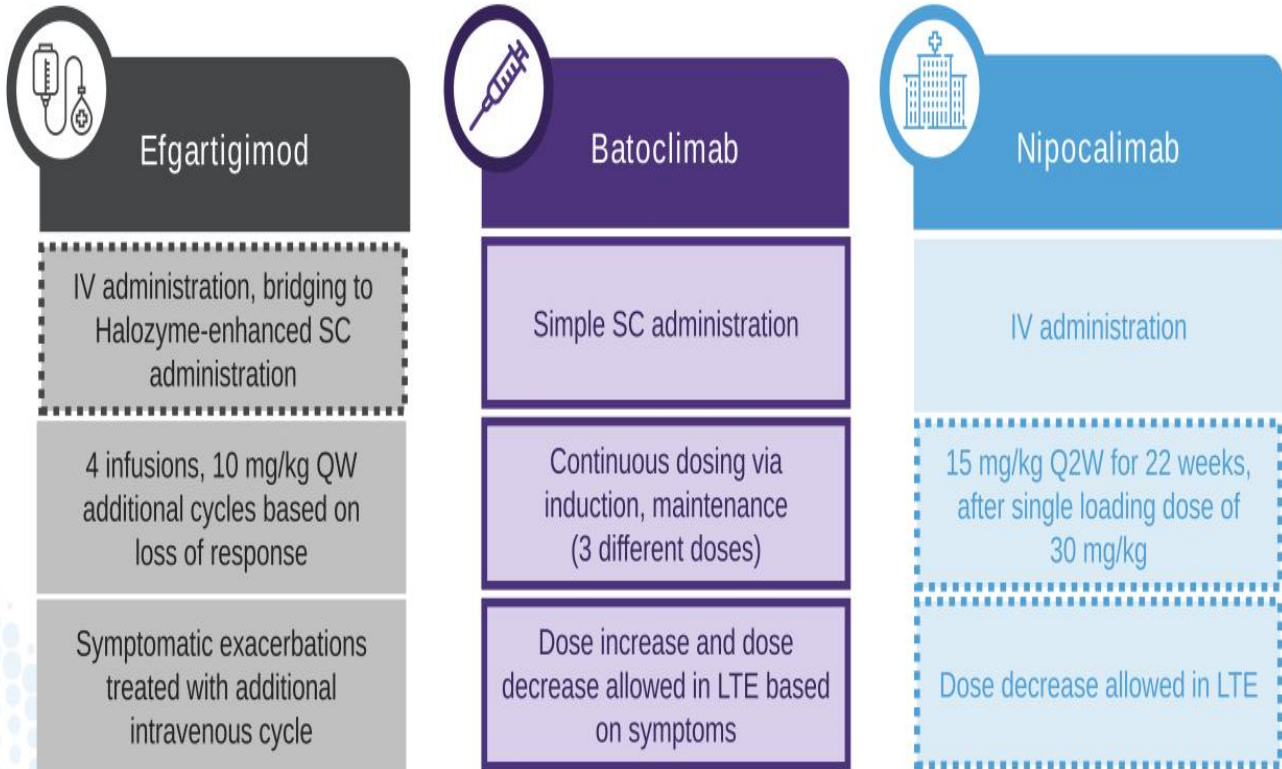
\*Primary endpoint: change in MG-ADL through 12 weeks

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



QW = weekly; Q2W = bi-weekly; SC = subcutaneous injection; AChR Ab+ = acetylcholine receptor antibody-positive; MG-ADL = Myasthenia Gravis Activities of Daily Living scale

# Batoclimab Potentially Well Positioned to Compete in Myasthenia Gravis Market



Source: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/761195s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761195s000lbl.pdf),  
<https://clinicaltrials.gov/ct2/show/NCT04951622>

IV = Intravenous infusion, LTE = Long-term extension, QW = weekly; SC = subcutaneous injection

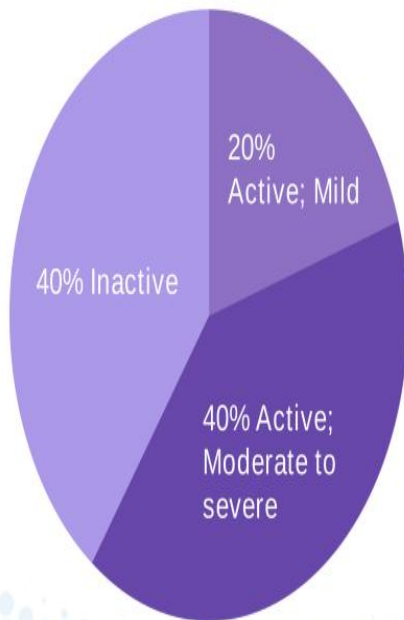
# Thyroid Eye Disease



# Thyroid Eye Disease (TED)

A Heterogeneous Condition that Presents with a Variety of Clinical Symptoms

## 8K-18K Total Addressable U.S. Population



## 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



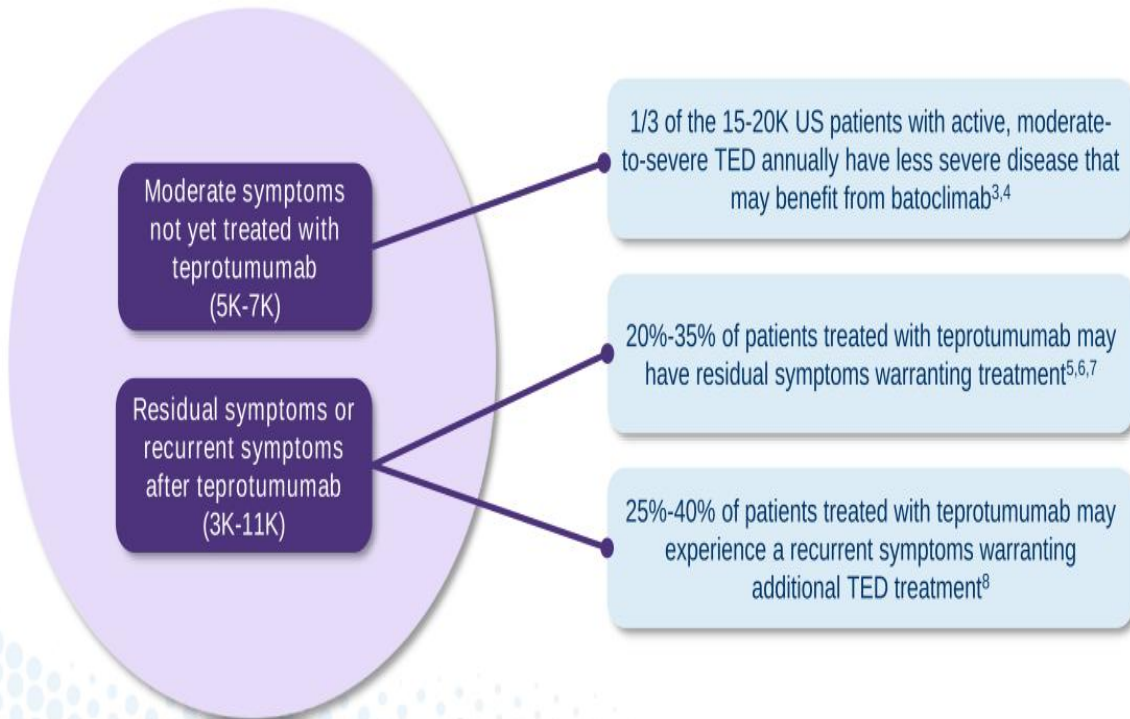
We anticipate that patients who do not maintain their proptosis response will be candidates for a new mechanism of action



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

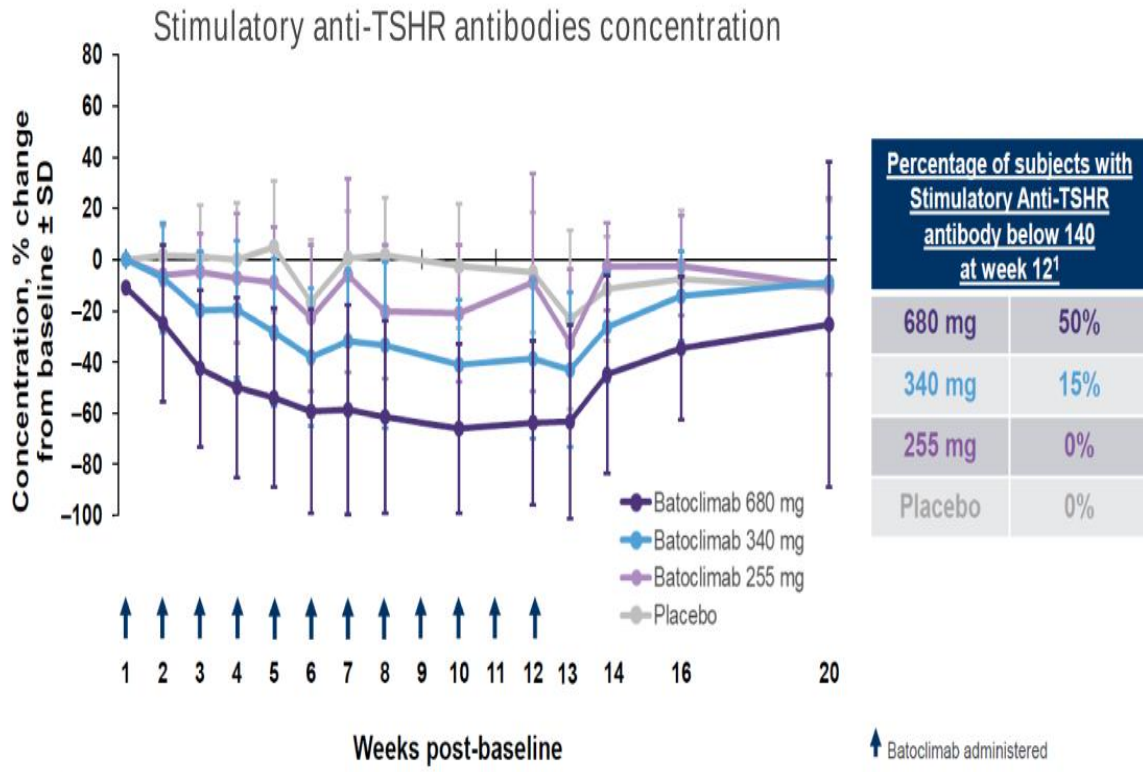
# We Believe Batoclimab is Well Positioned to Capture Significant Thyroid Eye Disease Market Share

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



Sources: 1. Based on clinicaltrial.gov database, last accessed on 1/5/2023. 2. Lane LC, et al. *Endocr Rev.* 2020 Dec 1;41(6):873-84. 3. Lazarus JH et al. *Best Practice & Research Clinical Endocrinology & Metabolism.* v26 (2012) 273-279. 4. HCP Qualitative Research, Immunovant, 2020. 5. 2021 Cowen Equity Research, March 2022 - surveyed 25 clinicians who treat 3,000+ patients with TED annually. 6. Horizon Therapeutics Investor Presentations. 7. Teprotumumab's US Prescribing Information. 8. Douglas R et al. *American Academy of Ophthalmology*, v129, No. 4,

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



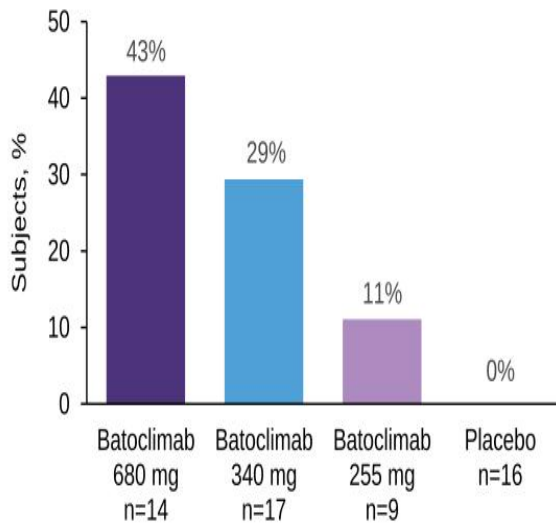
Source: Batoclimab Phase 2b TED trial data on file at Immunovant, Inc.  
<sup>1</sup>SRR is the "Sample to Reference Ratio". This cell-based assay readout is the ratio of the sample signal to that of a reference control, expressed as %.  
 A value less than 140 is considered negative for stimulatory 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

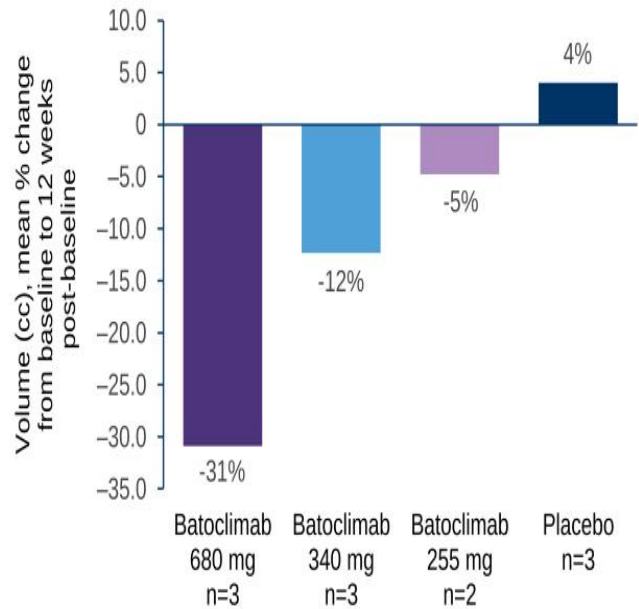
Post-hoc analysis of proptosis response at week 6<sup>1</sup>



Effect size similar at week 12 though confidence intervals wide

<sup>1</sup> Proptosis response defined as proptosis reduction  $\geq 2$  mm in study eye, without  $\geq 2$  mm increase in non-study 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

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.



Source: Batoclimab Phase 2b TED trial data on file at Immunovant, Inc.  
The efficacy of batoclimab and clinical outcomes were deemed inconclusive, in part, because the study was terminated early.

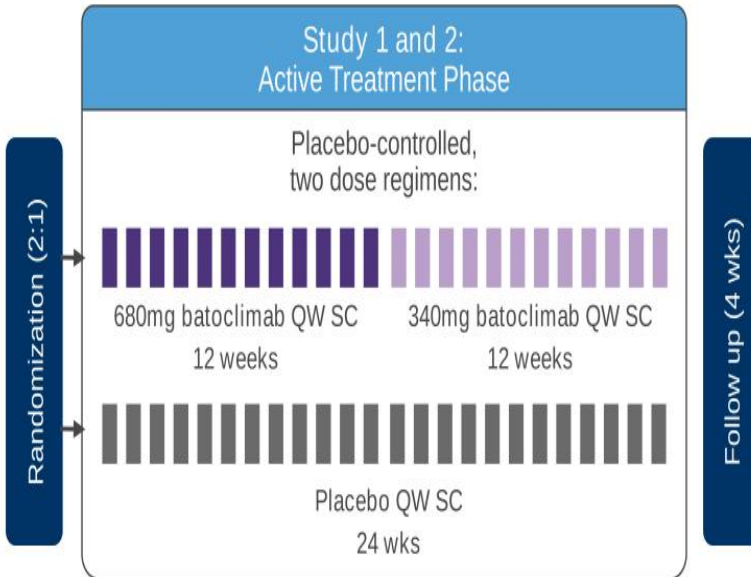
# Two Phase 3 Clinical Trials of Batoclimab in Thyroid Eye Disease Initiated



## Inclusion



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



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

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



Note: subset of inclusion criteria for TED Phase 3 trial shown on slide

CAS = Clinical Activity Score, anti-TSHR-Ab = anti-TSHR antibody, QW = weekly; SC = subcutaneous injection

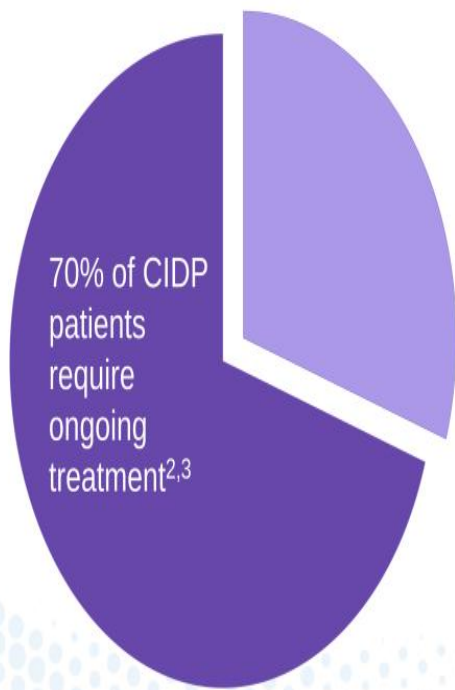
# Chronic Inflammatory Demyelinating Polyneuropathy



# Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

## An Important Disease in Neurology & Exciting Opportunity for the Anti-FcRn Class

16,000 Total CIDP Patients in the US<sup>1,2</sup>



### 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. <https://doi.org/10.1111/j.1529-8027.2009.00243>; 4. CSL Behring R&D Investor Briefing, 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

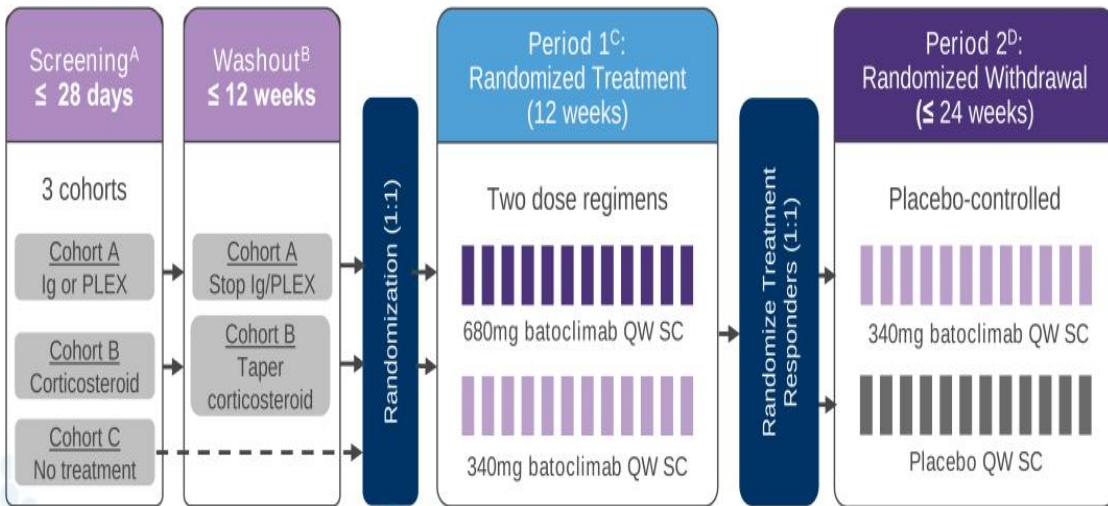
Trial risks	Mitigations	Mitigation included in other anti-FcRn Trials*	Mitigation included in IMVT trial
Disease heterogeneity and challenging diagnosis	Diagnostic algorithm	X	✓
Mix of active and inactive disease among those enrolled creates risk of low relapse rate in the placebo arm, thereby shrinking potential effect size for the investigational product	Double enrichment: 1. Subjects must worsen after withdrawal / taper of standard of care (e.g. IVIG/SCIG, PLEX, or steroids) on study entry, AND	Not All**	✓
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	Third enrichment: Primary endpoint on IVIG/SCIG/Plex cohort only to maximize the potential effect size	X	✓
Lack of dose exploration	Data on multiple doses 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	✓

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



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



**i**

Efficacy analysis based on relapse (adjusted INCAT)

Primary endpoint: proportion of relapse events in period 2 for patients receiving Ig or PLEX at time of screening (Cohort A)

Period 2 followed by LTE; 680mg QW x 4 for period 2 relapsers

Key selection criteria:

Adult participants diagnosed per EAN/PNS CIDP guidelines, 2021 revision

**Cohorts A (n=100):** Randomize participants who worsen  
**Cohort B:** Same as A  
**Cohort C:** Randomize all

**Period 1 data expected in the first half of 2024**

**Primary analysis only on Cohort A (IG/PLEX)**

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



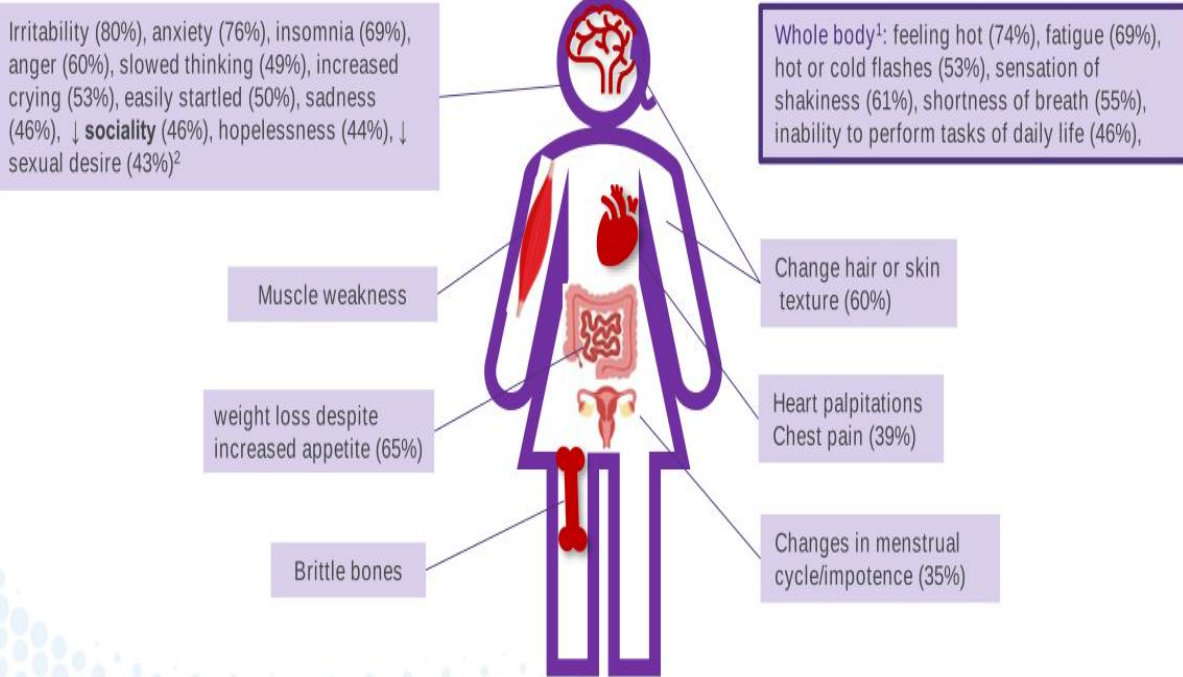
# Graves' Disease





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

Graves' disease incidence 116K / year<sup>3,4</sup>



Sources: 1. Stern RA, et al. J Neuropsychiatry Clin Neurosci. 1996 Spring;8(2):181-5. 2. Arruda et al A survey study of neuropsychiatric complaints in patients with Graves' disease: A reassessment of self-reported symptoms and current practice 20 years later: Graves' Disease and Thyroid Foundation, 2019; 3. Zimmermann MB, Boelaert K. Iodine deficiency and thyroid disorders. Lancet Diabetes Endocrinol. 2015 Apr;3(4):286-95. 4. Furszyfer J, et al. Graves' disease in Olmsted County, Minnesota, 1935 through 1967. Mayo Clin Proc. 1970 Sep;45(9):636-44

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

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

\*Surgical risks include laryngeal nerve damage, hypoparathyroidism and bleeding

# Large Population of Underserved Patients with Graves' Disease

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

Target population:

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

Persistent need for  
ATD and wish to avoid  
thyroid ablation  
(12K-15K)

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 46K<sup>3</sup> patients undergoing ablative procedure (radioactive iodine or surgery) may wish to avoid potential long-term risks (e.g. increased cancer, complications of thyroidectomy)



Sources: 1. Zimmermann MB, Boelaert K. Iodine deficiency and thyroid disorders. *Lancet Diabetes Endocrinol.* 2015 Apr;3(4):286-95. 2. Furszyfer J, et al. Graves' disease in Olmsted County, Minnesota, 1935 through 1967. *Mayo Clin Proc.* 1970 Sep;45(9):636-44; 3. Brito JP, et al. Antithyroid Drugs-The Most Common Treatment for Graves' Disease in the United States: A Nationwide Population-Based Study. *Thyroid.* 2016 Aug;26(8):1144-5. doi: 10.1089/thy.2016.0222. Epub 2016 Jul 5. PMID: 27267495.

# 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

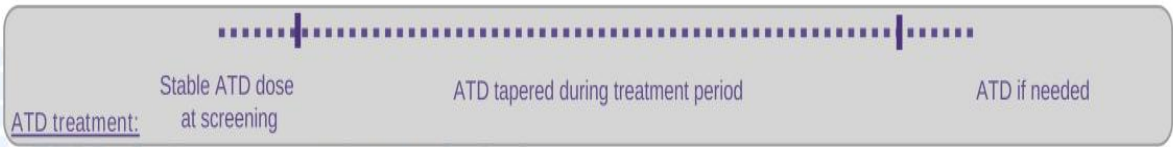
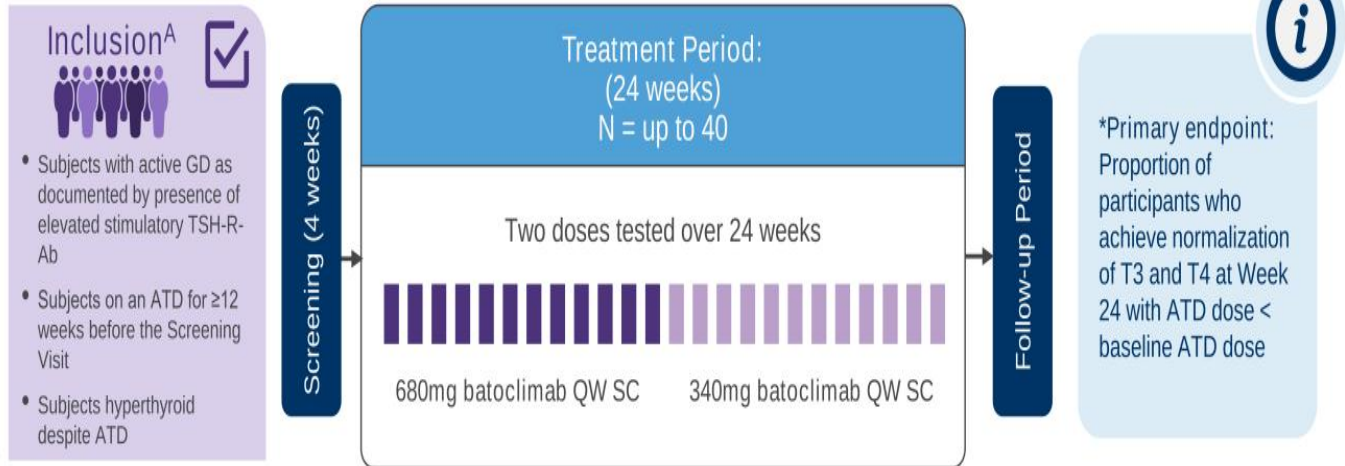
2

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

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>



Sources: 1. Based on clinicaltrials.gov database, last accessed on 1/5/2023. 2. Lane LC, et al. Endocr Rev. 2020 Dec 1;41(6):873–84  
A: Additional inclusion and exclusion criteria not listed on slide  
GD = Graves' Disease; ATD = anti-thyroid medications; QW = weekly; SC = subcutaneous injection

# A Potential Targeted Therapy for Graves' Disease



# Warm Autoimmune Hemolytic Anemia



# Warm Autoimmune Hemolytic Anemia (WAIHA)

Rare Blood Disorder Caused by Pathogenic IgG Attacking Red Blood Cells

01

Estimated prevalence of 42,000 patients in U.S. and 67,000 patients in EU

02

50-70% of patients relapsed/refractory to standard-of-care and enter into chronic condition; ~30% of total patients require life-time care

03

Current standard-of-care has high unmet need with the high risk of side effects on steroids and/or immunosuppressants

04

Involvement of pathogenic IgG represents a potentially important opportunity for the anti-FcRn class



# Limited Treatment Options Currently for Patients with WAIHA



Currently no FDA-approved therapies

- Standard-of-care includes: corticosteroids, immunosuppressive agents, RBC transfusion, rituximab<sup>3</sup>, splenectomy<sup>1,2</sup>



Majority of patients require long-term steroid treatment or additional therapies<sup>1</sup>

- Only one-third of all patients maintain sustained disease control once steroids are discontinued<sup>1</sup>



No clear guidelines on treatment choice in patients failing corticosteroids

- RBC transfusions are indicated in patients who require immediate stabilization; yet autoantibodies in WAIHA patients may react against RBCs in the transfusion product<sup>1,2</sup>

Approach to WAIHA to be finalized in early 2023 based on recent FDA interaction



1. Salama A. Treatment Options for Primary Autoimmune Hemolytic Anemia: A Short Comprehensive Review. *Transfusion Medical and Hemotherapy*, 2015.
2. Park S.H. Diagnosis and treatment of autoimmune hemolytic anemia: classic approach and recent advances. *Blood Research*, 2016.
3. Rituximab is not approved by the FDA for Warm Autoimmune Hemolytic Anemia.

# Building a Leading Anti-FcRn Franchise



# Differentiated Assets to Address a Range of Patient Needs

## Only Company with 2 Anti-FcRns Currently Targeting 5 Autoimmune Diseases

### 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

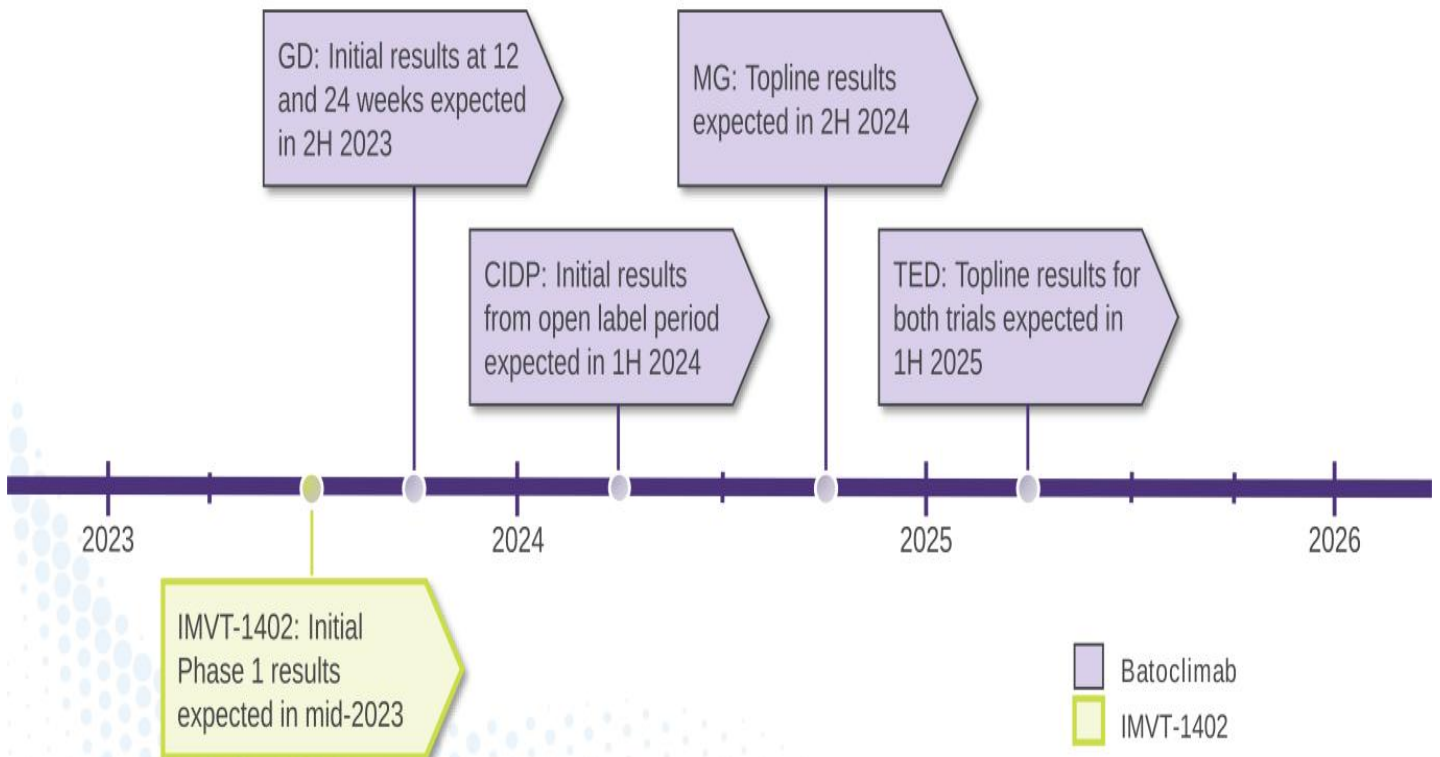
+

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 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 multi-indication development plan



Thank you



