

# Rethinking possibilities in autoimmune disease



Corporate Presentation January 2022



## Forward-looking statements

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## **Our vision:**

## Normal lives for people with autoimmune disease

#### **Driven by our core values**







Bolder, Faster



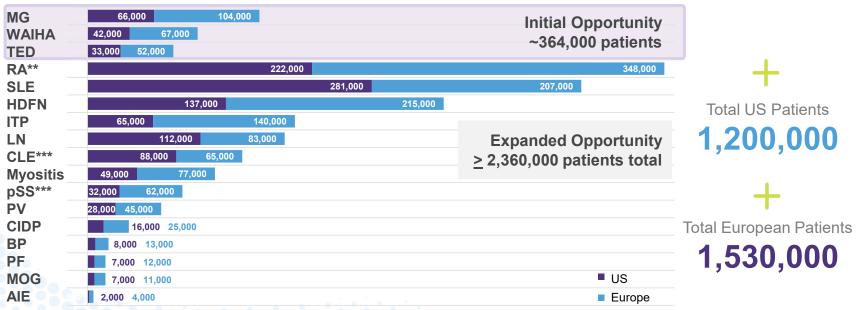
All Voices





# Wide potential for anti-FcRn technology in this large, double-digit billion Immunology market

Autoimmune diseases\* driven by pathogenic IgG + estimated prevalence (2021)



<sup>\*\*</sup>Refractory RA patient prevalence data shown



\*Note: List of diseases is illustrative only and does not represent our targeted indications (for more information, see Immunovant's most recent Annual Report on Form 10-K filed with the SEC on June 1, 2021 and Quarterly Report on Form 10-Q filed with the SEC on November 5, 2021). MG: Myasthenia Gravis; WAIHA: Warm Autoimmune Hemolytic Anemia; TED: Thyroid Eye Disease; ITP: Idiopathic Thrombocytopenic Purpura; PV: Pemphigus Vulgaris; CIDP: Chronic Inflammatory Demyelinating Polyneuropathy; BP: Bullous Pemphigoid; PF: Pemphigus Foliaceus; AIE: Autoimmune Encephalitis LG11+; MOG: Myelin oligodendrocyte glycoprotein antibody disorder; pSS: Primary Sjögren's Syndrome; SLE: Systemic Lupus Erythematosus; HDFN: Hemolytic Disease of the Fetus and Newborn; RA: Rheumatoid Arthritis; LN: Lupus Nephritis; CLE: Cutaneous Lupus Erythematosus Europe includes all EU countries, the UK and Switzerland

<sup>\*\*\*</sup>Moderate to Severe pSS and CLE prevalence data shown

# Pioneering FcRn technology to address patients' unmet need

#### Our asset: Batoclimab (IMVT-1401)

- Novel, fully human, monoclonal antibody inhibiting FcRn-mediated recycling of IgG
- Tailored dosing to uniquely address patient needs
- Simple, subcutaneous injection



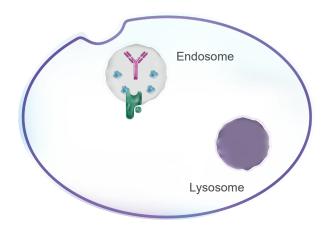
#### Our strategy

Pursue a bold, patient-centric development program spanning multiple autoimmune diseases in the double digit billion-dollar, clinically proven anti-FcRn class

Well-resourced with \$559M<sup>1</sup> in cash to support opportunity to address various patient unmet needs



## FcRn plays a pivotal role in modulating immune response







#### **IgG** antibodies

- Play an important role in immune defense against pathogens<sup>1</sup>
- Account for ~75% of antibodies in the plasma of healthy people<sup>1</sup>
- In many autoimmune diseases, IgG antibodies develop that can recognize and bind to normal tissues, causing debilitating symptoms<sup>2</sup>



#### FcRn

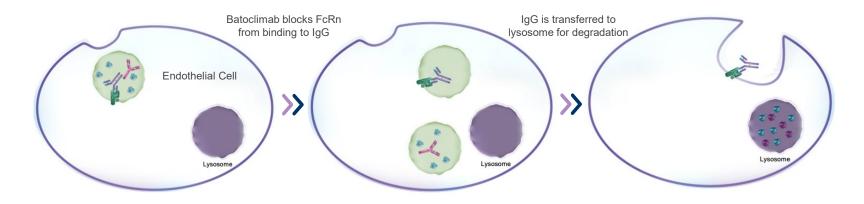
- Binds to IgG antibodies to keep them in circulation by avoiding degradation in lysosome (i.e., prolongs their half-life)<sup>3</sup>
- Expressed in a variety of cells (vascular, endothelial, keratinocytes, hepatocytes and hematopoietic)

Unlike broad-spectrum immunosuppressants, inhibiting the FcRn mechanism provides <u>targeted</u><sup>4</sup> immune-modulation by promoting IgG degradation to remove pathogenic antibodies

- 1. Leusen J.H.W. The Role of IgG in Immune Responses. Molecular and Cellular Mechanisms of Antibody Activity, 2013.
- 2. Isabela S., et al. The role of autoantibodies in health and disease. Romanian Journal of Morphology and Embryology, 2016.
- 3. Derry C., et al. FcRn: the neonatal Fc receptor comes of age. Nature Reviews Immunology, 2007.
  - 4. Batoclimab is not expected to impact mechanisms of innate immunity or non-IgG-dependent aspects of adaptive immunity.



# Batoclimab utilizes FcRn pathway to promote IgG degradation<sup>1</sup> and remove pathogenic antibodies









**Batoclimab** 

IgG antibody

FcR

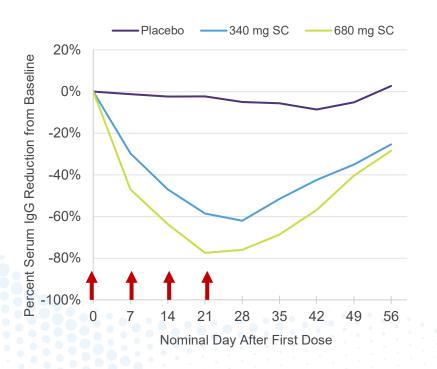
- · Novel, fully human, monoclonal antibody
- Binds to FcRn, thereby preventing it from recycling IgG antibodies back into circulation and promoting IgG degradation<sup>2</sup>
- Designed from the very beginning to be a sub-cutaneous injection



<sup>1.</sup> Collins J. and Jones L., et al. batoclimab (RVT-1401), A Novel Anti-FcRn Monoclonal Antibody, Was Well Tolerated in Healthy Subjects and Reduced Serum IgG Following Subcutaneous or Intravenous Administration. Presented at American Academy of Neurology Annual Conference, 2019. Program # P5.2-079

<sup>2.</sup> Derry C., et al. FcRn; the neonatal Fc receptor comes of age. Nature Reviews Immunology, 2007

# Batoclimab may offer sustained disease control with tailored dosing for a range of patient needs and diseases



#### Induction treatment

Maximize IgG suppression for fast, initial control with plan to titrate down

#### **Maintenance therapy**

Seek the least IgG suppression required to maintain efficacy

#### Rescue/Acute treatment

Simple subcutaneous dosing optimized for flexibility



## Plan to initiate three pivotal trials in 2022

### Batoclimab represents a robust pipeline in a product

Target Indication	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Myasthenia Gravis (MG)				Top Line Results expected 2024
Thyroid Eye Disease (TED)				Expecting to initiate pivotal trials in 2022 for two of these four indications
Warm Autoimmune Hemolytic Anemia (WAIHA)				
Indication 4*				
Indication 5*				

\*Two new indications to be announced by Aug 2022



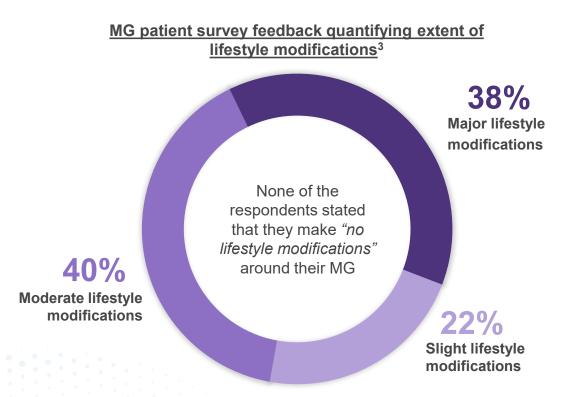
# Batoclimab for Myasthenia Gravis





## Myasthenia Gravis (MG) overview

- MG is a prototypical antibodymediated autoimmune disorder
- Characterized by weakness of voluntary muscles<sup>1</sup>
- MG associated with risk of disease exacerbation or crisis<sup>2</sup>
- Despite available treatments, patients still require substantial lifestyle modifications in living with MG





<sup>1.</sup> Meriggioli M.N. and Sanders D.B. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? Expert Review Clinical Immunology, 2012

11

<sup>2.</sup> Sudulagunta S.R., et al. Refractory myasthenia gravis – clinical profile, comorbidities and response to rituximab. *German Medical Science*, 2016 3. Source: MG Patient Quantitative Survey (n=50). Q: What is the extent of lifestyle modifications you make around your myasthenia gravis?

# People with MG recognize limitations of current therapies, which keep them from living their normal lives

MG patient research feedback promising for anti-FcRn class

Historical standards of care have important limitations

Episodic or cyclical treatment

– especially steroids and
IVIg

Prolonged time to onset for other immunosuppressants

Potential trade-offs to achieve therapeutic benefit

Potential safety concerns

Some invasive with burdensome route of administration

As medications are adjusted, anxiety about flares remain

Desire confidence in ability to sustain an adequate response

Fear of flare may limit patients' outlook of the future



Source: Immunovant Market Research 12

# 94% of MG patients surveyed preferred a chronic versus intermittent dosing approach

MG patient survey feedback, specifically incorporated into batoclimab trial design

94%

#### **Chronic Dosing:**

"I want to stay on my MG treatment, even when my symptoms are under control, so that I can maintain a response and avoid potential symptom flares"

"It's easier to schedule life around something so consistent"



6%

#### Intermittent Dosing:

"I only want MG treatment intermittently when my symptoms flare"



Phase 3 trial in MG is designed to address unmet patient needs and differentiate

batoclimab



#### **Need for significant improvement initially:**

High doses included in the induction period to achieve maximum efficacy at the beginning of treatment



#### Peace of mind over time:

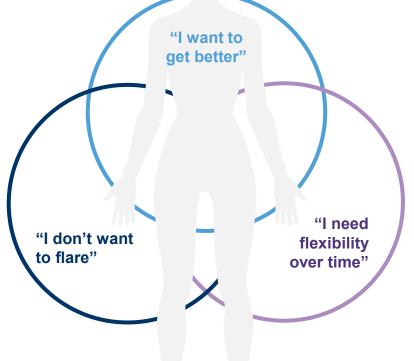
Chronic treatment to provide consistent symptom relief while lowering the dose to maintain efficacy with potentially fewer side effects



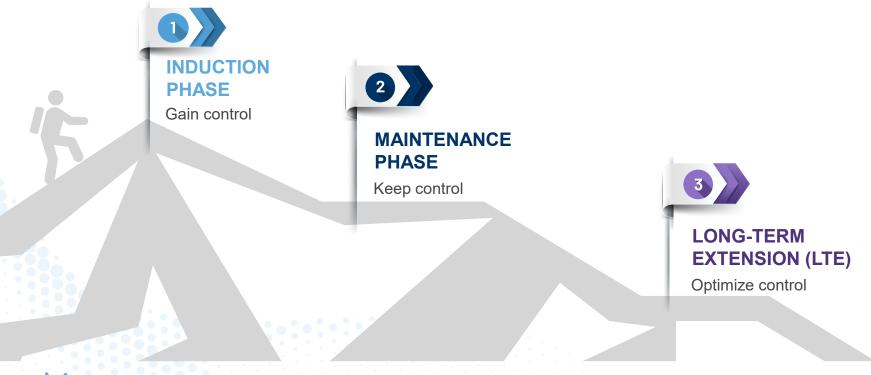
#### Flexible dosing to match disease fluctuations:

Myasthenia gravis waxes and wanes over time; clinicians and patients desire a data-driven approach to optimize care over time

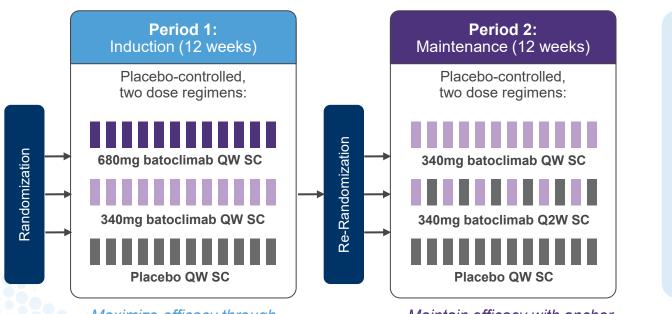




# Flexible Phase 3 design that is common in immunology trials but a first for an MG trial



## MG Phase 3 trial design (N ~ 200)





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

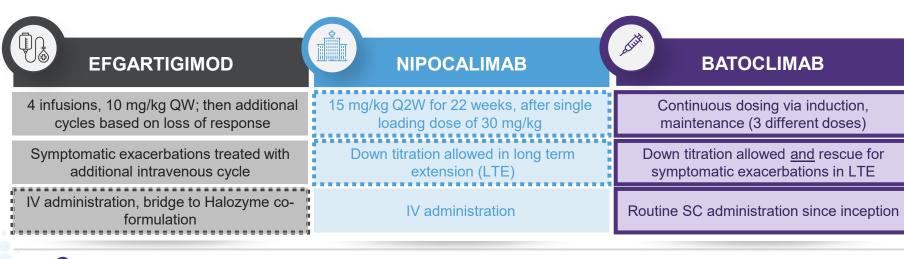
Period 2 followed by Long-Term Extension (LTE) study. Rescue therapy available during LTE per protocol.



Maintain efficacy with anchor dose and lower dose



# Batoclimab's Phase 3 trial in MG designed to deliver differentiated value







Flexible dosing in chronic phase for disease fluctuations

Steady, chronic dosing

Ease of administration



# Thyroid Eye Disease

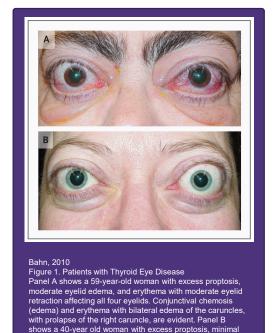






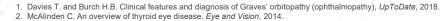
## Thyroid Eye Disease (TED) overview

- Also called Graves' orbitopathy or ophthalmopathy (GO)
- 15,000-20,000 patients with active TED in the United States per year
- Clinical features:<sup>1</sup>
  - Eye bulging ("Proptosis")
  - Eye pain
  - Double vision ("Diplopia")
  - Light sensitivity
- Can be sight-threatening<sup>2</sup>
- Caused by IgG autoantibodies that activate cell types present in tissues surrounding the eye<sup>2</sup>
- Close temporal relationship with Graves' disease



bilateral injection, and chemosis with slight erythema of the eyelids. She also had evidence, on slit-lamp examination, of

moderate superior limbic keratoconjunctivitis.





# Batoclimab could address TED caused by any IgG antibody, whether TSHR or IGF-1R

# TSHR IGF-1 Receptor Orbital Fibroblast Orbital Tissue

- Thyroid-stimulating hormone receptor (TSHR) highly expressed on ocular fibroblasts and adipocytes<sup>1</sup>
- Activation leads to inflammation and proliferation
- Autoantibodies against insulin-like growth factor-1 receptor (IGF-1R) also identified<sup>2</sup>

TSHR also highly expressed on thyroid gland cells (thyrocytes), and activation leads to increase production of thyroid hormone, causing Graves Disease<sup>3</sup>

<sup>3.</sup> Varewijck A.J., et al. Circulating IgGs may modulate IGF-I receptor stimulating activity in a subset of patients with Graves' ophthalmopathy. *Journal of Clinical Endocrinology & Metabolism*, 2013.



<sup>1.</sup> Smith T.J., et al. Role of IGF-1 pathway in the pathogenesis of Graves' orbitopathy. Best Practice & Research: Clinical Endocrinology & Metabolism, 2013.

<sup>2.</sup> Liaboe C.A., et al. An Introductory Tutorial and Overview of Disease – Thyroid Eye Disease (TED), 2016.

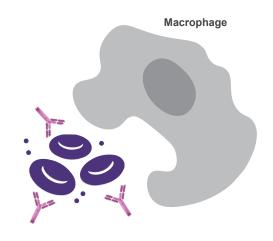
# Warm Autoimmune Hemolytic Anemia





## Warm Autoimmune Hemolytic Anemia (WAIHA) overview

- Rare blood disorder marked by red blood cell destruction
  - Pathogenic IgG antibodies attack red blood cells
  - Macrophages, which carry FcRn receptors, then destroy the red blood cells
- Estimated prevalence of 42,000 patients in US and 67,000 patients in EU
- Presentation typically non-specific and occurs over several weeks to months
  - · Fatigue, weakness, skin pallor, shortness of breath
- Severe cases can be fatal<sup>1</sup>







Roumier M., et al. Characteristics and outcome of warm autoimmune hemolytic anemia in adults: new insights based on a single-center experience with 60 patients. American Journal of Hematology, 2014.

## Limited options for treating WAIHA



## **Currently no FDA-approved** therapies

Standard of care includes: corticosteroids, RBC transfusion, immunosuppressive agents, 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>



<sup>1.</sup> Salama A. Treatment Options for Primary Autoimmune Hemolytic Anemia: A Short Comprehensive Review. Transfusion Medical and Hemotherapy, 2015.

<sup>2.</sup> Park S.H. Diagnosis and treatment of autoimmune hemolytic anemia: classic approach and recent advances. Blood Research, 2016.

<sup>3.</sup> Rituximab is not approved by the FDA for Warm Autoimmune Hemolytic Anemia.

# What's Next



## Our vision: normal lives for people with autoimmune diseases

#### Boldly developing therapies for a range of debilitating autoimmune diseases



We are wellpositioned in a double digit billiondollar class



Exciting path forward with five indications planned for 2022



Clear differentiation plan to create shareholder value



Strong balance sheet with \$559M<sup>1</sup> in cash

FcRn inhibition enables breakthrough in innovation in multiple autoimmune diseases

Batoclimab is a novel, fully human monoclonal antibody inhibiting FcRn-mediated IgG recycling, which is potent and predictable, with a manageable tolerability profile and simple subcutaneous administration

Planning to...

Initiate MG pivotal study in 1H 2022

Announce 2 new indications by August 2022

Initiate 2 additional pivotal studies in 2022



# Thank you



