

### Phase 3 Development for Batoclimab in Myasthenia Gravis

Corporate Update January 2022





### Forward-looking statements

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Alignment to move forward in myasthenia gravis (MG) is important for patients, with the potential to offer a differentiated treatment option in MG and enables broad development of batoclimab

We have achieved alignment with the FDA to move forward in MG. We plan to start a Phase 3 study for batoclimab (IMVT-1401) in MG in the first half of calendar year (CY) 2022.

In CY 2022, we expect to begin pivotal studies in three indications (including MG). We also plan to announce studies in at least two new indications (beyond MG, TED and WAIHA) by August 2022.

Our Phase 3 trial in MG is designed to uniquely address unmet patient needs by leveraging batoclimab's broad therapeutic window and simple subcutaneous delivery device to provide a differentiated offering.



# Aligned with FDA on required safety exposures and safety/monitoring plan for pivotal MG study

Inclusion and exclusion criteria for MG Ph3 trial enable access to broad population



score of 5 or more)

Exclusion



- Subjects with baseline LDLs greater than 190
- Subjects with a history of cardiovascular disease that have an LDL greater than 160
- Subjects with a cardiovascular event within the prior 6 months

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Statins will be permitted as concomitant medication but don't need to be initiated during blinded treatment periods. Statin initiation may occur, per protocol, in long term extension.

• Primary endpoint analysis

excludes AChR Ab- patients

Note: subset of inclusion and exclusion criteria for MG Ph3 trial shown on slide MGFA = Myasthenia Gravis Foundation of America; MG-ADL = Myasthenia Gravis Activities of Daily Living scale; AChR Ab+/- = acetylcholine receptor antibody-positive or negative 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

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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

## Nearly 80% of people with MG (on treatment) reported moderate or major lifestyle modifications

MG patient survey feedback, specifically incorporated into batoclimab trial design





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

## 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:

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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

INDUCTION PHASE Gain control



#### MAINTENANCE PHASE

Keep control

3 LONG-TERM EXTENSION (LTE)

Optimize control



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



Maximize efficacy through primary endpoint\* Maintain efficacy with anchor dose and lower dose



\***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's Phase 3 trial in MG designed to deliver differentiated value



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## Potential for anti-FcRn technology to help a broad range of people impacted by autoimmune disease

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



\*\*Refractory RA patient prevalence data shown \*\*\*Moderate to Severe pSS and CLE 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 Jun 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 LGI1+; 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 Eurytematosus

### 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*				



# Thank you

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