

# Phase 3 Development for Batoclimab in Thyroid Eye Disease

+ Investor Presentation

Investor Presentation June 8, 2022





# 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 "may," "might," "would," "expect," "believe," "estimate," "design," "plan," "potential," "intend," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant's plan to initiate a Phase 3 clinical trial for batoclimab in myasthenia gravis (MG) by the end of June 2022 with an expected topline data readout in the second half of calendar year 2024, and expectations with respect to the safety and monitoring plan and size of the safety database; Immunovant's plan to initiate two Phase 3 clinical trials for batoclimab in thyroid eye disease (TED) in the second half of calendar year 2022 with expected topline data readouts in the first half of calendar year 2025; Immunovant's plan to explore in subsequent study periods follow-on treatment with alternative dosing regimens; Immunovant's plan to develop batoclimab across a broad range of autoimmune indications; Immunovant's expectations regarding timing, the design and results of clinical trials of its product candidates and indication selections; the potential benefits of batoclimab's unique product attributes; whether, if approved, batoclimab will be successfully distributed, marketed and commercialized; and Immunovant's expected cash runway. 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 final trial results or of the results of later clinical trials; 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 candidate, 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 product candidate may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic on Immunovant's clinical development plans and timelines; Immunovant's business is heavily dependent on the successful development, regulatory approval and commercialization of its sole product candidate, batoclimab; Immunovant is at an early stage in development of batoclimab; and Immunovant will require additional capital to fund its operations and advance batoclimab 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 Annual Report on Form 10-K for the year ended March 31, 2022 filed with the SEC on June 8, 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



We have achieved alignment with the FDA to move forward in Thyroid Eye Disease (TED) as our second pivotal program with batoclimab



TED represents a meaningful and unique opportunity – program designed to show a differentiated clinical benefit in an exciting indication



Pivotal program to include two placebo-controlled Phase 3 clinical trials that will run in parallel and that are each expected to enroll approximately 100 subjects



Planning to initiate TED Phase 3 program in calendar year 2022, with topline results expected from both trials in the first half of calendar year 2025



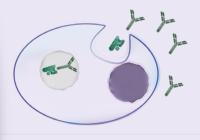
# Batoclimab's MOA is designed to foster the degradation of autoantibodies, such as pathogenic IgG anti-TSHR autoantibodies

#### In the absence of batoclimab.

FcRn binds to the anti-TSHR autoantibodies, inhibiting their degradation and returning them into the circulation

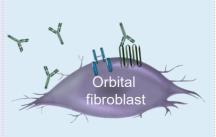
With batoclimab. FcRn is blocked from binding to anti-TSHR autoantibodies, which are then transported to the lysosome for degradation, decreasing their levels in the circulation

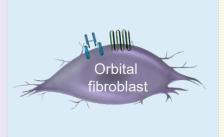
#### **Endothelial Cell**





#### **Ocular orbit**





#### **Thyroid**





Legend:



IGF-1R



Anti-TSHR autoantibodies







# Thyroid eye disease is a heterogeneous condition that presents with a variety of clinical symptoms

#### **UNDERSTANDING TED:**

- Progressive disease marked by inflammation that can lead to fibrosis
- Clinical features are variable, including but not limited to<sup>1</sup>:
  - Eye bulging ("proptosis")
  - Eye pain
  - Double vision ("diplopia")
- Swollen/red eyes
- Impaired visual ability
- May become sight-threatening if under-treated<sup>2</sup>
- Most patients with active TED on therapy report making substantial lifestyle modifications around their disease<sup>3</sup>
- Beyond IV teprotumumab, disease-modifying treatments are currently limited



Bahn, 2010
Figure 1. Patients with Thyroid Eye Disease
Panel A shows a 59-year-old woman with excess proptosis,
moderate eyelid edema, and erythema with moderate eyelid
retraction affecting all four eyelids. Conjunctival chemosis
(edema) and erythema with bilateral edema of the caruncles, with
prolapse of the right caruncle, are evident. Panel B shows a 40year old woman with excess proptosis, minimal bilateral injection,
and chemosis with slight erythema of the eyelids. She also had
evidence, on slit-lamp examination, of moderate superior limbic
keratoconjunctivitis.



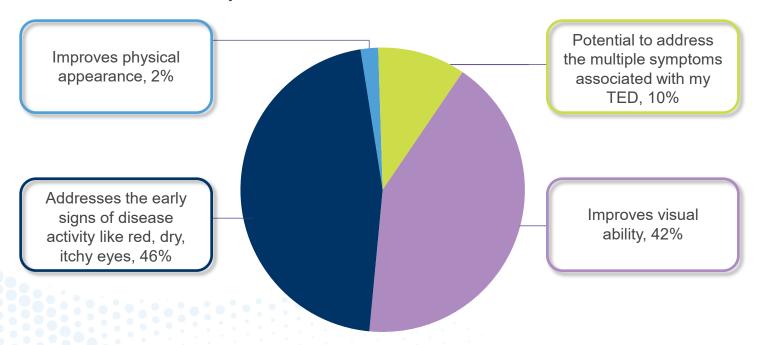
<sup>1.</sup> Davies T. and Burch H.B. Clinical features and diagnosis of Graves' orbitopathy (ophthalmopathy), UpToDate, 2018.

<sup>2.</sup> McAlinden C. An overview of thyroid eye disease. Eye and Vision, 2014.

<sup>3.</sup> TED Patient Quantitative Survey (n=50) by Immunovant, 2022

# Not surprisingly for a heterogeneous disease, people with active TED prioritize different treatment goals

#### **Most Important Treatment Goals to be Addressed**





# Unique dynamics of thyroid eye disease market make this a very favorable commercial opportunity for new mechanisms of action



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 Tepezza 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

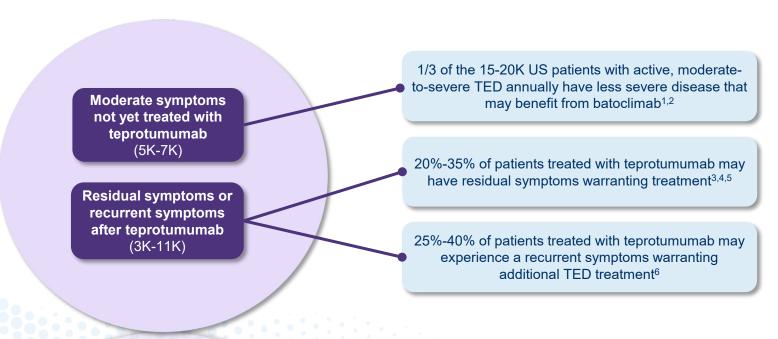


We believe that a simple subcutaneous route of administration is also important to patients, and perhaps more so during retreatment due to total duration



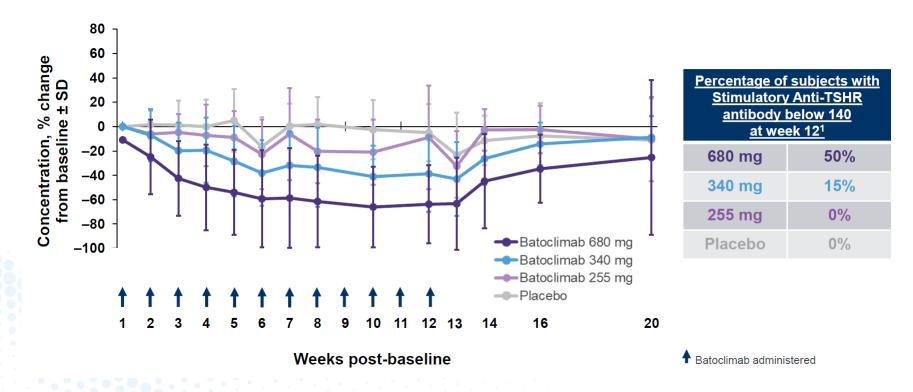
## Many TED patients can benefit from a new therapy

### A Total Addressable Population of 8K – 18K (US)



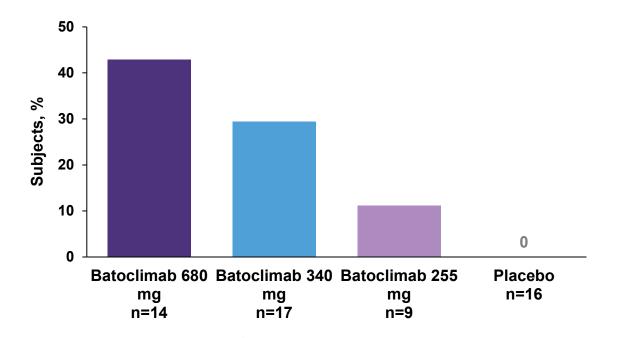


## Observed reductions in stimulatory anti-TSHR antibodies with batoclimab TED Phase 2b clinical trial





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



#### Effect size similar at week 12 though confidence intervals wide

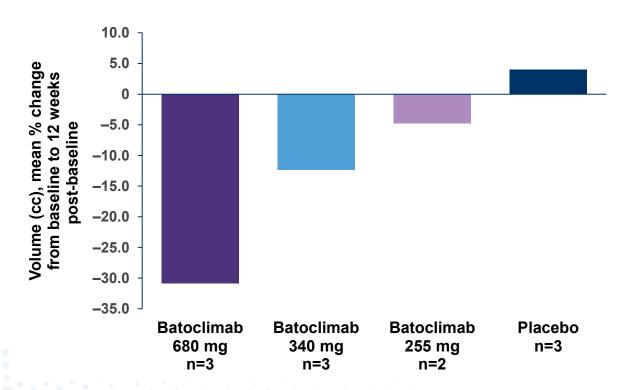


<sup>1</sup> Proptosis response defined as proptosis reduction ≥2 mm in study eye, without ≥2 mm increase in non-study eye at same visit. Week 6 data selected as it represents the latest time point at which the largest amount of patient data is available prior to the voluntary pause

Source: Data on File Immunovant Loc.

For In

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

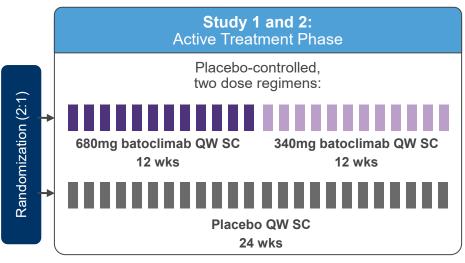




# TED Phase 3 clinical trial design – two studies to be run in parallel



- Subjects with clinical diagnosis of TED (active, moderate to severe TED with a **CAS** ≥ **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



Planning for two studies to run in parallel that follow trial design outlined above



#### **Primary endpoint:**

Follow up (4 wks)

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

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



## Pursuing a broad development program with batoclimab

\$494M¹ in cash expected to fund Immunovant's operating plans into calendar year 2025²

Target Indication	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Myasthenia Gravis (MG)				Phase 3 initiation planned by end of June
			•	2022; topline results expected in second half
				of calendar year 2024
Thyroid Eye Disease (TED)				Phase 3 initiation planned in second half of
				calendar year 2022; topline results expected
				in first half of calendar year 2025
Warm Autoimmune				
Hemolytic Anemia (WAIHA)				
				One of these three indications expected to be
Indication 4*				initiated as a pivotal trial (for a total of three planned pivotal trials to be initiated in calendar year 2022)
Indication 5*				
Indication 5*				January John Loully

\*Two new indications expected to be announced by August 2022



As of March 31, 2022, per Annual Report on Form 10-K filed with the SEC on June 8, 2022

# Thank you



