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

FORM 8-K

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 5, 2022

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

Delaware	**001-38906**	**83-2771572**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

320 West 37th Street	
New York, NY	**10018**
(Address of principal executive offices)	**(Zip Code)**

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

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
Common Stock, $0.0001 par value per share	**IMVT**	**The Nasdaq Stock Market LLC**

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. ☐

Item 7.01 Regulation FD Disclosure.

On January 5, 2022, Immunovant, Inc. will hold a pre-announced webcast and provide investors with a business update. A copy of the presentation to be used during the webcast is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by Immunovant, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation, dated January 5, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IMMUNOVANT, INC.

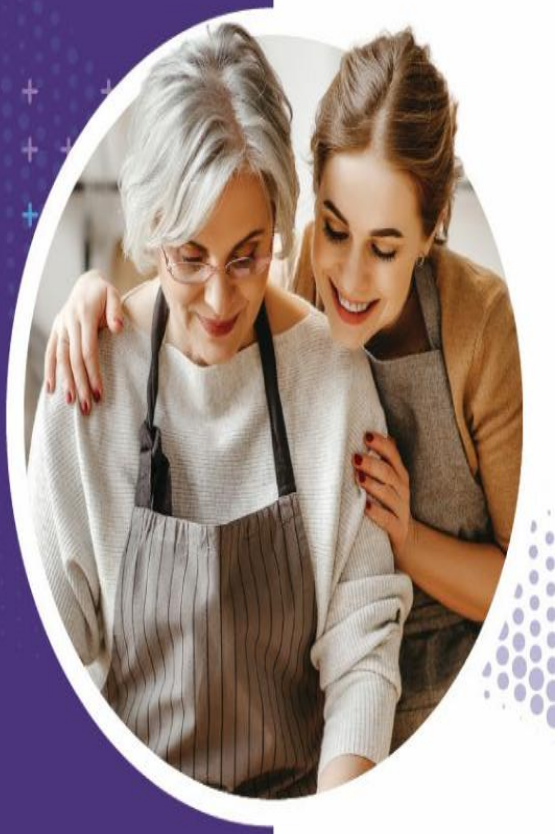
By: /s/ Eva Renee Barnett
Eva Renee Barnett
Chief Financial Officer

Date: January 5, 2022

Exhibit 99.1

IMMUNOVANT

Phase 3 Development for Batoclimab in Myasthenia Gravis



Corporate Update January 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," "will," "would," "should," "expect," "believe," "estimate," "design," "plan," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant's plan to start a Phase 3 study for batoclimab in myasthenia gravis (MG) in the first half of calendar year 2022 with a likely data readout in 2024, and expectations with respect to the safety and monitoring plan and size of the safety database; 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; and the potential benefits of batoclimab's unique product attributes. 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 most recent Annual Report on Form 10-K, its Form 10-Q filed with the SEC on November 5, 2021, 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.

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

Inclusion

Subjects with **MGFA class** II-IVA MG

Subjects with wide range of severity (baseline **MG-ADL** score of 5 or more)

AChR Ab+ and AChR Ab- patients

- *Primary endpoint analysis excludes AChR Ab- patients*

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

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.

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

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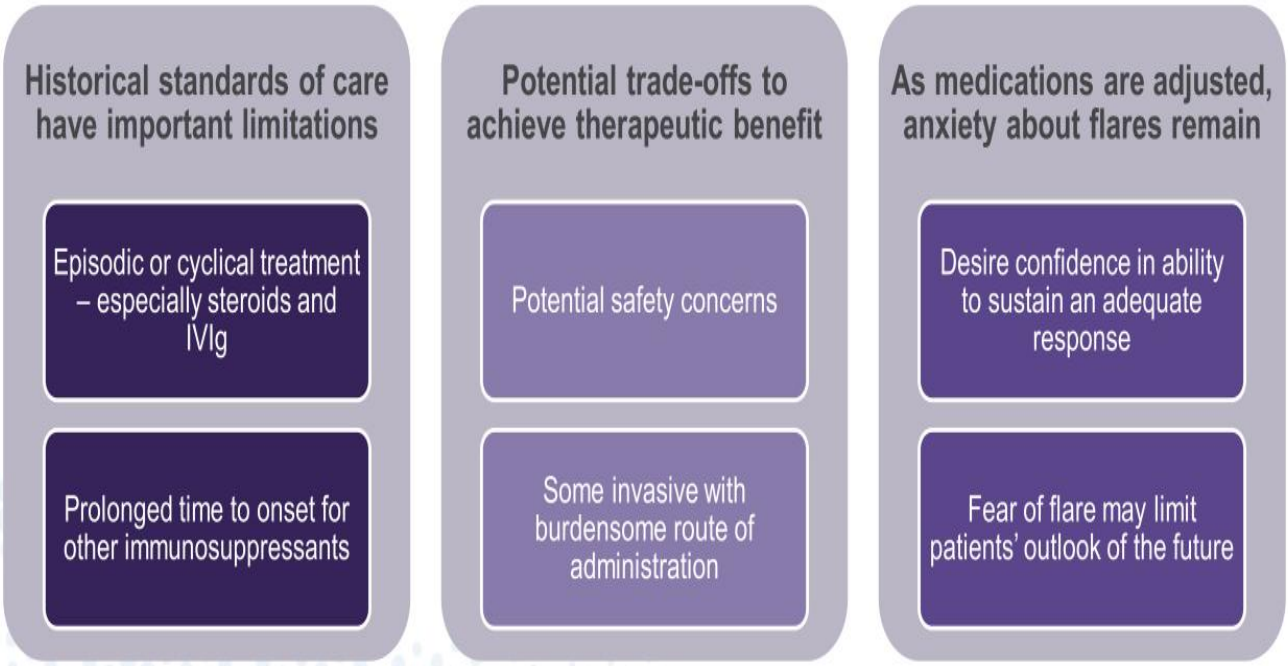
People with MG recognize limitations of current therapies, which keep them from living their normal lives

MG patient research feedback promising for anti-FcRn class



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Source: Immunovant Market Research

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

MG patient survey feedback, specifically incorporated into batoclimab trial design

38%
Major lifestyle modifications

40%
Moderate lifestyle modifications

22%
Slight lifestyle modifications

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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"

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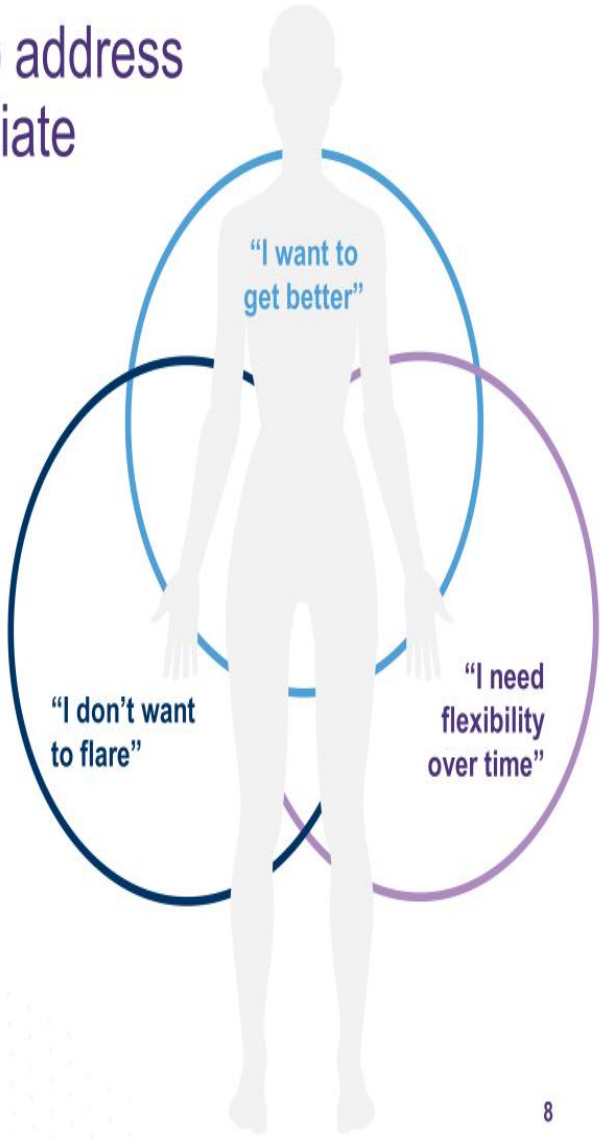
Source: Analysis – MG Patient Quantitative Survey (n=50)

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



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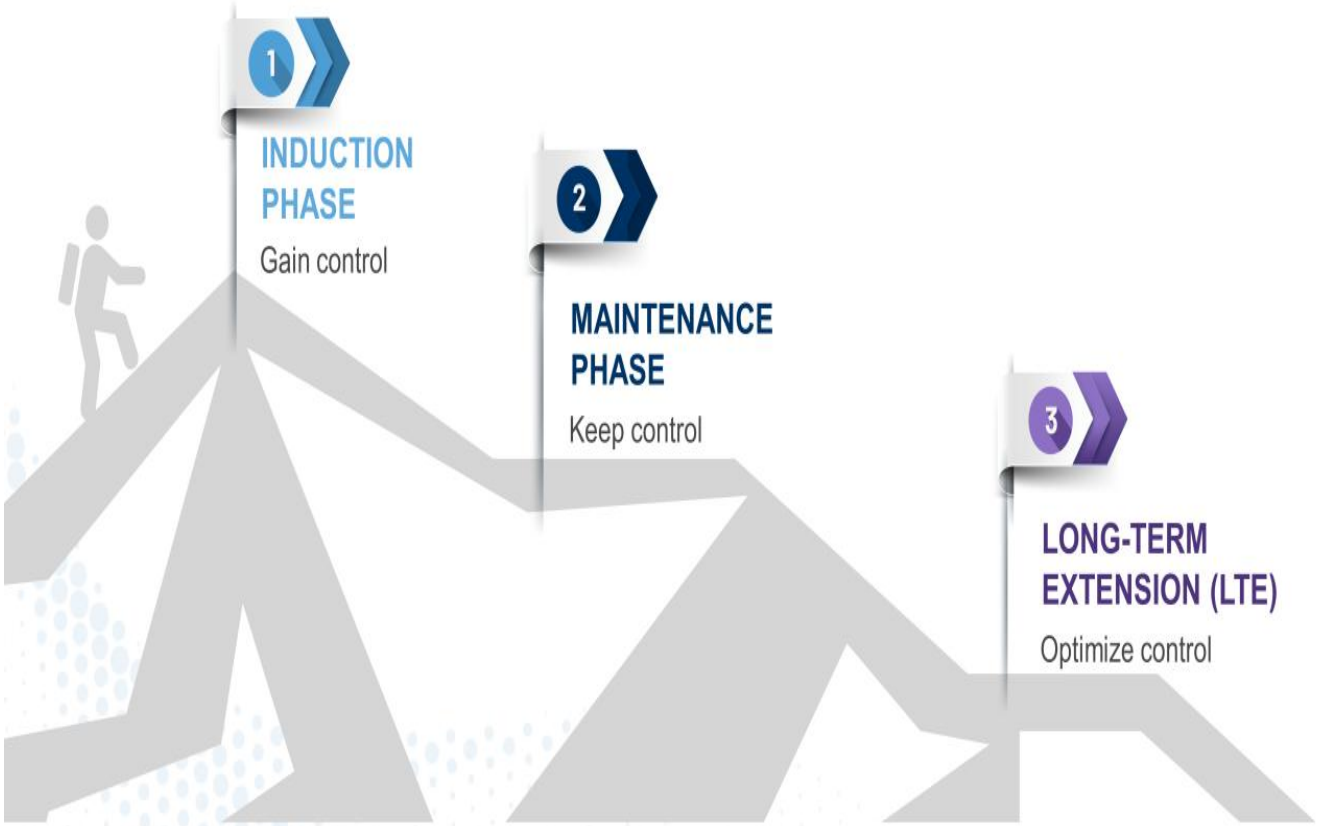
Flexible Phase 3 design that is common in immunology trials but a first for an MG trial



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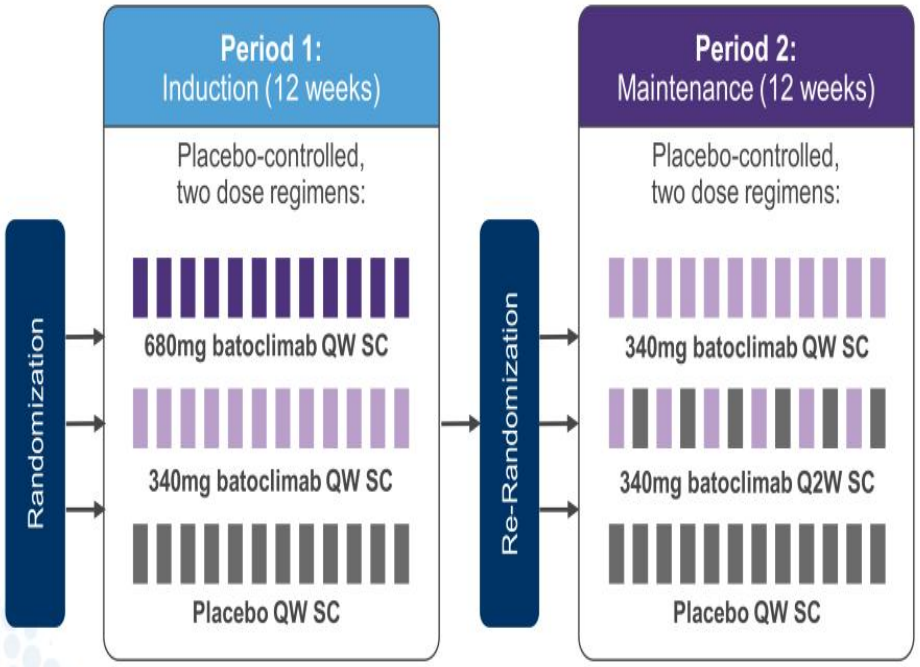
MG Phase 3 trial design (N ~ 200)



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.

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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

EFGARTIGIMOD	NIPOCALIMAB	BATOCLIMAB
4 infusions, 10 mg/kg QW; then additional cycles based on loss of response	15 mg/kg Q2W for 22 weeks, after single loading dose of 30 mg/kg	Continuous dosing via induction, maintenance (3 different doses)
Symptomatic exacerbations treated with additional intravenous cycle	Down titration allowed in long term extension (LTE)	Down titration allowed and rescue for symptomatic exacerbations in LTE
IV administration, bridge to Halozyme	IV administration	Routine SC administration

Patient Needs Addressed

1. Quick, deep response to gain control
2. Steady, chronic dosing
3. Flexible dosing in chronic phase for disease fluctuations
4. Ease of administration

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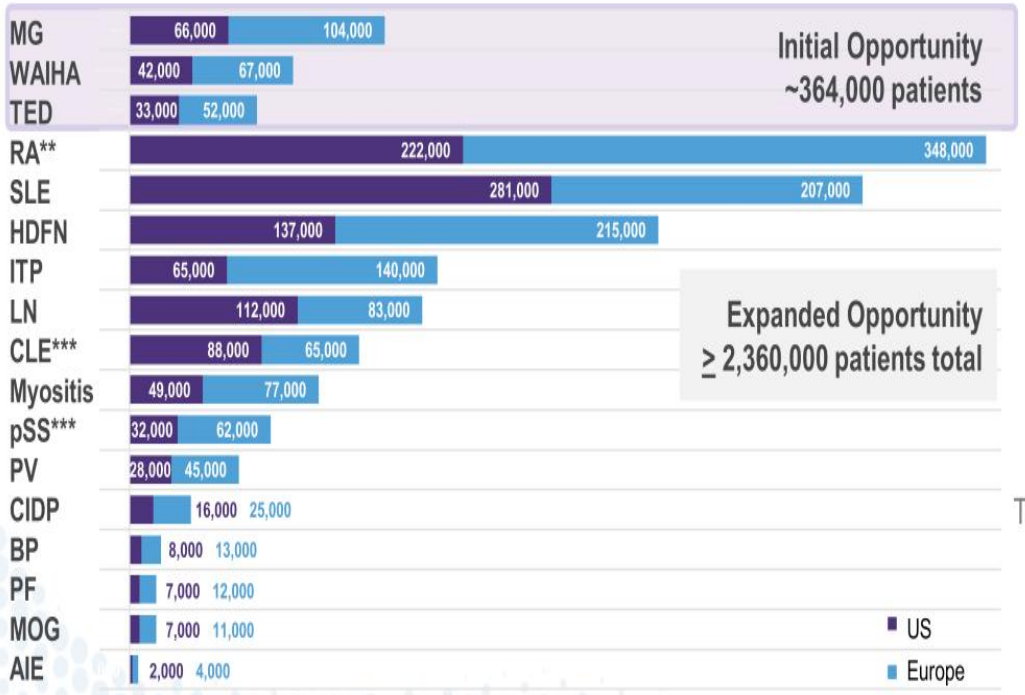
Potential for anti-FcRn technology to help a broad range of people impacted by autoimmune disease

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



Initial Opportunity
~364,000 patients

Expanded Opportunity
≥ 2,360,000 patients total

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Total US Patients

1,200,000

\+

Total European Patients

1,530,000

**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 Europe includes all EU countries, the UK and Switzerland

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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

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Thank you

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