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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): September 28, 2022**

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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 7.01 Regulation FD Disclosure.**

On September 28, 2022, Immunovant, Inc., or the Company, issued a press release announcing IMVT-1402, a Next Generation Anti-FcRn. A copy of the press release 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, or the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission, or the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 8.01 Other Events.**

On September 28, 2022, the Company will provide a corporate update regarding its business at Roivant's Investor Day webcast. A copy of the presentation to be used during the webcast is attached hereto as Exhibit 99.2 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="#">Press release dated September 28, 2022.</a>
99.2	<a href="#">Presentation dated September 28, 2022.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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### Immunovant Announces IMVT-1402, a Next Generation Anti-FcRn

- In animal studies, deep IgG lowering similar to batoclimab with no or minimal impact on albumin and low-density lipoprotein (LDL) was observed.
- Plan to submit IND and initiate Phase 1 study in early 2023 with initial data expected in mid-2023.
- Previously announced programs for lead asset batoclimab continue at full speed.
- Two asset anti-FcRn franchise offers multiple potential development and commercial synergies, with composition of matter patent protection expected for IMVT-1402 through at least 2042.

**NEW YORK, September 28, 2022 – Immunovant, Inc.** (Nasdaq: IMVT), a clinical-stage biopharmaceutical company committed to enabling normal lives for people with autoimmune diseases, today announced a new anti-FcRn, IMVT-1402, at Roivant's Investor Day at 11:00am on September 28, 2022. The presentation can be accessed at the Investor Relations section of the Company's website, located at [www.immunovant.com](http://www.immunovant.com).

"We are excited to unveil IMVT-1402, which has a combination of features that we believe could make a significant impact in the lives of people with autoimmune diseases," said Pete Salzmann, M.D., Chief Executive Officer at Immunovant. "As with batoclimab, IMVT-1402 may offer deep, potentially best-in-class IgG reduction formulated for the same simple subcutaneous route of administration delivered in a matter of seconds. Additionally, IMVT-1402 has been observed to have minimal or no impact on levels of albumin and LDL in animal studies. With these encouraging preclinical results, we are pursuing an accelerated development plan to bring IMVT-1402 to the clinic, with a Phase 1 study planned to start in early 2023 contingent on IND clearance. Importantly, our cash runway guidance into calendar year 2025 remains unchanged, as expected Phase 1 development costs for IMVT-1402, have been included," Dr. Salzmann added.

The combined franchise of batoclimab and IMVT-1402 may enable multiple paths to enhanced value creation for Immunovant. From a development perspective, proprietary patient level data from batoclimab complements the general strength of IgG as a biomarker, and these data together may allow us to accelerate the development of IMVT 1402 from our planned Phase 1 trial directly to planned pivotal studies. IMVT-1402 may also create an expanded opportunity for Immunovant in therapeutic areas such as Rheumatology, Hematology, and others, where chronic, maximal IgG reduction may be required to deliver the most robust clinical efficacy. From a commercial standpoint, if approved, the two-asset franchise may offer a range of synergies in addition to faster cash flow from batoclimab's potential launches. IMVT-1402 is also expected to have composition of matter patent protection through at least 2042, assuming issuance of the pending patent.

Immunovant's previously announced programs studying batoclimab in Myasthenia Gravis, Thyroid Eye Disease, Chronic Inflammatory Demyelinating Polyneuropathy and Graves' Disease continue at full speed. The trial design and lead asset for Warm Autoimmune Hemolytic Anemia will be determined based on an expected engagement with the FDA in calendar year 2022.

#### About Immunovant, Inc.

Immunovant, Inc. is a clinical-stage biopharmaceutical company dedicated to enabling normal lives for people with autoimmune diseases. As a leader in FcRn inhibitor technology, the Company is boldly developing innovative therapies for a range of debilitating autoimmune diseases with significant unmet patient needs. For additional information on the Company, please visit [www.immunovant.com](http://www.immunovant.com).

#### Forward Looking Statement

This press release 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 plan to complete a toxicology study in IMVT-1402 for a planned IND filing in early calendar year 2023 and to start a Phase 1 study in IMVT-1402 in the first quarter of calendar year 2023 with initial results expected in the

middle of calendar year 2023, Immunovant's plan to initiate a Phase 2b clinical trial for batoclimab in Chronic Inflammatory Demyelinating Polyneuropathy in the second half of calendar year 2022 with initial results from open-label period 1 expected in the first half of calendar year 2024; Immunovant's plan to initiate a Phase 2 clinical trial for batoclimab in Graves' Disease in early 2023 with initial results expected in the second half of calendar year 2023; Immunovant's plan to report topline data from its Phase 3 trial for batoclimab in Myasthenia Gravis in the second half of calendar year 2024; Immunovant's plan to initiate two Phase 3 clinical trials for batoclimab in Thyroid Eye Disease 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 finalize its trial design and compound selection in Warm Autoimmune Hemolytic Anemia following expected interactions with FDA in calendar year 2022; 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 patient enrollment, timing, the design and results of clinical trials of its product candidates and indication selections; Immunovant's beliefs regarding its cash runway, and the potential benefits of batoclimab's and IMVT-1402's unique product attributes; and expectations regarding the issuance 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 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 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 press release; 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 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, 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 of 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 August 5, 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.

**Contact:**

Chau Cheng, PhD, MBA  
VP Investor Relations  
Immunovant, Inc.  
info@immunovant.com



Exhibit 99.2

# Building a Leading Franchise

Next Generation FcRn: IMVT-1402



September 2022



# Forward-looking statements

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*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

## Driven by our core values



Love  
Trailblazing



Bolder,  
Faster



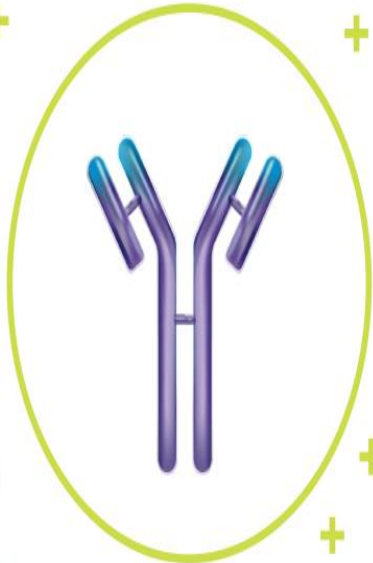
All  
Voices





# Building a leading anti-FcRn franchise: Introducing IMVT-1402

## IMVT-1402



Novel, fully human, monoclonal antibody inhibiting FcRn-mediated recycling of IgG



**IMVT-1402** is the successful culmination of in-house development

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Animal studies<sup>1</sup> have demonstrated **IMVT-1402** may have deep, potentially best-in-class IgG lowering, similar to batoclimab, and yet may have minimal impact on albumin and LDL

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**IMVT-1402** development can be accelerated by leveraging proprietary insights and well-known biology: IgG lowering has translated into clinical efficacy in 10+ late-stage trials<sup>2</sup>, including trials with batoclimab

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**Phase 1** study planned to initiate in Q1 2023 with initial data expected in mid-2023

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Development of **IMVT-1402** and batoclimab intended to maximize our FcRn franchise value, with potential composition of matter patent protection for IMVT-1402 to 2042+<sup>3</sup>

1. Data on file at Immunovant
2. Source: Anti-FcRn data publicly disclosed by Immunovant, Argenx, UCB, and Momenta
3. Assuming issuance of pending patent

# FcRn inhibition has broad potential in autoimmune diseases: 19 announced indications<sup>1</sup> across multiple therapeutic areas create clinical and commercial<sup>2</sup> opportunity for a franchise approach



## 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



1. Indications announced or in development with anti-FcRn assets by Immunovant, Argenx, JNJ, and UCB  
2. If approved by regulatory authorities

## Anti-FcRn market is unique in terms of breadth of potential indications and in terms of having a strong biomarker

»» IgG reduction is a well-established biomarker for degree of clinical response<sup>1</sup>

»» Some patient populations and indications likely need **maximal IgG suppression** (up to ~80%) to maximize clinical benefit and duration of this need will vary

»» We believe broad validity of IgG as a biomarker across indications enables an **accelerated development** path for a **new anti-FcRn** particularly with proprietary patient level data on file

# Next generation anti-FcRn: IMVT-1402





# IMVT-1402 has potentially best-in-class attributes to address large unmet need in autoimmune disease

01

## DEEP IgG LOWERING

Animal studies suggest deep dose-dependent IgG lowering similar to batoclimab<sup>1</sup>

02

## CONVENIENT ADMINISTRATION

Formulated for simple subcutaneous injection that may enable self-administration at home

03

## FAVORABLE ANALYTE PROFILE

Animal studies support the potential for a favorable analyte profile with no or minimal effect on albumin and LDL

04

## COMPELLING PATENT PROTECTION<sup>2</sup>

Pending 1402 composition of matter patent expiring 2042+

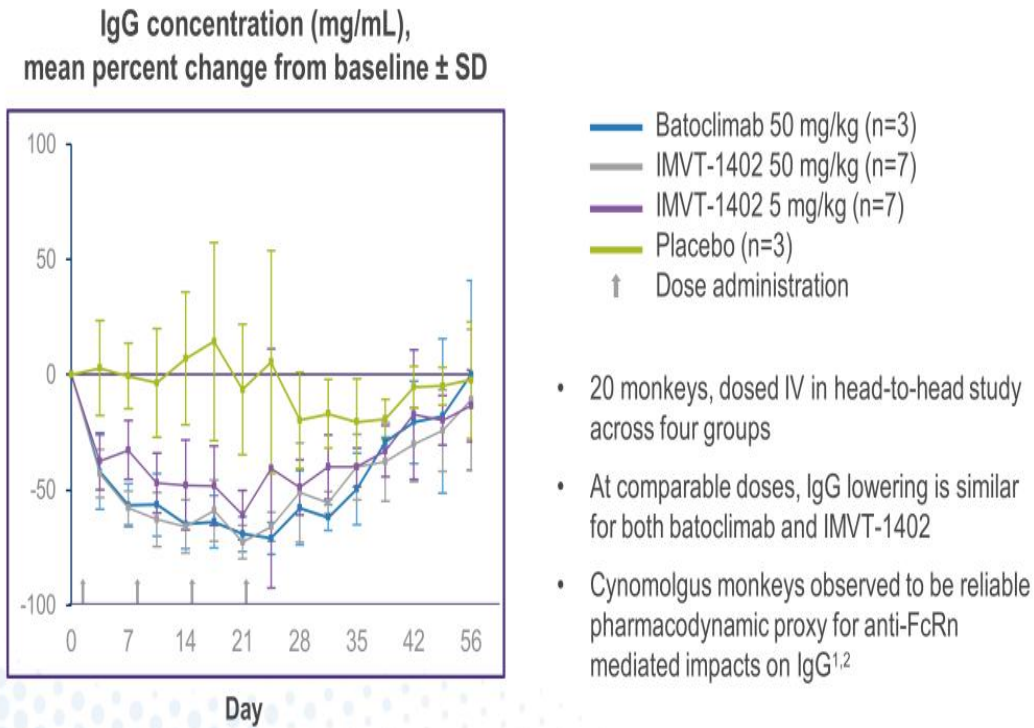


1. Data on file at Immunovant

2. Assuming issuance of pending composition of matter patent as anticipated

# IMVT-1402 and batoclimab demonstrated similar, maximum IgG reduction

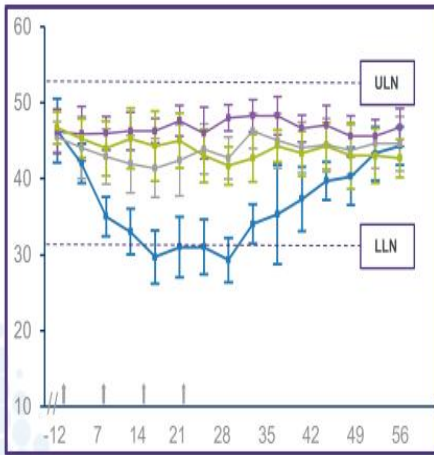
## Head-to-Head Monkey Study



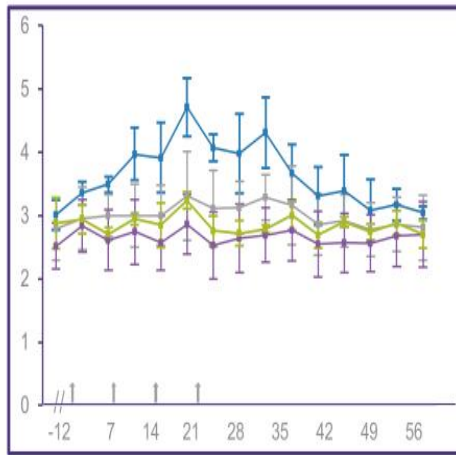
# IMVT-1402 and placebo demonstrated similar albumin and LDL

## Head-to-Head Monkey Study

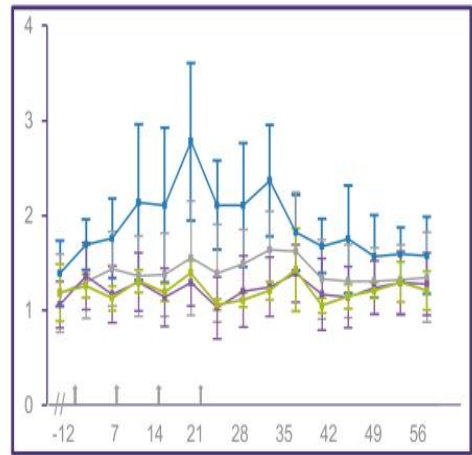
Albumin concentration (g/L), mean  $\pm$  SD



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)



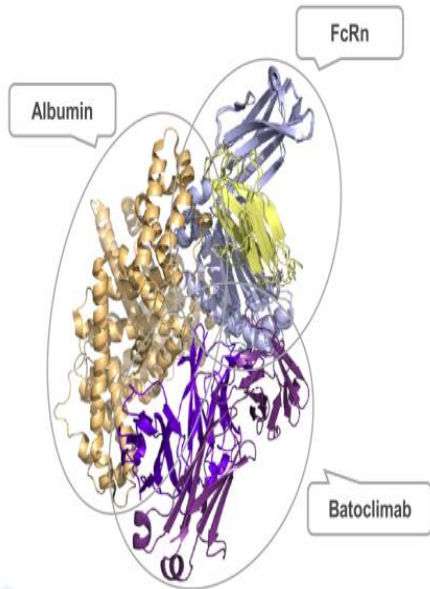
SD, standard deviation; ULN, upper limit of normal; LLN, lower limit of normal; Arrows indicate time of dosing.  
Data on file at Immunovant

For Investor Audiences Only 10

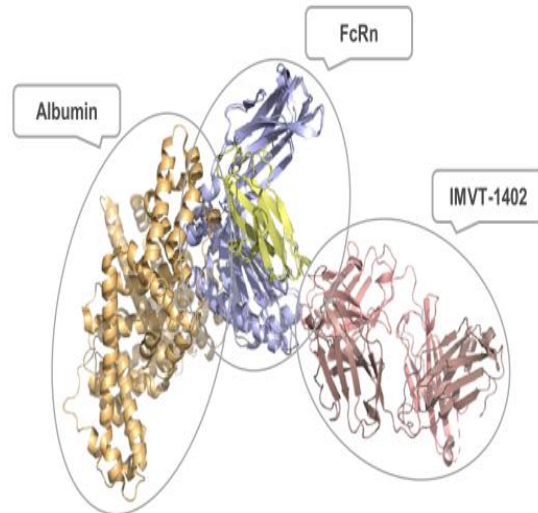


# IMVT-1402 is designed to deliver maximum IgG reduction while minimizing interference with the albumin binding site

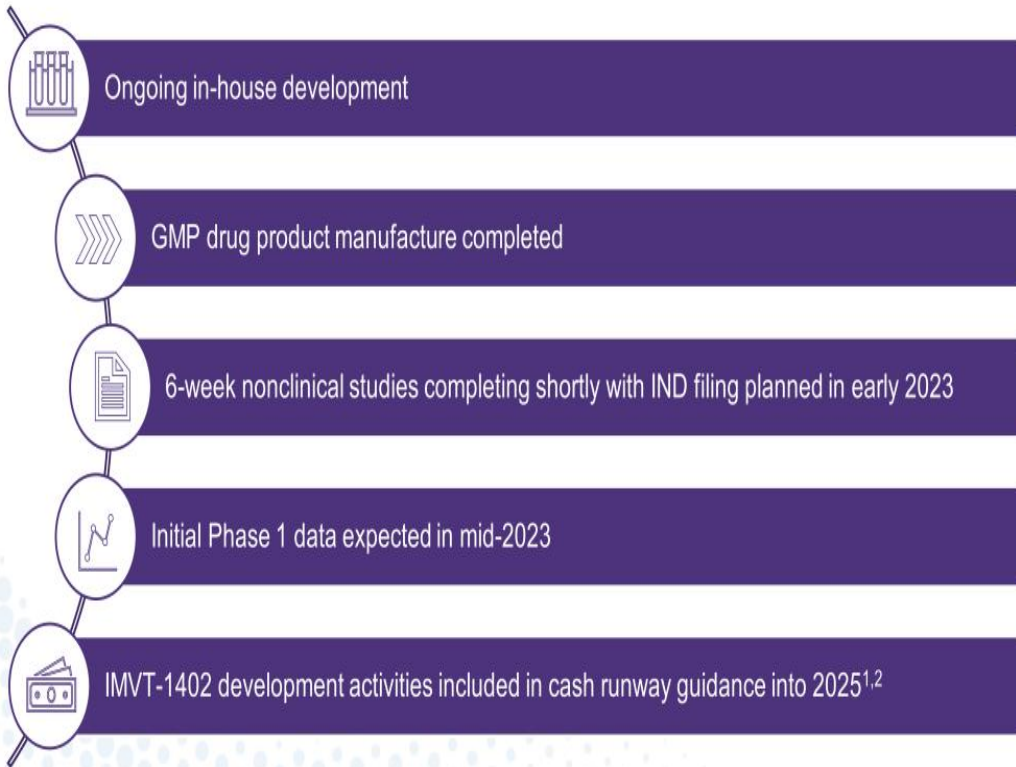
Batoclimab



IMVT-1402



# IMVT-1402 development is well underway, with initial Phase 1 data expected in mid-2023



## IMVT-1402



Novel, fully human, monoclonal antibody inhibiting FcRn-mediated recycling of IgG



1. 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

2. As of September 22, 2022, our cash balance was approximately \$410M, and our cash burn for the period from July 1, 2022 to September 22, 2022 was approximately \$17M

# Anti-FcRn Franchise Strategy



# Building an anti-FcRn franchise with differentiated assets to address a range of patient needs

## 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

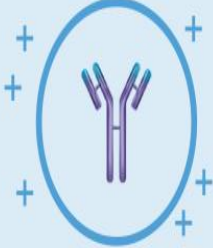


**Chronic dosing** to address symptom severity and duration for extended periods of time (>12 weeks)<sup>1</sup>

- Sustained maximal IgG suppression where needed
- Chronic delivery with simple subcutaneous delivery in seconds
- No or minimal impact to albumin / LDL

# Building an anti-FcRn franchise with differentiated assets and a rational development strategy to optimize ability to address unmet need

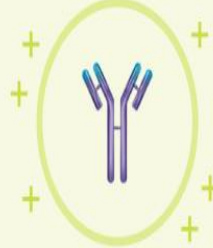
**Batoclimab**



Induction and Maintenance in **MG, CIDP**  
Fixed Duration in **TED**

The diagram shows a Y-shaped antibody structure in blue and purple, enclosed within a blue circle. Six plus signs (+) are arranged around the circle, representing the antibody's interaction with FcRn receptors.

**IMVT-1402**



Sustained, maximal IgG suppression in additional therapeutic areas such as **Rheumatology** and **Hematology**

The diagram shows a Y-shaped antibody structure in blue and purple, enclosed within a green circle. Six plus signs (+) are arranged around the circle, representing the antibody's interaction with FcRn receptors.



# Planning to leverage data and learnings from batoclimab to accelerate development of IMVT-1402

Potential case study in Graves' Disease

Batoclimab Phase 2 trial in Graves' Disease to define effect size and trial design

IMVT-1402 dosing to be informed by parallel planned Phase 1 trial

Combine learning to initiate planned pivotal trial with IMVT-1402

# Batoclimab and IMVT-1402 have the potential to offer multiple differentiated product features, if approved

		Immunovant Franchise	
Product and program attributes	efgartigimod <sup>1</sup>	batoclimab	IMVT-1402 <sup>2</sup>
IgG reduction ~65%	X	X	X
IgG reduction ~80%		X	X
Albumin/LDL changes: none or minimal	X		X
<b>Subcutaneous (SC) formulation delivered in seconds</b>		X	X
Chronic dosing to achieve ~65%	X	X	X
Chronic dosing to achieve ~65% with SC in seconds		X	X
<b>Chronic dosing to achieve ~80% with SC in seconds</b>			X
Induction and maintenance dosing <sup>3</sup>	N/A, requires high dose	MG Ph 3, CIDP	Possible
Fixed duration dosing	Possible	TED Ph 3	Possible
Chronic higher dosing (with saturating dose)	N/A, requires high dose	Not planned	Possible
As needed cyclic dosing	X	Not planned	Not planned
<b>Key product candidate advantages favor batoclimab and IMVT-1402</b>	1.No Albumin/LDL changes 2.Exclusive Halozyme partnership	1.Deeper IgG reduction with 680 mg 2.SC delivery in seconds	1.680 mg-like IgG reduction 2.SC delivery in seconds 3.Minimal Albumin/LDL change



1. Source: Argenx Corporate Presentation, June 2022  
 2. Potential outcomes if Phase 1 results are as predicted by pre-clinical studies in cynomolgus monkeys  
 3. Induction refers to starting with saturating dose that can achieve ~80% IgG reduction



# We believe franchise value is maximized by developing both batoclimab and IMVT-1402



Lead asset **batoclimab** full speed ahead in pivotal programs for **MG**, **TED** and **CIDP**



Earlier **batoclimab** launches may provide faster path to positive cash flow and enable commercial<sup>1</sup> synergies across the franchise



Complementary new asset **IMVT-1402** expected<sup>2</sup> to expand opportunity in additional therapeutic areas and increase the clinical and commercial potential of the combined franchise



We believe patient level data from **batoclimab** and strength of IgG as a biomarker can accelerate the development of **IMVT-1402**



**IMVT-1402** composition of matter patent protection to 2042+<sup>3</sup>

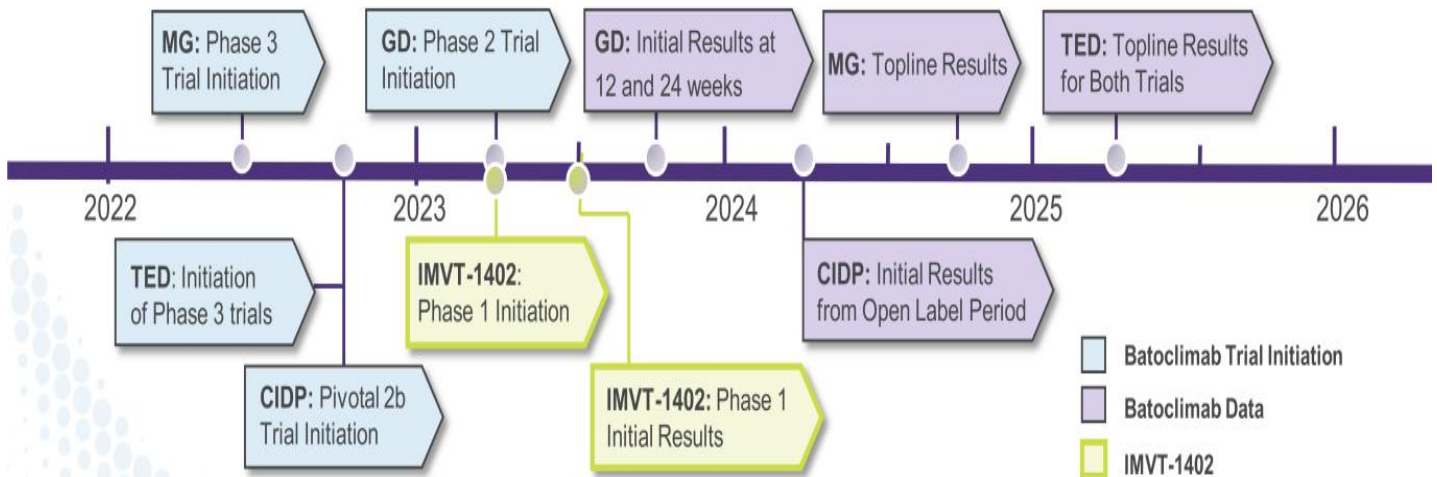


# + Summary




# Multiple paths to enhanced value creation when batoclimab and IMVT-1402 are developed together


We believe franchise value is maximized in both the near and longer term<sup>1</sup>



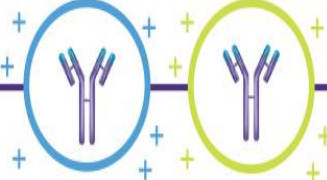
# A leader in FcRn inhibitor technology dedicated to enabling normal lives for people with autoimmune diseases



**Batoclimab full speed ahead in MG, TED and CIDP**



**IMVT-1402 designed for differentiation across the key product features for anti-FcRns**



**Multiple paths to enhanced value creation when batoclimab and IMVT-1402 are developed together**

