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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): November 7, 2024**

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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 2.02. Results of Operations and Financial Condition**

On November 7, 2024, Immunovant, Inc., or the Company, issued a press release announcing its financial results for its fiscal second quarter and six months ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02, 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 in this Item 2.02 shall not be incorporated by reference in any filing with the U.S. Securities and 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**

As described in the press release, the Company will host a conference call and webcast to provide business updates for investors at 8:00 a.m. ET on November 7, 2024. A copy of the presentation to be used by the Company during the conference call is filed as Exhibit 99.2 to this Current Report on Form 8-K 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 November 7, 2024.</a>
99.2	<a href="#">Presentation, dated November 7, 2024.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**Immunovant Provides Development Updates and Reports Financial Results for the Quarter Ended September 30, 2024**

- Five Investigational New Drug (IND) applications cleared across a range of therapeutic areas and FDA divisions for lead asset, IMVT-1402
- Proof of concept data from batoclimab trial in Graves' disease (GD) demonstrate potential of deeper IgG reduction with potent FcRn inhibition to transform treatment for GD patients who are not well controlled on antithyroid drugs (ATDs); initiation of potentially registrational trial to evaluate IMVT-1402 in GD expected by year end
- IND cleared for IMVT-1402 in rheumatoid arthritis (RA), with potential best-in-class profile in difficult-to-treat (D2T) RA; initiation of potentially registrational trial to evaluate IMVT-1402 in D2T RA expected by March 31, 2025
- On track to initiate potentially registrational trials with IMVT-1402 in four to five indications, inclusive of GD and D2T RA, by March 31, 2025
- Batoclimab trials in myasthenia gravis (MG) and chronic inflammatory demyelinating polyneuropathy (CIDP) fully enrolled to support data disclosures by March 31, 2025; data from batoclimab trials in thyroid eye disease (TED) now expected in the second half of calendar year 2025; all batoclimab data will inform future trials with IMVT-1402
- Immunovant to host development update call today, November 7, at 8 a.m. ET

**NEW YORK, November 7, 2024 – Immunovant, Inc. (Nasdaq: IMVT)** a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today reported development updates and financial results for its fiscal second quarter ended September 30, 2024.

Immunovant continues to focus on moving rapidly to unlock the full potential of its lead asset, IMVT-1402, for the benefit of people with underserved autoantibody-driven diseases. With five IND applications now cleared, the company remains on course to initiate four to five potentially registrational clinical development programs by March 31, 2025. These INDs are expected to support evaluation of IMVT-1402 in a variety of indications and therapeutic areas. As previously announced, Immunovant anticipates initiating clinical trials evaluating IMVT-1402 in a total of ten indications by March 31, 2026.

“Since announcing the Phase 1 data for IMVT-1402 a year ago, we have made tremendous progress in advancing IMVT-1402 towards multiple potentially registrational study initiations. We’re ahead of our goal to activate three INDs by calendar year end and we are very excited about all five cleared INDs – both those that have been announced and those that have not yet been announced. In terms of announced indications, we believe our first-in-class program with IMVT-1402 in GD has the potential to transform the treatment of GD patients who respond poorly to ATDs,” said Pete Salzmann, M.D., chief executive officer of Immunovant.

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“We are also excited to announce expansion of our IMVT-1402 development program into Rheumatology. Our first program in Rheumatology will be a potentially registrational study in patients with D2T RA where we believe that deeper IgG reduction has the potential to deliver better clinical outcomes in an important subset of patients with elevated RA-specific autoantibodies (ACPA). People living with D2T RA have already exhausted multiple therapeutic options yet continue to suffer from active disease, persistent disability and pain,” Salzmann continued. “We believe IMVT-1402 can deliver meaningful clinical benefit in ACPA-positive (ACPA+) D2T RA patients, with a potentially best-in-class profile driven by deeper IgG reduction.”

FcRn inhibition represents an attractive mechanism as a potential treatment for the approximately 70,000 US patients with D2T, ACPA+ RA. Recently disclosed in-class data demonstrated that both higher baseline ACPA levels and deeper ACPA reduction correlated with better clinical improvement in ACPA+ RA patients treated with an FcRn inhibitor. Having received FDA clearance of the IND for IMVT-1402 in RA, Immunovant plans to initiate a potentially registrational trial in ACPA+ D2T RA by March 31, 2025. The trial builds on in-class learning in terms of its target population (enriched for above-normal ACPA levels) and trial design (open-label lead-in followed by randomized withdrawal). The trial will leverage IMVT-1402’s higher dose (600 mg) during the open-label induction phase of the clinical trial to maximize reduction in ACPA levels.

## Recent Highlights and Upcoming Milestones

### Endocrinology Program

In September 2024, Immunovant provided a GD program update consisting of new epidemiologic data characterizing unmet need in GD patients who are relapsed, uncontrolled or intolerant of ATDs, additional results from the batoclimab GD study, and an overview of the IMVT-1402 development program in GD. In November 2024, additional data on the efficacy and safety of batoclimab in Graves’ thyroidal and extrathyroidal disease were presented in an oral presentation at the American Thyroid Association (ATA) 2024 Annual Meeting. These data showed that a 60% response rate (defined as T3 and T4 falling below the upper limit of normal (ULN) without increasing the ATD dose) was achieved by Week 2, demonstrating the rapidity of response to batoclimab 680mg dosed weekly. Meaningful improvements in proptosis and lid aperture were also observed at both Week 12 and Week 24. Pronounced improvements in multiple Thyroid-Related Patient-Reported Outcomes (ThyPRO-39) measurement scales were also observed, with ATD-Free Responders (defined as T3 and T4 falling below the ULN and ceasing all ATD medications) reporting greater improvements than other participants.

The batoclimab data in Graves’ disease support the potential for deep IgG reduction to modify the underlying pathophysiology of the disease, which could enable a transformation of the treatment of Graves’ disease for patients not well controlled on ATDs. Immunovant remains on track to initiate the first potentially registrational trial of IMVT-1402 in GD by calendar year end.

Competition for clinical trial participants with acute, active TED has increased over the course of the company’s Phase 3 program to evaluate batoclimab for the treatment of thyroid eye disease (TED). As a result, top-line results are now expected to be available in the second half of calendar year 2025, along with a decision on whether to advance batoclimab to registration in TED. Data from this trial will be leveraged to inform the overall program in GD for the Company’s lead asset, IMVT-1402.

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## Neurology Program

As previously reported, Immunovant completed enrollment of the batoclimab pivotal trial in MG, with top-line results expected to be reported by March 31, 2025. Results from this trial are expected to inform a decision regarding next steps for batoclimab in MG and the design of the MG program for IMVT-1402, which Immunovant expects to initiate by March 31, 2025.

Enrollment of study participants has completed in the Phase 2b trial evaluating batoclimab in chronic inflammatory demyelinating polyneuropathy (CIDP) for those patients to be included in the period 1 data readout expected by March 31, 2025. A decision to enroll additional patients in the batoclimab CIDP study will be made following the readout of period 1 data. Those results, as well as observations drawn from public disclosures of other studies in CIDP, will be used to inform the trial design for a potentially registrational program for IMVT-1402 in CIDP.

## Corporate Update

Immunovant also announced today that it appointed Melanie Gloria as Chief Operating Officer, effective November 18, 2024. Ms. Gloria brings over 20 years of experience in the biotechnology industry, including leadership roles at Acelyrin, Horizon Therapeutics and AbbVie. At AbbVie and Horizon she led teams to achieve global approvals of HUMIRA®, Viekera Pak®, Mavyret®, Skyrizi®, Rinvoq®, TEPEZZA®, and ORILISSA®. “I am thrilled to welcome Melanie to Immunovant where her success in driving late-stage drug development will be incredibly valuable,” said Salzmann. “Melanie’s proven drug development capabilities are a great fit for Immunovant’s portfolio.”

## Webcast Details

Immunovant will host a webcast at 8:00 a.m. ET today to discuss these updates. **Please click [register here](#) to register for the event.** The live webcast will also be available under the News & Events section of Immunovant’s website. A replay of the event and presentation will be available immediately following the event.

## Financial Highlights for Fiscal Second Quarter Ended September 30, 2024:

**Cash Position:** As of September 30, 2024, Immunovant’s cash and cash equivalents totaled approximately \$472.9 million.

**R&D Expenses:** Research and development expenses were \$97.3 million for the three months ended September 30, 2024, compared to \$48.0 million for the three months ended September 30, 2023. The increase was primarily due to activities in preparation for potential future clinical trials of IMVT-1402, including contract manufacturing costs for drug substance, higher overall clinical trial costs related to our batoclimab pivotal clinical trials, and elevated personnel-related expenses. The increase was partially offset by lower overall costs related to our IMVT-1402 Phase 1 trial and nonclinical studies.

**G&A Expenses:** General and administrative expenses were \$18.5 million for the three months ended September 30, 2024, compared to \$13.8 million for the three months ended September 30, 2023. The

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increase was primarily due to higher personnel-related expenses, legal and other professional fees, and information technology costs.

**Net Loss:** Net loss was \$109.1 million (\$0.74 per common share) for the three months ended September 30, 2024, compared to \$58.7 million (\$0.45 per common share) for the three months ended September 30, 2023. Net loss for the three months ended September 30, 2024 and September 30, 2023 included \$12.7 million and \$10.5 million, respectively, related to non-cash stock-based compensation expense.

**Common Stock:** As of September 30, 2024, there were 146,565,049 shares of common stock issued and outstanding.

#### **Financial Highlights for Fiscal Six Months Ended September 30, 2024:**

**R&D Expenses:** Research and development expenses were \$172.7 million for the six months ended September 30, 2024, compared to \$98.5 million for the six months ended September 30, 2023. The increase was primarily due to activities in preparation for potential future clinical trials of IMVT-1402, including contract manufacturing costs for drug substance, higher overall clinical trial costs related to our batoclimab pivotal clinical trials, and elevated personnel-related expenses. The increase was partially offset by lower overall costs related to our IMVT-1402 Phase 1 trial and nonclinical studies.

**IPR&D Expenses:** There were no acquired in-process research and development expenses for the six months ended September 30, 2024. During the six months ended September 30, 2023, acquired in-process research and development expenses were \$12.5 million related to the achievement of development and regulatory milestones for batoclimab under the terms of the HanAll in-license agreement.

**G&A Expenses:** General and administrative expenses were \$37.3 million for the six months ended September 30, 2024, compared to \$29.2 million for the six months ended September 30, 2023. The increase was primarily due to higher personnel-related expenses, legal and other professional fees, and information technology costs.

**Net Loss:** Net loss was \$196.3 million (\$1.34 per common share) for the six months ended September 30, 2024, compared to \$132.6 million (\$1.01 per common share) for the six months ended September 30, 2023. Net loss for the six months ended September 30, 2024 and September 30, 2023 included \$26.1 million and \$21.2 million, respectively, related to non-cash stock-based compensation expense.

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## **About Immunovant, Inc.**

Immunovant, Inc. is a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases. As a trailblazer in anti-FcRn technology, the Company is developing innovative, targeted therapies to meet the complex and variable needs of people with autoimmune diseases. For additional information on the Company, please visit [immunovant.com](https://immunovant.com).

## **Forward-Looking Statements**

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,” “anticipate,” “intend,” and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include statements regarding Immunovant’s expectations regarding the timing, design, and results of clinical trials of IMVT-1402 and batoclimab, including the number and timing of (a) FDA clearance with respect to IND applications, (b) potential registrational programs and clinical trials of IMVT-1402, (c) expected data readouts from batoclimab trials in MG and CIDP, and (d) estimates of the target populations for IMVT-1402, including in RA; Immunovant’s plan to develop IMVT-1402 and batoclimab across a broad range of indications; and potential benefits of IMVT-1402’s unique product attributes and potential best-in-class profile. 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: Immunovant may not be able to protect or enforce its intellectual property rights; initial results or other preliminary analyses or results of early clinical trials may not be predictive of 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 candidates, including the number and timing of the commencement of additional clinical 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 product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of macroeconomic and geopolitical factors on Immunovant’s business operations and supply chain, including its clinical development plans and timelines; Immunovant’s business is heavily dependent on the successful development, regulatory approval, and commercialization of IMVT-1402 and/or batoclimab; Immunovant is at various stages of clinical development for IMVT-1402 and batoclimab; and Immunovant will require additional capital to fund its operations and advance IMVT-1402 and 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 Form 10-Q to be filed with the SEC on November 7, 2024, 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.

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**IMMUNOVANT, INC.**

**Consolidated Statements of Operations**

*(Unaudited, in thousands, except share and per share data)*

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
<b>Operating expenses:</b>				
Research and development	\$97,272	\$47,959	\$172,745	\$98,534
Acquired in-process research and development	—	—	—	12,500
General and administrative	18,471	13,841	37,279	29,243
Total operating expenses	115,743	61,800	210,024	140,277
Interest income	(6,073)	(3,572)	(13,254)	(7,637)
Other income, net	(629)	(20)	(657)	(484)
Loss before provision for income taxes	(109,041)	(58,208)	(196,113)	(132,156)
Provision for income taxes	78	454	156	443
<b>Net loss</b>	<b>\$(109,119)</b>	<b>\$(58,662)</b>	<b>\$(196,269)</b>	<b>\$(132,599)</b>
Net loss per common share – basic and diluted	\$(0.74)	\$(0.45)	\$(1.34)	\$(1.01)
Weighted-average common shares outstanding – basic and diluted	146,468,991	131,155,642	146,313,696	130,872,717

**IMMUNOVANT, INC.**

**Consolidated Balance Sheets**

*(Unaudited, in thousands, except share and per share data)*

	September 30, 2024	March 31, 2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 472,941	\$ 635,365
Accounts receivable	1,876	5,337
Prepaid expenses and other current assets	32,555	25,068
Total current assets	507,372	665,770
Operating lease right-of-use assets	45	133
Other assets	7,619	—
Property and equipment, net	671	462
<b>Total assets</b>	<b>\$ 515,707</b>	<b>\$ 666,365</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 20,727	\$ 7,155
Accrued expenses	45,879	41,315
Current portion of operating lease liabilities	47	138
Total current liabilities	66,653	48,608
Total liabilities	66,653	48,608
Commitments and contingencies		
Stockholders' equity:		
Series A preferred stock, par value \$0.0001 per share, 10,000 shares authorized, issued and outstanding at September 30, 2024 and March 31, 2024	—	—
Preferred stock, par value \$0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2024 and March 31, 2024	—	—
Common stock, par value \$0.0001 per share, 500,000,000 shares authorized, 146,565,049 shares issued and outstanding at September 30, 2024 and 500,000,000 shares authorized, 145,582,999 shares issued and outstanding at March 31, 2024	14	14
Additional paid-in capital	1,469,082	1,441,518
Accumulated other comprehensive income	1,910	1,908
Accumulated deficit	(1,021,952)	(825,683)
Total stockholders' equity	449,054	617,757
<b>Total liabilities and stockholders' equity</b>	<b>\$ 515,707</b>	<b>\$ 666,365</b>

**Contact:**

Renee Barnett, MBA  
Chief Financial Officer  
Immunovant, Inc.

[info@immunovant.com](mailto:info@immunovant.com)



# Immunovant Development Update



November 7, 2024



# 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 "can," "may," "might," "will," "would," "should," "expect," "believe," "estimate," "design," "plan," "intend," "anticipate," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant's expectations regarding patient enrollment, timing, design, and results of clinical trials of its product candidates and indication selections; Immunovant's plan to develop IMVT-1402 and batoclimab across a broad range of autoimmune indications; expectations with respect to these planned clinical trials including the number and timing of (a) trials Immunovant expects to initiate, (b) FDA clearance with respect to IND applications, and (c) potential pivotal or registrational programs and clinical trials of IMVT-1402; the size and growth of the potential markets for Immunovant's product candidates and indication selections, including any estimated market opportunities; Immunovant's plan to explore in subsequent study periods follow-on treatment with alternative dosing regimens; Immunovant's beliefs regarding the potential benefits of IMVT-1402's and batoclimab's unique product attributes and first-in-class or best-in-class potential, as applicable; Immunovant's anticipated strategic reprioritization from batoclimab to IMVT-1402; and whether, if approved, IMVT-1402 or batoclimab will be successfully distributed, marketed or commercialized. 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 of 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 candidates, including the timing of the commencement of additional clinical 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 candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the effect of global factors such as geopolitical tensions and adverse macroeconomic conditions on Immunovant's business operations and supply chains, including its 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 in various stages of clinical development for IMVT-1402 and batoclimab; and Immunovant will require additional capital to fund its operations and advance IMVT-1402 and 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 7, 2024, 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.

 IMMUNOVANT<sup>®</sup> and IMMUNOVANT<sup>®</sup> are registered trademarks of Immunovant Sciences GmbH. All other 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.

# Agenda

- 1 Significant progress on IMVT-1402 development plan
- 2 Graves' Disease, potential First-in-Class Opportunity, with impact on thyroidal and extrathyroidal disease
- 3 Difficult-to-Treat Rheumatoid Arthritis, potential Best-in-Class Opportunity
- 4 Conclusion



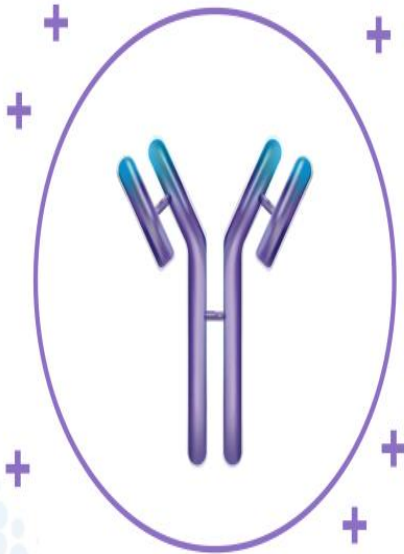
# IMVT-1402 Development Progress



## Our lead asset:

IMVT-1402 has a combination of potentially best-in-class attributes not seen with other anti-FcRns

IMVT-1402



**Deep IgG Lowering** Phase 1 data suggests deep dose-dependent IgG lowering



**Favorable Analyte Profile** Phase 1 data supports a favorable analyte profile with no or minimal effect on albumin and LDL



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



**Compelling Patent Protection** Issued U.S. patent covers composition of matter, method of use and methods for manufacturing to 2043<sup>1</sup>

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



1. Not including any potential patent term extension



# Potential best-in-class product profile opens broad range of indication opportunities for IMVT-1402

## First-in-Class

- Assuming differentiated benefit/risk profile and simple SC delivery, opportunity to leverage potency of IMVT-1402 to further expand applicable patient types for anti-FcRn development
- Example – Graves' disease

**High unmet need, biologic plausibility**

## Best-in-Class

- IgG autoantibodies part of disease pathophysiology
- Insights from later-stage anti-FcRn programs may be leveraged together with IMVT-1402 potency to optimize development approach for IMVT-1402
- Example – Myasthenia Gravis

**Classic autoAb, class data positive**

## Best-in-Class

- Other underserved patient populations
- Potential to enhance PTS via focus on subset of patients with autoantibodies of interest and leverage IMVT-1402 potency
- Examples – ACPA+ Difficult-to-Treat Rheumatoid Arthritis

**Other auto-immune, class data suggestive**

## Significant progress in advancing lead asset IMVT-1402 to potentially pivotal study initiations across broad development portfolio



Five INDs cleared across a range of therapeutic areas and FDA divisions, including GD (Endocrinology) and RA (Rheumatology)



On track to initiate an exciting portfolio of 10 indications by March 2026



Batoclimab experience informs ability to accelerate IMVT-1402 development

# Graves' Disease

First-in-class Potential



## Proof of concept achieved in Graves' Disease, positioning IMVT-1402 to potentially be best-in-class and first-in-class



**>75% Response Rate in Patients Uncontrolled on Anti-Thyroid Drugs (ATDs):** T3 and T4 rapidly normalized by Week 12 without an increase in ATDs in 76% of patients



**>50% of Patients are ATD-Free Responders:** 56% of patients not only achieved normal T3 and T4 levels but also ceased ATD therapy entirely by 12 weeks



**Lower is Better:** Deeper IgG reductions drove meaningfully higher response rates, positioning IMVT-1402 to potentially be best-in-class



**High Unmet Need Yields Attractive Commercial Opportunity:** 25-30% of Graves' Disease patients per year are uncontrolled on / intolerant to ATDs with no pharmacologic options

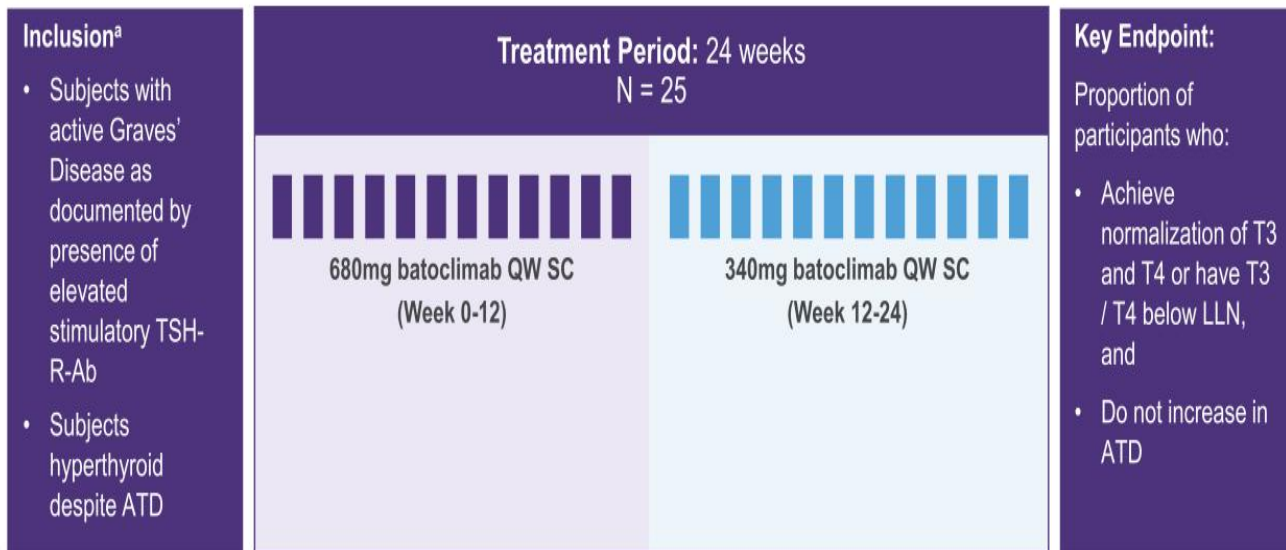


**IMVT-1402 IND Cleared:** Received FDA greenlight, enabling straight to pivotal transition

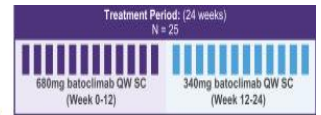


# Graves' Disease Phase 2 study design tests two doses of batoclimab

12 weeks of 680mg followed by 12 weeks of 340mg in Graves' Disease patients uncontrolled on ATDs



<sup>a</sup>: Additional inclusion and exclusion criteria not listed on slide  
ATD: Anti-thyroid medications; QW: Weekly; SC: Subcutaneous; LLN: Lower limit of normal

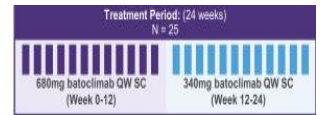


Deeper IgG reduction at 24 weeks was associated with a meaningfully higher ATD-free responder rate

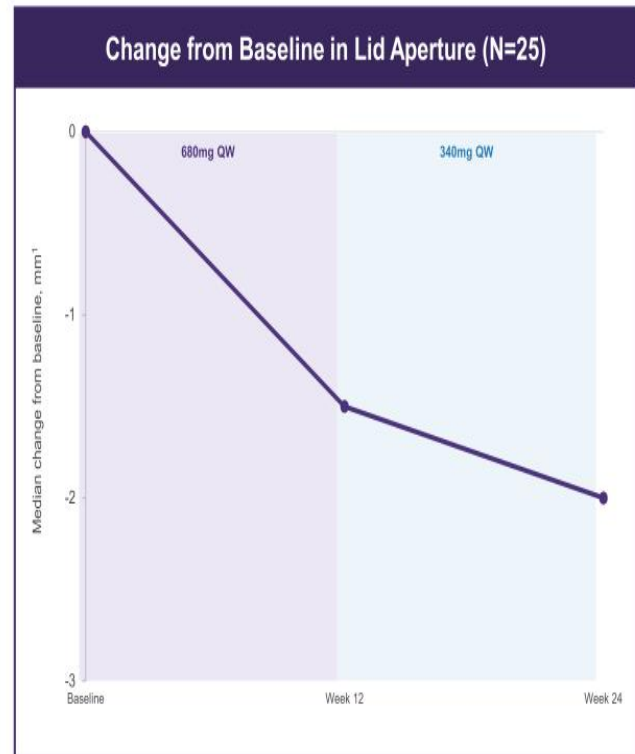
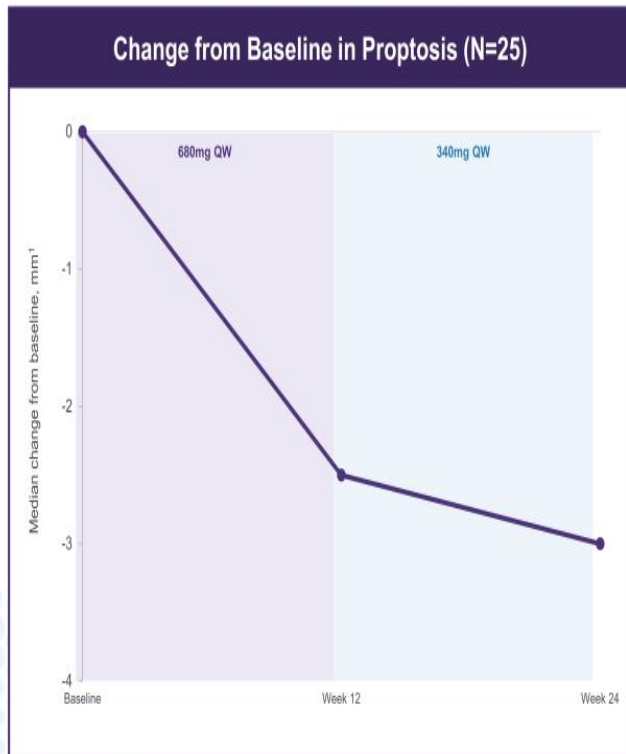
% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, and ceased all ATD medications



Note: Excludes two patient discontinuations given no IgG data available for these patients at this time point.

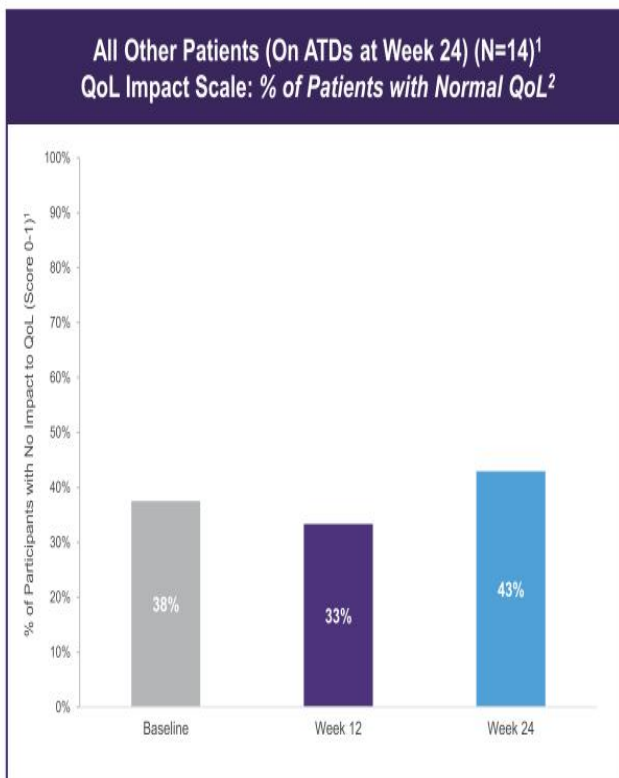
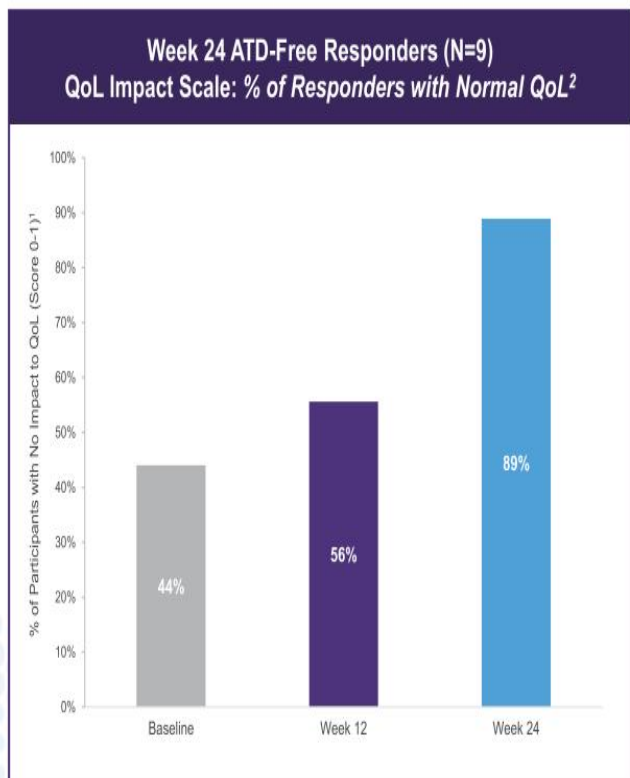


We observed meaningful improvements in proptosis and lid aperture in Graves' Disease patients treated with batoclimab



Note: Excludes one patient discontinuation at Week 12 (N=24) and two patient discontinuations at Week 24 (N=23) given no data available for these patients at these timepoints.

# ATD-free responders reported more pronounced improvements to quality of life, with ~90% experiencing normal quality of life by Week 24



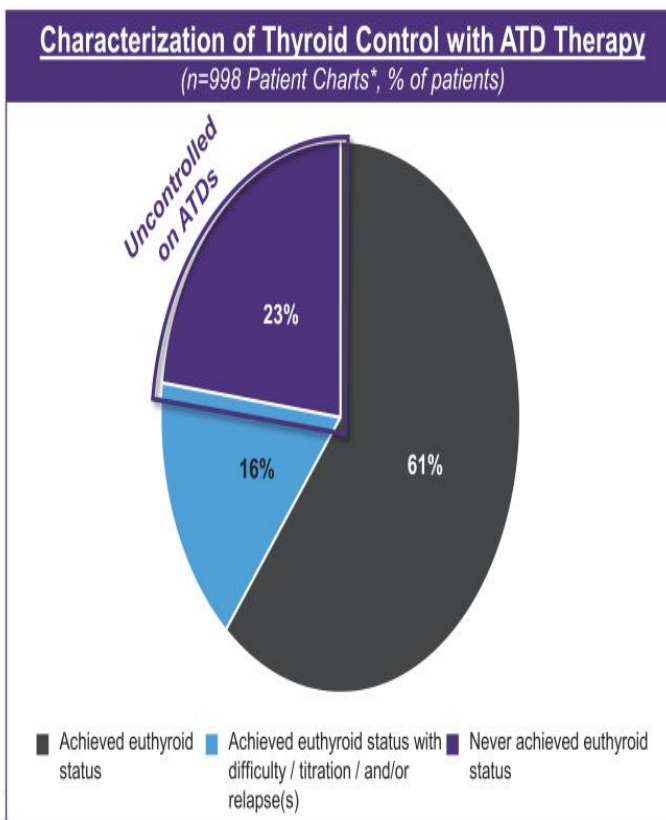
Notes: ThyPRO-39: Thyroid-Related Patient-Reported Outcome; 1) Includes N=14 patients who were not ATD-free responders at Week 24; 2) Patients represented if selected 0 or 1 = "No Impact at All" to Question: *In the past 4 weeks, has your thyroid disease had a negative effect on your quality of life?*



# Real-world in-depth chart review of 1,000+ patient records from 140 endocrinologists indicates ~25% have never achieved euthyroid status on ATDs

## Real World Chart Audit Methodology

1. As part of the endocrinologist survey, each healthcare provider was asked to complete N=8 Graves' Disease patient charts for a total of 1,120 charts collected via randomized selection to minimize bias
2. Chart selection followed various qualifications:
  1. Diagnosed with Graves' Disease
  2. Seen by the healthcare provider in the past 3 months
  3. Under the healthcare provider's care for at least 6 months
  4. First visit in the past 3 years
  5. Either on ATD therapy currently or previously

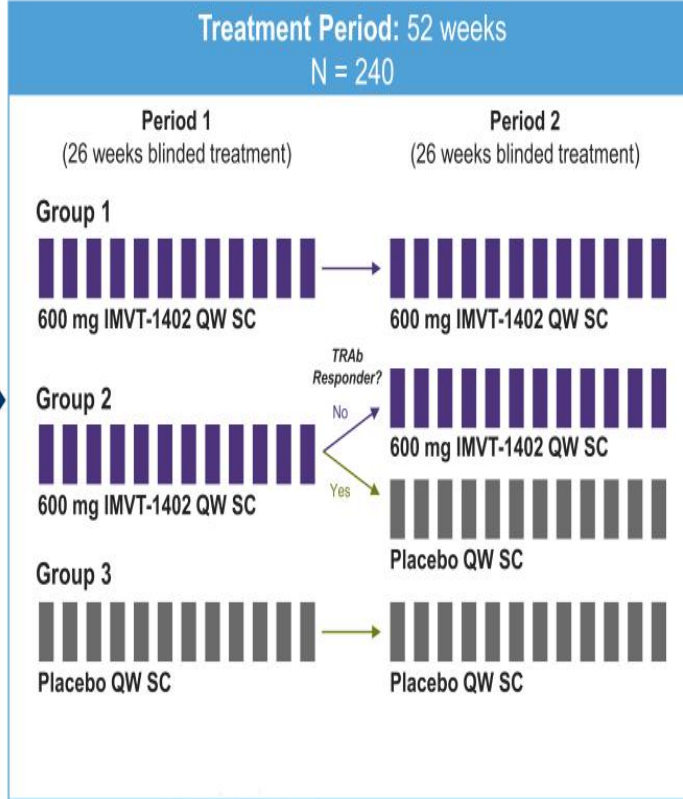


# First pivotal trial for IMVT-1402 in Graves' Disease

## Inclusion<sup>a</sup>

- Adults with active Graves' Disease as documented by presence of TSH-R binding autoantibodies
- Subjects on an ATD for  $\geq 12$  weeks before the Screening Visit
- Subjects who are hyperthyroid based on suppressed TSH despite ATD

Randomization (1:1:1)



Off-Treatment Follow-up (52 weeks)

## Primary Endpoint at Week 26:

Proportion of participants who become euthyroid<sup>b</sup> and stop ATD

## Key Secondary Endpoint at Week 52:

Proportion of participants who become euthyroid<sup>b</sup> and stop ATD

Design enables study of remission as upside

ATD titration to lowest effective dose (including 0 mg/day) to maintain euthyroidism



a: Additional inclusion and exclusion criteria not listed on slide  
b: Euthyroid = T3/T4 and TSH within normal limits  
QW: Weekly, SC: Subcutaneous

## IMVT-1402 is potentially best and first-in-class in Graves' Disease

01

High dose batoclimab rapidly achieved a 76% response rate in patients uncontrolled on ATDs, meaningfully exceeding 50% response rate bar

02

High dose batoclimab rapidly achieved a 56% ATD-free response rate in patients uncontrolled on ATDs, meaningfully exceeding 30% ATD-free response rate bar

03

Strong correlation observed between degree of IgG lowering and clinical outcomes yields potential best-in-class and first-in-class opportunity for IMVT-1402

04

IMVT-1402 Graves' Disease IND cleared, enabling straight to pivotal transition

05

Real world claims data indicates 25-30% of Graves' Disease patients per year are relapsed, uncontrolled on or intolerant to ATDs with no existing pharmacologic options representing an attractive commercial opportunity with limited competition

# Difficult-to-Treat Rheumatoid Arthritis

Best-in-Class Potential





# KOL Discussion



**Pete Salzmann, MD**  
Chief Executive Officer,  
Immunovant



**Peter Taylor, MA, PhD, FRCP, FRCPE**  
University of Oxford

# Despite tremendous progress in the treatment of rheumatoid arthritis (RA), a subset of patients do not respond well to available therapies

## Key Takeaways<sup>1</sup>

- RA is a chronic, progressive disease that causes joint inflammation and pain
- Most common systemic autoimmune disease, affecting 18M globally and 1.5M in the US
- Medical therapy is used to help control joint inflammation; treatment options include a variety of conventional oral, targeted synthetic and biologic DMARDs
- Inadequate disease control can result in irreversible joint erosions

## Significant Impact

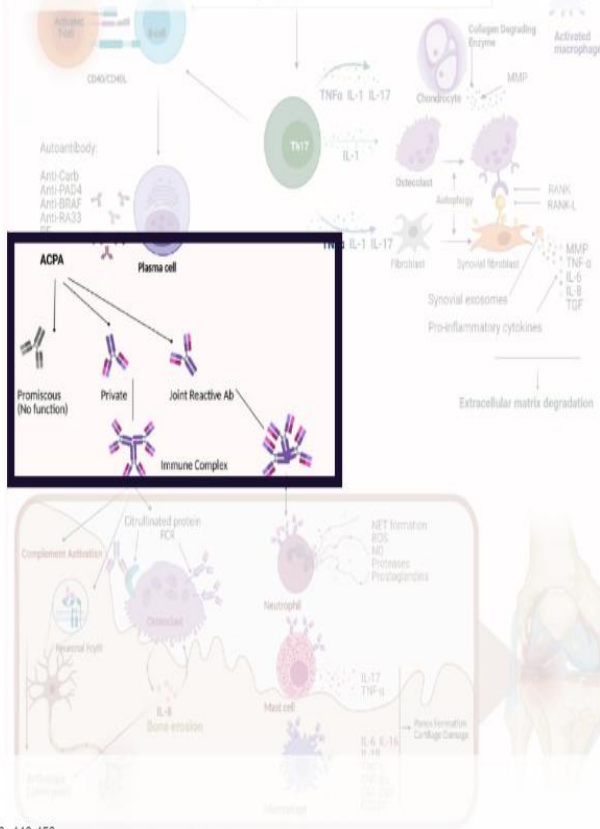


PA view of the hands shows joint space narrowing, erosions, and diffused osteoporosis  
Source: Nakshabandi N et al. *Radiology in Rheumatology*, 2021.

In addition to cellular autoimmunity and cytokine dysregulation, autoantibodies also play a role in the pathophysiology of RA

Rheumatoid factor (RF) and ACPA autoantibodies are present in ~75% of RA patients<sup>1</sup>

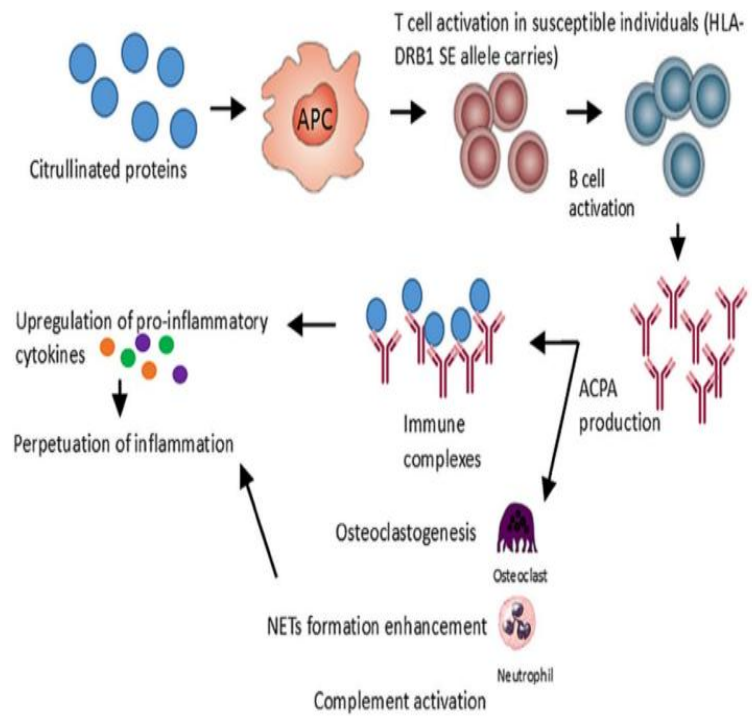
Anti-FcRn mechanism may lower pathogenic IgG autoantibodies and immune complexes



1. Okada et al. Ann Rheum Dis 2019;78; 446-453  
 2. Image: Mueller A-L et al. Cells, 2021; 10(11), 3017  
 RF: rheumatoid factor, ACPA: anti-citrullinated protein autoantibodies

# Understanding the pathophysiologic relevance of ACPA autoantibodies in rheumatoid arthritis

- Antigen presenting cells (APCs) process and present citrullinated peptides to T cells
- T cells activate B cells to generate autoantibodies
- Immune complex formation upregulates pro-inflammatory cytokines
- ACPA may bind to osteoclasts and thereby promote bone erosion





# What is difficult-to-treat RA and why is innovation needed?

## Need for More Options

- Estimated 5-20% of patients remain symptomatic despite multiple treatment rounds<sup>1</sup>
  - These patients need new therapies and approaches, according to a global survey of 410 rheumatologists
- Difficult-to-treat (D2T) RA defined by EULAR as:<sup>2</sup>
  - Multiple DMARD failures
  - Signs suggestive of active/progressive disease
  - Symptom management viewed as problematic to doctor and/or patient



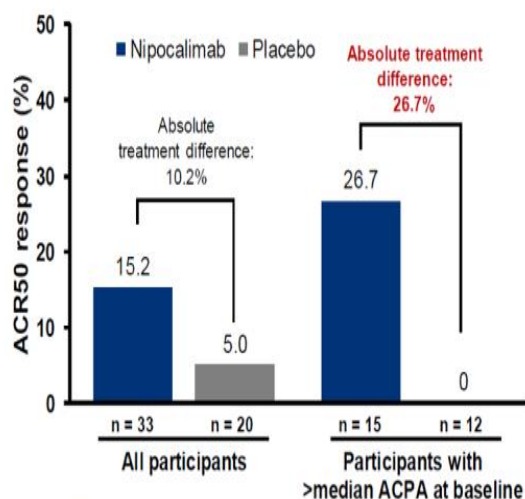
## D2T RA Criteria

- At least moderate disease activity as defined by composite endpoints which include tender and swollen joint counts
- Progressive joint damage on imaging
- Inability to decrease chronic glucocorticoid therapy below 7.5mg/day
- Ongoing RA symptoms and QoL impact despite therapy

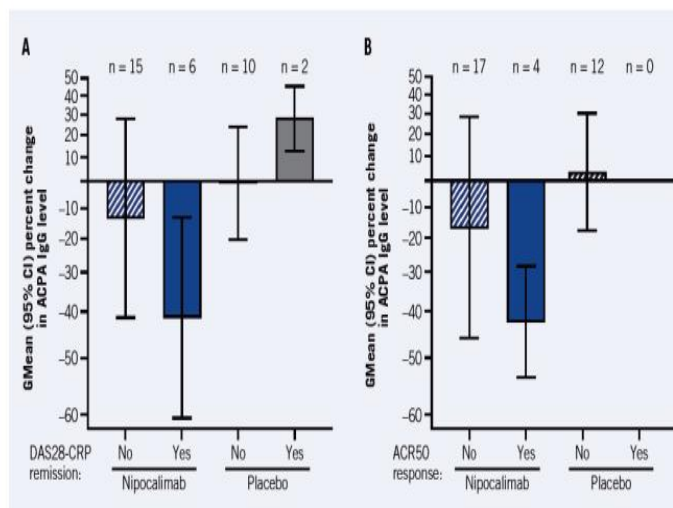
# Publicly available nipocalimab data in RA demonstrated proof of mechanism and showed that deeper ACPA IgG reduction correlated with clinical response<sup>1</sup>

## Select results from a study of FcRn inhibition vs placebo in biologic experienced RA patients

Proportions of Participants Who Achieved ACR50 Response at Week 12 by ACPA



Percent Changes from Baseline at Trough in ACPA IgG Levels versus (A) DAS-28 CRP Remission and (B) ACR50 Response at Week 12



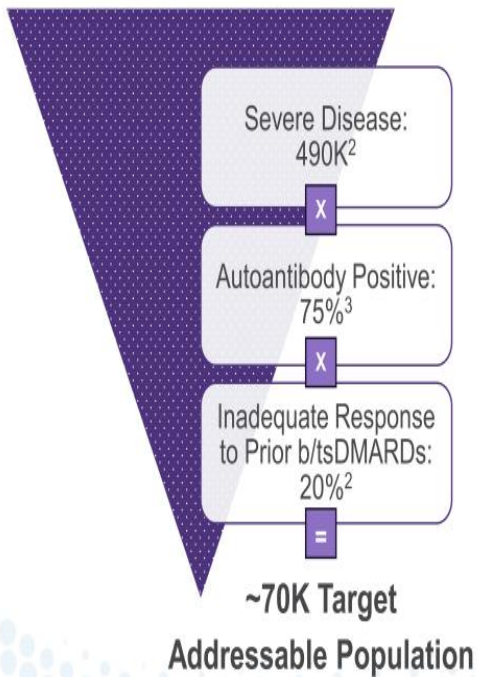
ACPA, anti-citrullinated protein autoantibody; ACR50, ≥50% response in American College of Rheumatology response criteria; anti-CCP2, anti-cyclic citrullinated peptide 2 antibody; CI, confidence interval; DAS28-CRP, Disease Activity Score 28 using C-reactive protein; GMean, geometric mean; IgG, immunoglobulin G.



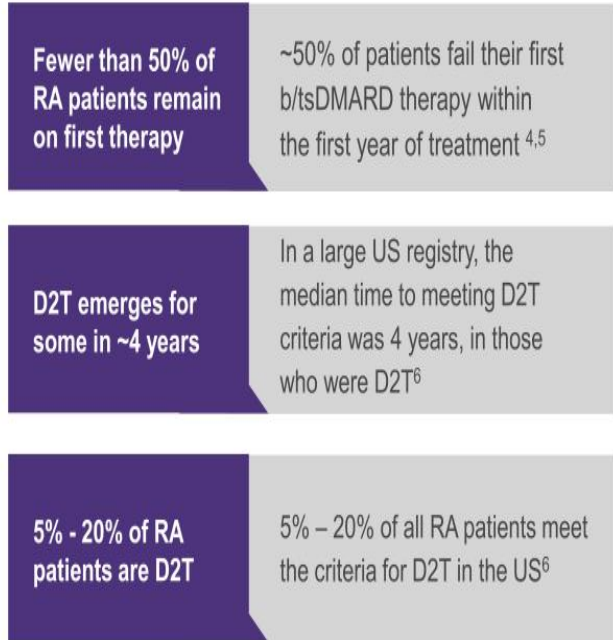
1. Pharmacodynamic effects of nipocalimab in patients with moderate to severe active rheumatoid arthritis (RA): Results from the multicenter, randomized, double-blinded, placebo-controlled Phase 2A IRIS-RA study. Janssen Research & Development, ACR poster, November 2023.

Of the 1.5M US RA patients<sup>1</sup>, a subset progresses to D2T status in a relatively short period of time and requires new therapeutic options

### Epidemiology



### Patient Journey Learnings

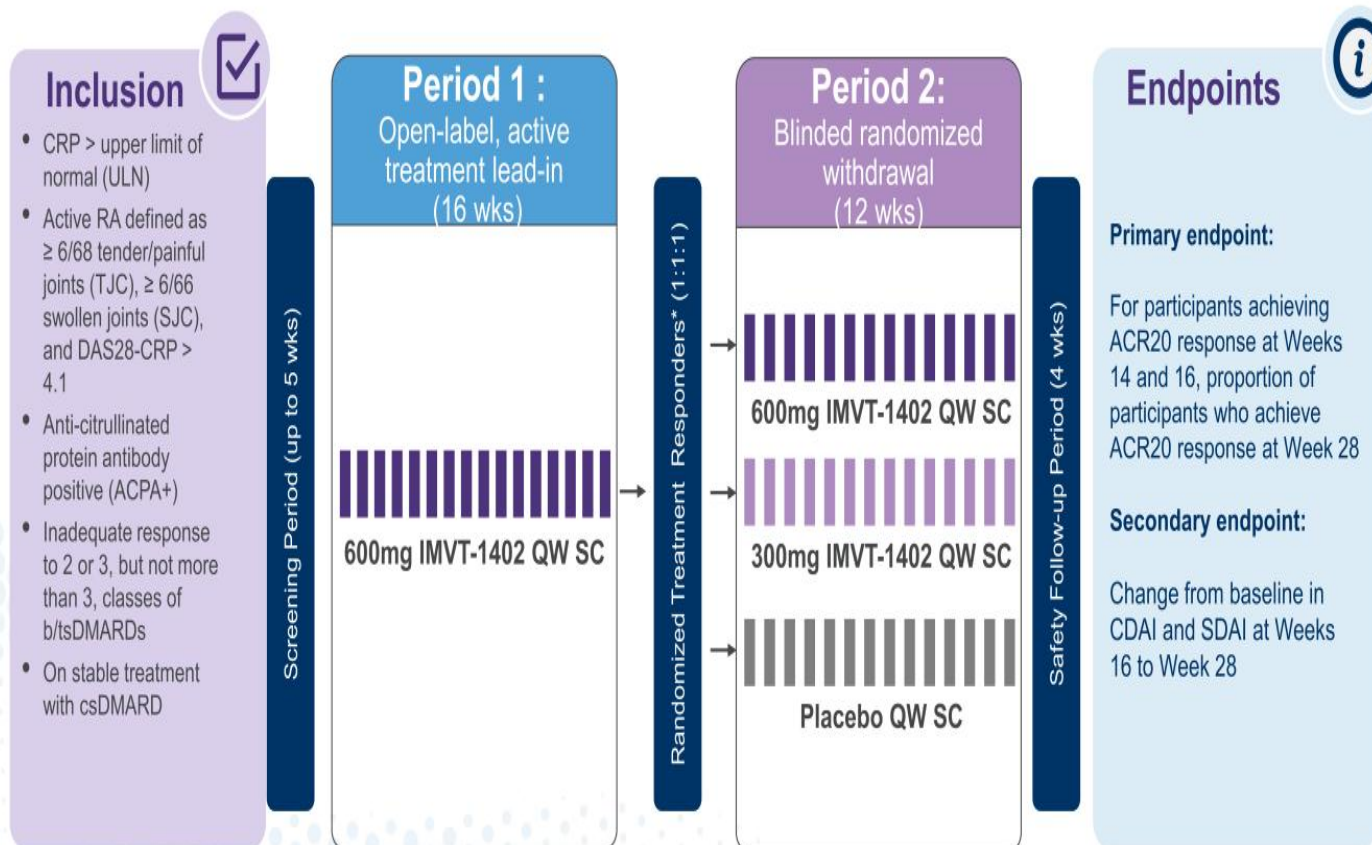


# IMVT-1402 Path Forward in Difficult-to-Treat Rheumatoid Arthritis



# Pivotal study design in rheumatoid arthritis

## Global Trial with N=120 Participants



## With pivotal program in RA, IMVT-1402 has the potential to achieve a best-in-class profile for people with difficult-to-treat RA

<b>High Unmet Need Subgroup</b>	5-20% of RA patients are difficult-to-treat (D2T) (failed at least 3 therapies) <sup>1</sup>
<b>Autoantibody Pathology</b>	ACPA positive RA is associated with severe disease and poor outcomes; publicly disclosed, in-class data from another FcRn inhibitor encouraging <sup>2</sup>
<b>Enhanced Study Design</b>	Open label lead-in with randomized withdrawal attractive for D2T population that is enriched for higher baseline ACPA levels
<b>Lower is Better</b>	We believe deeper ACPA antibody reduction expected to correlate with improved clinical efficacy within the anti-FcRn class
<b>IMVT-1402 IND Active</b>	Received FDA IND clearance, enabling planned study initiation in early calendar year 2025



ACPA: anticitrullinated protein autoantibodies

1. Paudel ML. *Rheumatology (Oxford)* 2024; 318. 2. Taylor PC et al. 'Efficacy and Safety of Nipocalimab in Patients with Moderate to Severe Active Rheumatoid Arthritis (RA): The Multicenter, Randomized, Double-blinded, Placebo-controlled Phase 2a IRIS-RA Study Presented at ACR, Nov 10-15, 2023.

# Two opportunities for lead asset IMVT-1402 to potentially transform the treatment paradigm for patients struggling to achieve success with existing therapies

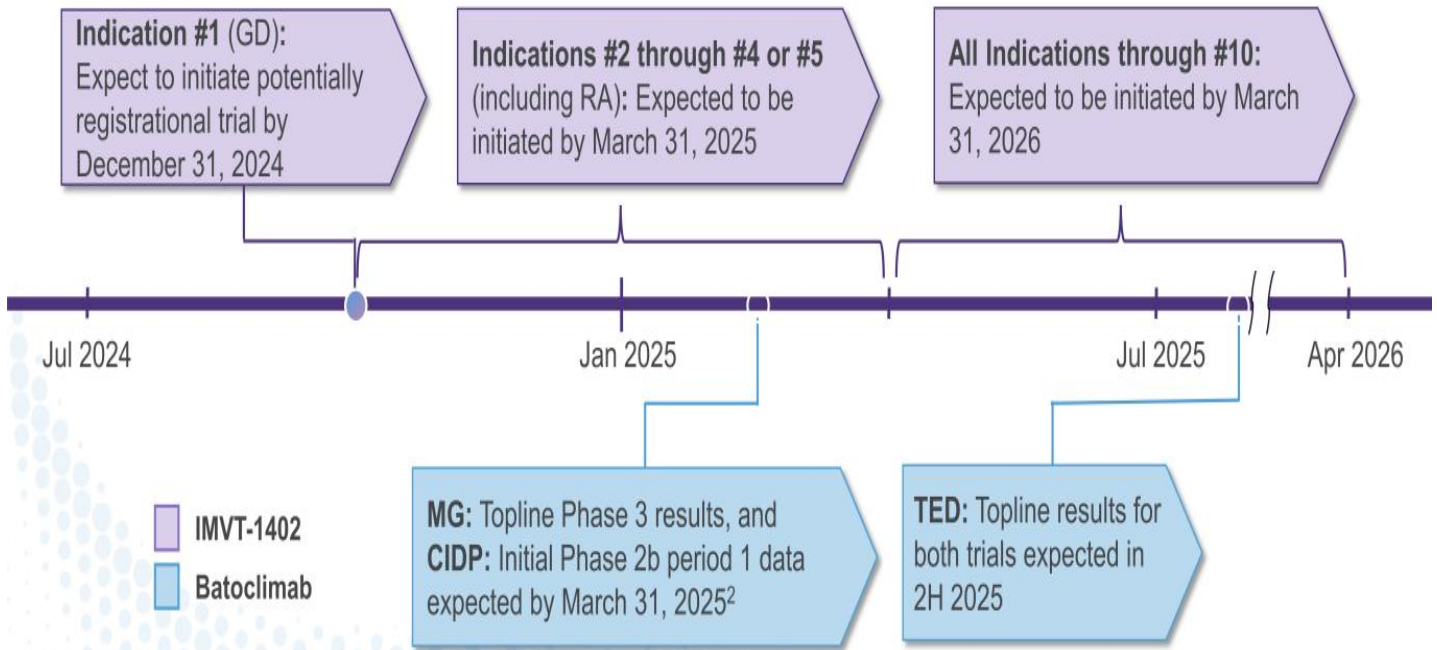
	Graves' Disease First-in-Class Potential	Rheumatoid Arthritis Best-in-Class Potential
01	Meaningful unmet need for subset of patients	Patients not well controlled on ATDs
02	Underlying pathology driven by IgG Ab	Patients with D2T RA, multiple therapies failed
03	In-class proof-of-concept data	Higher response rate across multiple measures with $\geq 70\%$ IgG reduction <sup>1</sup>
04	IMVT-1402 trial design	Response rate higher for patients with high baseline ACPA & deep IgG reduction <sup>2</sup>
	600mg dose for deep IgG reduction; Primary endpoint includes off-ATD	600mg dose for deep IgG reduction; Open-label lead-in



1. Data on file at Immunovant 2. Pharmacodynamic effects of nipocalimab in patients with moderate to severe active rheumatoid arthritis (RA): Results from the multicenter, randomized, double-blinded, placebo-controlled Phase 2A IRIS-RA study. Janssen Research & Development, ACR poster, November 2023.

# Multiple near-term milestones for enhanced value creation

On track to initiate 4-5 potentially registrational programs for IMVT-1402 by March 31, 2025 and trials in a total of 10 indications by March 31, 2026<sup>1</sup>



1. Indications #1 through #5 will be potentially registrational programs, Indications #6 through #10 may be proof-of-concept or potentially registrational programs 2. Enrollment completed for MG. For CIDP, enrollment completed for patients included in the period 1 data expected by March 31, 2025. No further patients will be enrolled until after such period 1 data is disclosed.



