UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): November 28, 2023

Roivant Sciences Ltd.

(Exact Name of Registrant as Specified in Charter)

Bermuda	**001-40782**	**98-1173944**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

7th Floor
50 Broadway
London SW1H 0DB
United Kingdom
(Address of Principal Executive Offices, and Zip Code)

+44 207 400-3347
Registrant's Telephone Number, Including Area Code

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (*see* General Instruction A.2. below):

☐ Written communication 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 Shares, $0.0000000341740141 per share	**ROIV**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 8.01. Other Events.

On November 28, 2023, Roivant Sciences Ltd. issued a press release announcing initial data from the 600 mg multiple-ascending dose cohort from Immunovant's Phase 1 clinical trial of IMVT-1402 for the treatment of IgG-mediated autoimmune diseases. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference into this Item 8.01.

As described in the press release, Immunovant will host a conference call and webcast to discuss the 600 mg multiple-ascending dose data at 8:00 a.m. EST on November 28, 2023. A copy of the presentation to be used by Immunovant during the conference call is attached hereto as Exhibit 99.1 and incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release dated November 28, 2023
99.2	Presentation dated November 28, 2023
104	Cover Page Interactive Data File (embedded with 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.

ROIVANT SCIENCES LTD.

By: /s/ Matt Maisak
Name: Matt Maisak
Title: Authorized Signatory

Dated: November 28, 2023

Exhibit 99.1

Roivant Announces Positive IMVT-1402 Initial 600 mg MAD Results that Confirm Best-in-Class Potential

- Results from the 600 mg MAD cohort for IMVT-1402 similar to previously disclosed results from the 300 mg MAD cohort for IMVT-1402
- IMVT-1402 was observed to deliver dose dependent and deep IgG reductions similar to batoclimab in its Phase 1 study
- IMVT-1402 600 mg was observed to deliver placebo-like impact on albumin and low-density lipoprotein cholesterol (LDL-C), similar to the previously disclosed 300 mg MAD cohort data
- Potential best-in-class profile enables broad and exciting portfolio of indications, taking advantage of IgG reduction we expect will reach 80% with continued weekly dosing of 600 mg delivered by simple subcutaneous injection

NEW YORK, November 28, 2023 (GLOBE NEWSWIRE) – Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today announced initial data from 600 mg MAD cohort of a Phase 1 clinical trial of IMVT-1402 in healthy adults. The results show that four subcutaneously administered doses of 600 mg produced a mean **IgG reduction similar to high dose batoclimab**, but with minimal changes in albumin and LDL-C similar to those in placebo, confirming the potential of IMVT-1402 as a best-in-class neonatal fragment crystallizable receptor (FcRn) inhibitor.

"We are energized by this potential best-in-class profile, which opens the door to a unique portfolio of first-in-class and best-in-class indications for IMVT-1402, with an emphasis on those indications where potency matters most," said Pete Salzmann, M.D., chief executive officer at Immunovant. "FcRn inhibition is a proven mechanism with broad applicability, and we believe that a growing body of evidence supports a consistent correlation between deeper IgG reduction and greater efficacy. This translates to the potential to build a class-leading anti-FcRn franchise with IMVT-1402.**"**

The Phase 1 clinical trial is a randomized, double-blind, placebo-controlled ascending dose study to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of IMVT-1402 in healthy adults. Four once-weekly SC injections of 600 mg IMVT-1402 reduced total IgG level by a mean of 74%, a potency that is similar to batoclimab at 680 mg that reduced IgG by 76% after 4 weekly doses. In disease settings where batoclimab was administered continuously, a reduction of 80% was observed at steady state after about 6-8 weeks. We believe steady state IgG reduction with IMVT-1402 will match this result and timing.

Across all doses evaluated, treatments with IMVT-1402 were generally well tolerated with only mild or moderate treatment-emergent adverse events observed. Serum albumin and LDL-C at Day 29 (peak pharmacodynamic impact) did not show a significant decrease or increase, respectively, from baseline (p-values > 0.05).

Conference Call & Webcast:

Immunovant will host a conference call with accompanying slides and a simultaneous webcast today, November 28, 2023 at 8:00 a.m. EST to discuss the 600 mg multiple-ascending dose data. To participate in the conference call, please register in advance here. To access the live and archived webcast, please visit Immunovant's website at https://www.immunovant.com/investors/news-events. The archived webcast will be available for a limited time on the Company's website.

About IMVT-1402

IMVT-1402 is designed to be a potentially best-in-class anti-FcRn antibody for the treatment of IgG-mediated autoimmune diseases. In the initial results of a Phase 1 clinical trial in healthy adults, IMVT-1402 demonstrated favorable pharmacodynamic and safety data. These attributes, combined with a convenient route of administration that may enable patient self-administration, position IMVT-1402 well as a potential treatment for a variety of autoimmune diseases associated with patient unmet need.

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 www.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,” "intend," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant’s expectations regarding the timing, design, and results of clinical trials of its product candidates; Immunovant's plan to develop batoclimab and IMVT-1402 across a broad range of autoimmune indications; potential benefits of batoclimab’s and IMVT-1402’s unique product attributes; and IMVT-1402’s potential best-in-class profile including IgG reduction and tolerability. 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 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 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 global factors, such as the post-COVID-19 environment, geopolitical tensions, and adverse macroeconomic conditions 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 batoclimab and IMVT-1402; Immunovant is at an early stage of development 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 Form 10-Q filed with the SEC on November 9, 2023, 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.

About Roivant

Roivant (Nasdaq: ROIV) is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant’s pipeline includes VTAMA®, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; batoclimab and IMVT-1402, fully human monoclonal antibodies targeting the neonatal Fc receptor (“FcRn”) in development across several IgG-mediated autoimmune indications; brepocitinib, a novel TYK2/JAK1 inhibitor in late stage development for dermatomyositis and other autoimmune conditions, in addition to other clinical stage molecules. We advance our pipeline by creating nimble subsidiaries or “Vants” to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business. For more information, www.roivant.com.

Roivant Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are usually identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and variations of such words or similar expressions. The words may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act.

Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, and statements that are not historical facts, including statements about the clinical and therapeutic potential of our products and product candidates, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our products and product candidates. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements.

Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the Risk Factors section of our filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts:

Investors
Roivant Investor Relations
ir@roivant.com

Media
Stephanie Lee
Roivant Sciences
stephanie.lee@roivant.com

Exhibit 99.2

IMMUNOVANT

Targeted science, Tailored solutions

for people with autoimmune disease

Portfolio Update
November 28, 2023

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," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include the timing and results of Immunovant's clinical trials of IMVT–1402; expectations with respect to these planned clinical trials; the size and growth of the potential markets for Immunovant's product candidates and indication selections; Immunovant's beliefs regarding the potential benefits of IMVT-1402's unique product attributes including IMVT-1402's potential best-in-class Immunoglobulin G (IgG) reduction and tolerability and IMVT-1402's potential as a treatment for chronic inflammatory demyelinating polyneuropathy, Graves' disease, rheumatoid arthritis, and other autoimmune diseases; whether, if approved, IMVT-1402 will be successfully distributed, marketed, and commercialized; and Immunovant's expectations regarding the issuance and term 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 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 pending composition of matter patent for IMVT-1402 may not be issued; 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 impacts from the post-COVID-19 environment, 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 at an early stage in development 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 Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2023, filed with the SEC on November 9, 2023, 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.

Our Vision:
Normal Lives for People with Autoimmune Disease

What we do:

We are developing targeted therapies that are designed to address the complex and variable needs of people with autoimmune diseases.

Love
Trailblazing

Bolder,
Faster

All
Voices

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Goals for the Phase 1 Program

- Demonstrate potential best-in-class IgG reductions similar to batoclimab 
- Demonstrate minimal to no impact on albumin 
- Demonstrate minimal to no impact on LDL 
- Achieve all of the above with a simple, commercially attractive subcutaneous injection 

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Note: Based on data to date

Best-in-Class Potential for IMVT-1402 – Why it Matters

- FcRn inhibition is a proven mechanism with broad potential applicability based on targeted reduction of IgG as an improved and more targeted modality
- Evidence across broad range of auto-antibody conditions that deeper IgG reduction correlates with greater efficacy
- IMVT-1402 demonstrates potentially best-in-class IgG reduction, similar to batoclimab, delivered via a simple subcutaneous injection and with minimal to no impact on albumin and LDL, similar to placebo
- Immunovant has the potential to create a unique and class-leading portfolio of indications with IMVT-1402

Multiple-Ascending Subcutaneous Doses

(Once-weekly dosing x 4 weeks)

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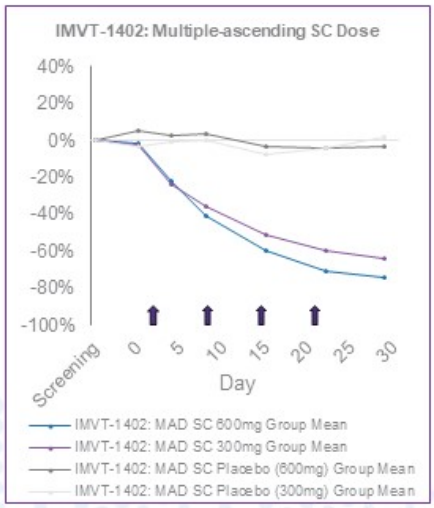
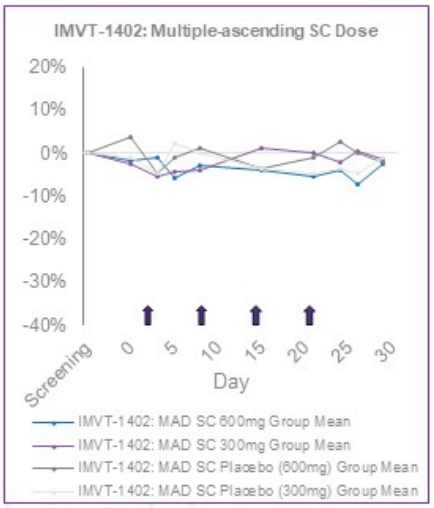
IMVT-1402 600mg MAD Data Consistent with 300mg MAD Data

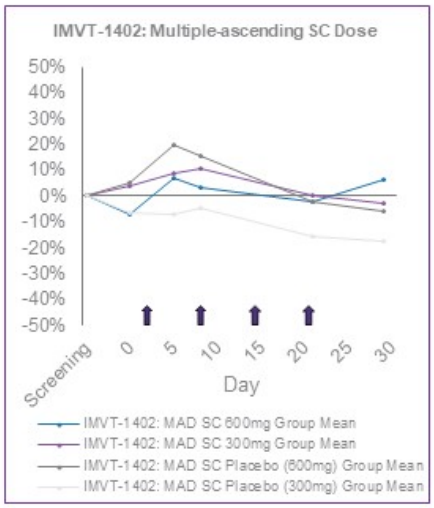
IgG % change over time



Albumin % change over time



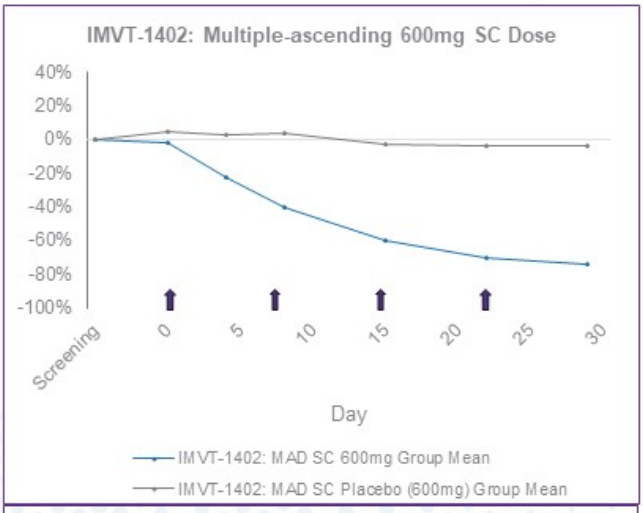
LDL % change over time



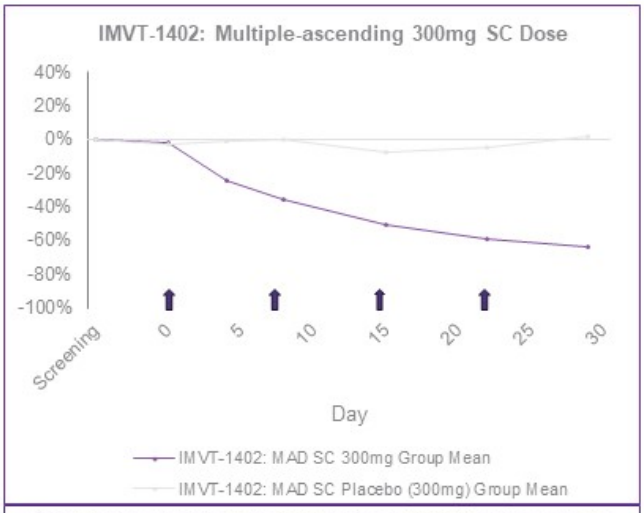
IMMUNOVANT ⬆ Dose administration

IMVT-1402 MAD Data Suggests Potential Best-in-Class IgG Reduction

IgG % change over time



All IgG values starting with day 4 in the IMVT-1402 arm showed a significant decrease from baseline (all nominal p-values < 0.05)

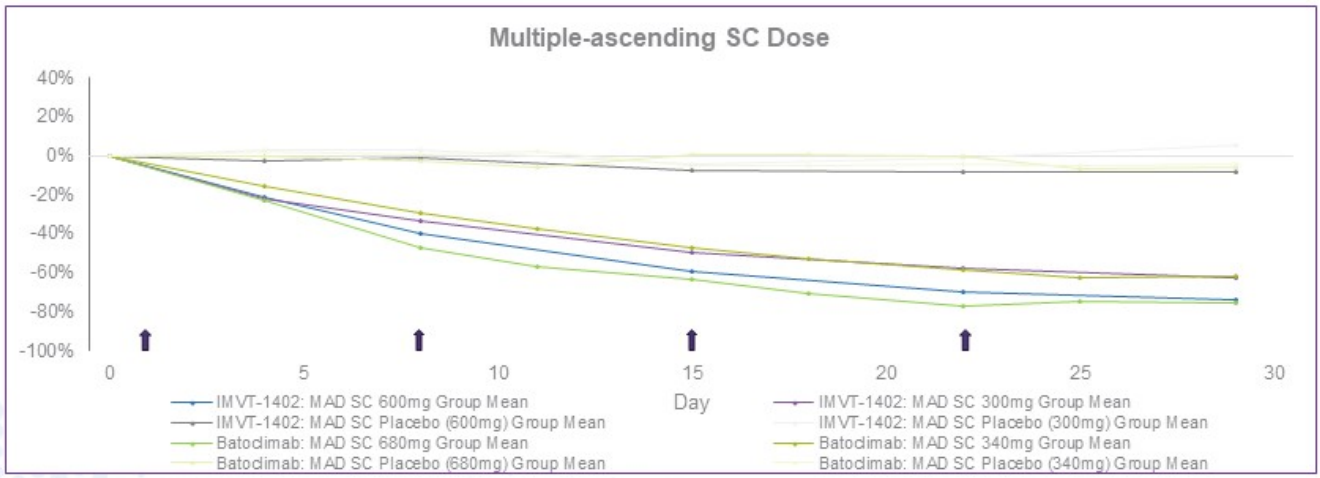


All IgG values starting with day 4 in the IMVT-1402 arm showed a significant decrease from baseline (all nominal p-values < 0.05)

IMMUNOVANT ⬆ Dose administration

IMVT-1402 MAD Data Suggests Potential Best-in-Class IgG Reduction Similar to Batoclimab*

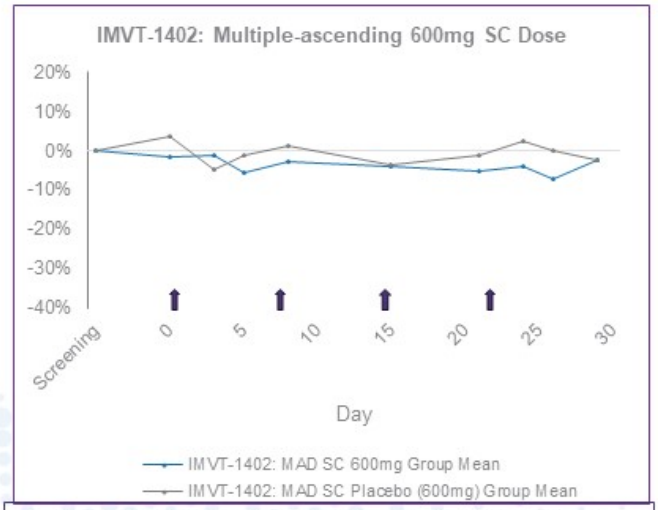
IgG % change over time



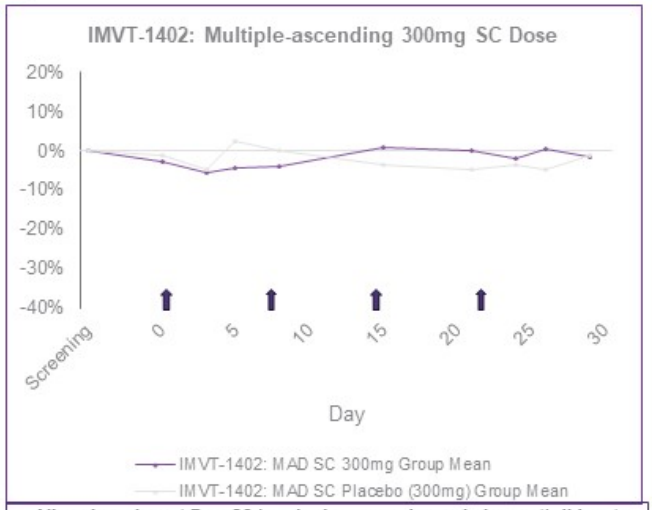
IMMUNOVANT ⬆ Dose administration *Data presented are from separate clinical trials, not a head-to-head study, conducted by Immunovant

IMVT-1402 MAD Data: Minimal to No Albumin Reduction, Similar to Placebo, After Four Weeks of Dosing

Albumin % change over time



Albumin value at Day 29 (peak pharmacodynamic impact) did not show a significant decrease from baseline (nominal p-values > 0.05)

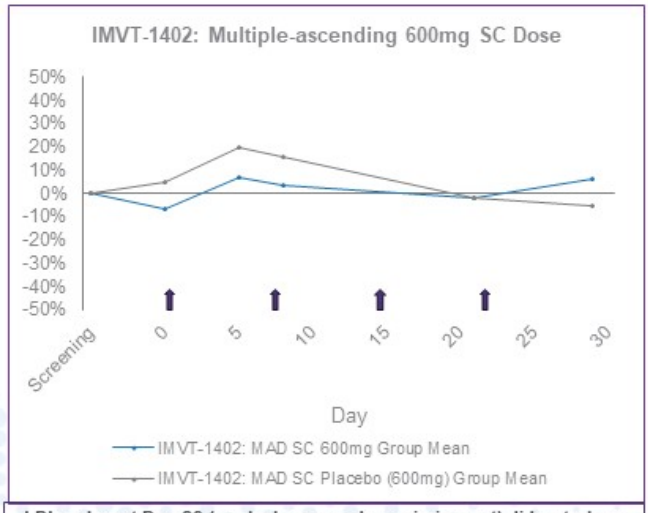


Albumin value at Day 29 (peak pharmacodynamic impact) did not show a significant decrease from baseline (nominal p-values > 0.05)

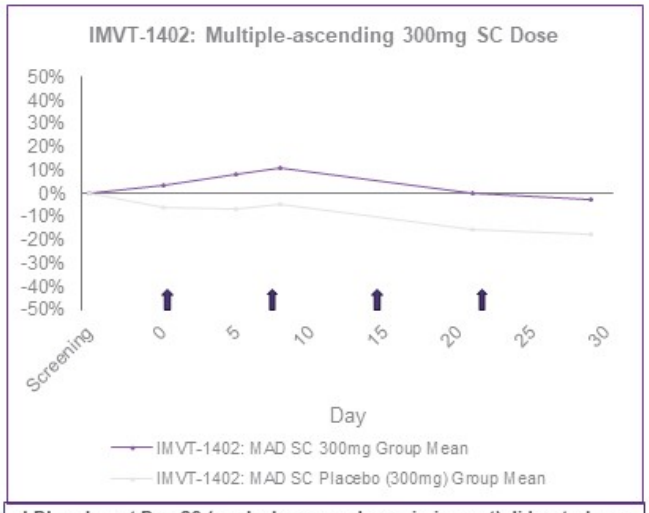
IMMUNOVANT ⬆ Dose administration

IMVT-1402 MAD Data: Minimal to No LDL Increase, Similar to Placebo, After Four Weeks of Dosing

LDL % change over time



LDL value at Day 29 (peak pharmacodynamic impact) did not show a significant increase from baseline (nominal p-values > 0.05)



LDL value at Day 29 (peak pharmacodynamic impact) did not show a significant increase from baseline (nominal p-values > 0.05)

IMMUNOVANT ⬆ Dose administration

IMVT-1402 Showed a Favorable Safety Profile in Initial Phase 1 Data Set

	SC SAD			SC MAD		
	Placebo	300mg	600mg	Placebo	300mg	600mg
	N = 4 n (%)	N = 6 n (%)	N = 6 n (%)	N = 4 n (%)	N = 10 n (%)	N = 10 n (%)
Participants with at least one TEAE	3 (75)	4 (67)	5 (83)	4 (100)	7 (70)	6 (60)
Participants with at least one TESAE	0	0	0	0	0	0
Participants discontinued study due to TEAEs	0	0	0	0	1 (10)[1]	0
Participants with dose reduction or interruption due to TEAE	0	0	0	0	0	0
Deaths	0	0	0	0	0	0
TEAE (≥ 2 Participants in any 1402 treated cohort)						
Injection site pain	0	1 (17)	0	1 (25)	0	3 (30)
Catheter site bruise[2]	0	0	0	1 (25)	0	2 (20)
Catheter site pain[2]	0	1 (17)	0	1 (25)	2 (20)	0

All TEAEs were either mild or moderate with no severe TEAEs reported across any arm to date

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1. Participant who discontinued experienced a Mild TEAE. The event was considered not related to study treatment.
2. A catheter was used for frequent blood draws
TEAE = treatment emergent adverse event; TESAE = treatment emergent serious adverse event

IgG Reduction and Clinical Efficacy Correlation

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Best-in-Class Potential for IMVT-1402 – Why it Matters

- FcRn inhibition is a proven mechanism with broad potential applicability based on targeted reduction of IgG as an improved and more targeted modality
- Evidence across broad range of auto-antibody conditions that deeper IgG reduction correlates with greater efficacy
- IMVT-1402 demonstrates potentially best-in-class IgG reduction, similar to batoclimab, delivered via a simple subcutaneous injection and with minimal to no impact on albumin and LDL, similar to placebo
- Immunovant has the potential to create a unique and class-leading portfolio of indications with IMVT-1402

Consistent Evidence Across Programs and Indications that Greater IgG Reduction Leads to Greater Efficacy*

	Company	Evidence of Greater IgG Reductions Translating to Clinical Benefit
MG	argenx / janssen	Patient-level scatter plot showed that greater IgG declines ➔ greater MG-ADL improvements
TED	IMMUNOVANT	Greater IgG reduction across arms ➔ higher rates of anti-TSHR antibody reduction and greater clinical response rates
PV	argenx	Greater sustained IgG reduction across arms ➔ higher complete clinical response and lower relapse rates
ITP	ucb	Greater IgG reduction across arms ➔ greater platelet responses
RA	janssen	In those patients with greater IgG reduction ➔ correlation with greater autoAb reduction ➔ correlation with greater clinical response

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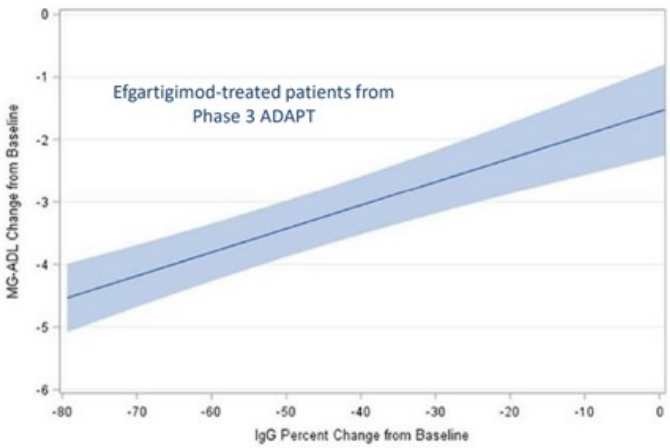
*Many of the analyses above were post-hoc and not all were statistically significant. Cross trial and post-hoc analyses are inherently limited and are presented for hypothesis generating purposes only, nevertheless consistent and numerically positive increases in efficacy were observed as noted above.
MG: Myasthenia gravis, TED: Thyroid eye disease, PV: Pemphigus vulgaris, ITP: Immune thrombocytopenic purpura, RA: Rheumatoid arthritis

Efgartigimod MG and PV Data Showed Higher Clinical Response with Deeper IgG Reduction

ADAPT Phase 3 trial of IV efgartigimod in MG showed a correlation between IgG reductions and clinical response



Source: argenx JP Morgan Healthcare Conference Presentation January 2021

In efgartigimod Phase 2 in PV, more intensive dosing regimens led to deeper skin responses

	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Dosing				
Dose	10mg/kg	10mg/kg	10mg/kg	25mg/kg
Induction Dose Regimen	QW, 4 weeks	QW, 4 weeks	QW, 4 weeks	QW, until EoC
Maintenance Dose Regimen	Week 2, Week 6	Q2W, 8 weeks	Q2W, 12 weeks	Q2W, up to 34 weeks
*IgG Reduction**				
Est. Max IgG Reduction (Day 28)	-56%	-69%	-62%	-67%
Est. IgG Reduction Day 120	11%	-33%	-52%	-54%
Efficacy†				
Complete Response	0%	0%	71%	60%
Relapse	50%	67%	43%	29%

argenx phase 2 PV/PF publication, Br J Dermatol. 2022 Mar;186(3):429-439; * Estimated by WebPlotDigitizer
† End of Consolidation (EoC): the time at which no new lesions had developed for min. 2 weeks and ~80% of lesions had healed; Disease control (DC): no new lesions and established lesions starting to heal; Complete response (CR): no new lesions and established lesions completely healed; Relapse: Appearance of three or more new lesions per month that do not heal spontaneously in 1 week, or extension of established lesions, evaluated after DC

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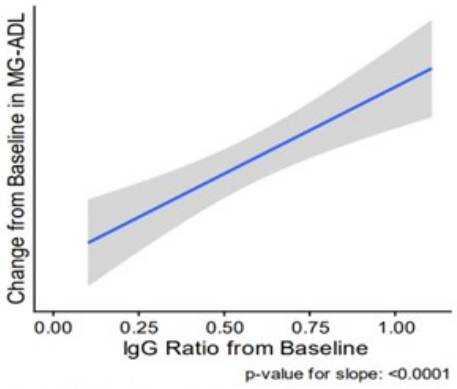
No clinical head-to-head comparisons of Immunovant product candidates and third party anti-FcRn assets has been conducted

Nipocalimab MG and RA Data Showed Higher Clinical Response with Deeper IgG Reduction

Nipocalimab Phase 2 trial in MG showed a correlation between IgG reductions and clinical response

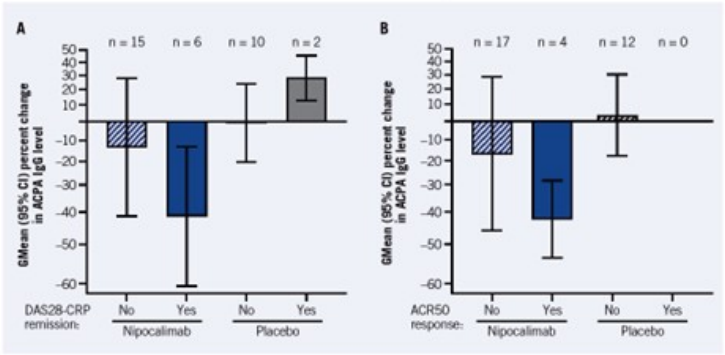
Comparison of MG-ADL Score and IgG Levels



Source: Momenta Vivacity-MG Interim Phase 2 Investor Presentation, 2020

Nipocalimab Phase 2 trial in RA showed a correlation between auto-Ab reductions and clinical response

Figure 4. Percent Changes From Baseline at Trough in ACPA IgG (Anti-CCP2) Levels Versus (A) DAS28-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.

Source: 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.

No clinical head-to-head comparisons of Immunovant product candidates and third party anti-FcRn assets has been conducted

Batoclimab TED Data Showed Higher Clinical Response with Deeper IgG Reduction

Deeper IgG reduction led to greater restoration of normal levels of pathogenic antibodies and greater proptosis response in Phase 2 trial in TED

	Placebo	Batoclimab 255 mg	Batoclimab 340 mg	Batoclimab 680 mg
Median Max % IgG Reduction at Week 5*	3%	54%	63%	79%
% Subjects with Stimulatory anti-TSHR Antibody below 140 at Week 5	0%	0%	12%	57%
Proptosis Response Rate at Week 5**	0%	11%	29%	43%

*Week 5 data (study day 36) selected as it represents the latest time point at which the largest amount of patient data is available prior to the voluntary pause of the study. **Post-hoc analysis of proptosis response at week 5. Proptosis response defined as proptosis reduction ≥2 mm in study eye, without ≥2 mm increase in non-study eye at same visit.

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Rozanolixizumab ITP Data Showed Higher Clinical Response with Deeper IgG Reduction

In UCB's Phase 2 trial in ITP, higher doses and greater IgG reductions were associated with better platelet responses

Single Dose of Rozanolixizumab	Data at Day 8		
	Estimated IgG Reduction	Mean platelet count (x109/L)	% change platelet count (x109/L)
4 mg/kg	27%*	27	53%
7 mg/kg	27%*	21	53%
10 mg/kg	47%*	41	122%
15 mg/kg	52%	108	409%
20 mg/kg	60%	145	706%

*IgG reduction at day 8 estimated by WebPlotDigitizer for 4mg/kg, 7mg/kg and 10mg/kg doses.

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Source: Robak T et al. Phase 2 multiple-dose study of an FcRn inhibitor, rozanolixizumab, in patients with primary immune thrombocytopenia. Blood Adv. 2020 Sep 8;4(17):4136-4146. No clinical head-to-head comparisons of Immunovant product candidates and third party anti-FcRn assets has been conducted.

Portfolio Development for IMVT-1402

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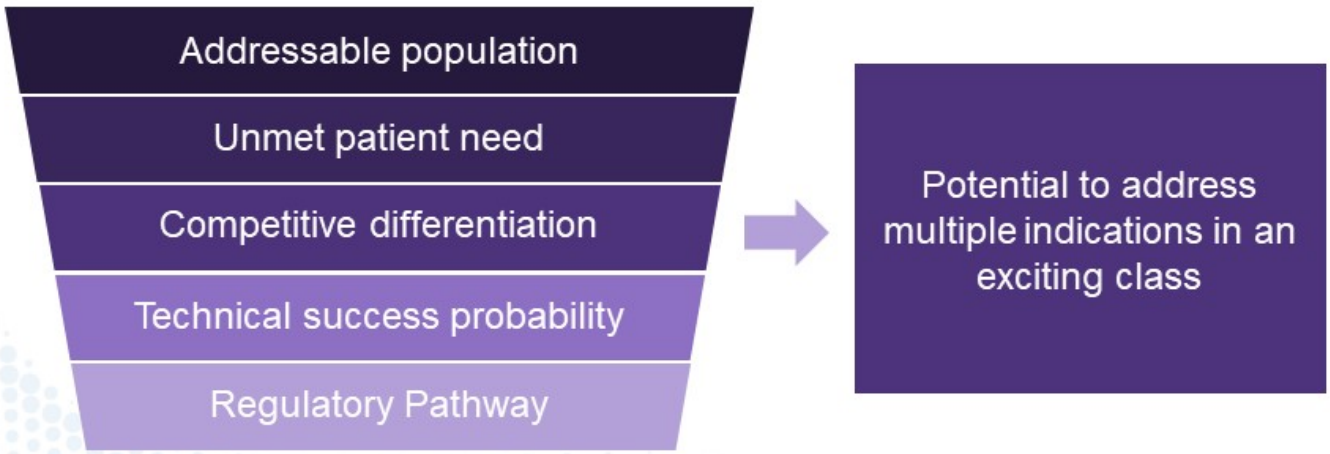
Best-in-Class Potential for IMVT-1402 – Why it Matters

- FcRn inhibition is a proven mechanism with broad potential applicability based on targeted reduction of IgG as an improved and more targeted modality
- Evidence across broad range of auto-antibody conditions that deeper IgG reduction correlates with greater efficacy
- IMVT-1402 demonstrates potentially best-in-class IgG reduction, similar to batoclimab, delivered via a simple subcutaneous injection and with minimal to no impact on albumin and LDL, similar to placebo
- Immunovant has the potential to create a unique and class-leading portfolio of indications with IMVT-1402

Creating the Best Portfolio of Indications for IMVT-1402

Guided by IgG biomarker in proven mechanism with well-characterized safety profile



Potential Best-in-Class Product Profile Opens Broad Range of Indication Opportunities for IMVT-1402

First-in-Class	• Assuming differentiated benefit/risk and simple SC delivery, opportunity to leverage potency of 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 1402 potency to optimize development approach for IMVT-1402 • Examples – MG, CIDP	**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 1402 potency • Examples – Refractory rheumatoid arthritis	**Other auto-immune, class data suggestive**

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Examples of Potential First-in-Class and/or Best-in-Class Indications*

Graves' Disease

1. Large unmet need between oral anti-thyroid medications (ATD) that work for many & definitive therapies that many others require
2. Ablative 2L therapy (30K/yr in the US) carries radiation or surgical risks and commits the patient to lifelong thyroid replacement therapy
3. Remaining euthyroid off ATD, for those who achieve it without definitive therapy, is associated with normalizing stimulating anti-TSHR antibodies
4. **High absolute anti-TSHR antibody titers found in many Graves' patients are likely to require deeper IgG reduction for a durable response**

Rheumatoid Arthritis

1. Large unmet need in refractory rheumatoid arthritis (RA) for patients who fail to respond to more than 1 biologic therapy
2. Recently presented data for nipocalimab showed a correlation between depth of auto-antibody reduction and clinical response
3. In the same study, nipocalimab achieved a 58% mean total IgG reduction at trough
4. **Taken together, we believe these points could translate to greater – and meaningful – efficacy in refractory RA with deeper IgG reduction**

*For illustration/discussion only. Final indication selection will depend on a variety of factors.

Concluding Thoughts

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IMVT-1402 Has Potentially Best-In-Class Attributes to Address Large Unmet Need in Autoimmune Disease

IMVT-1402

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

Deep IgG Lowering Initial Phase 1 data suggests deep dose-dependent IgG lowering similar to batoclimab

Favorable Analyte Profile Initial 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 Pending composition of matter patent expected for IMVT-1402 to 2043*

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* Not including any potential patent term extension

Concluding Thoughts

The proven anti-FcRn class keeps getting more exciting

IMIVT-1402's profile and potency creates an exciting range of potential indications

2024 will be a big year for IMVT-1402 as we announce a broad portfolio of pivotal trials and POCs