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): September 26, 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**	**NASDAQ**

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 September 26, 2023, the Company's subsidiary, Immunovant, Inc., issued a press release and provided a corporate update announcing initial data from a Phase 1 trial of IMVT-1402. Copies of the press release and presentation are attached hereto as Exhibits 99.1 and 99.2 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 September 26, 2023
99.2	Presentation dated September 26, 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: September 26, 2023

Exhibit 99.1

Immunovant Announces Positive Initial IMVT-1402 Phase 1 SAD and 300 mg Subcutaneous MAD Results

- IMVT-1402 subcutaneous (SC) doses achieved peak Immunoglobulin G (IgG) reductions that are similar to those previously observed with batoclimab
- No decrease in serum albumin below baseline or increase in low-density lipoprotein cholesterol (LDL-C) above baseline was observed after 4 weeks of dosing in the 300 mg multiple-ascending dose (MAD) SC cohort
- IMVT-1402 is being developed as a simple SC injection

NEW YORK, September 26, 2023 – Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today announced that subcutaneously administered doses of IMVT-1402 produced dose-dependent reductions in IgG in initial data from a Phase 1 clinical trial in healthy adults, with no dose-related changes in serum albumin or LDL-C, bolstering IMVT-1402 as a potential best-in-class neonatal fragment crystallizable receptor (FcRn) inhibitor.

“We are encouraged by the strong pharmacodynamic data observed to date with IMVT-1402,” said Pete Salzmann, M.D., chief executive officer of Immunovant. “These first-in-human results are consistent with those observed in prior non-human primate studies, and we look forward to sharing additional MAD data in November.”

This 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.

In the single-ascending dose (SAD) portion of the study, subcutaneously administered IMVT-1402 demonstrated a consistent reduction in IgG with potency that was similar to or greater than that of batoclimab. The safety data were generally favorable, with all adverse events (AEs) mild or moderate, and no significant reduction from baseline in serum albumin or increase in LDL-C observed at any timepoint measured (all $p>0.05$).

Immunovant is also pleased to announce that initial MAD study results for the 300 mg cohort were released ahead of schedule today. These data represent all the MAD data currently available. Dosing for the 600 mg cohort has recently begun. After four weekly 300 mg SC doses of IMVT-1402, the mean total IgG reduction from baseline in this MAD cohort was 63%, with no decrease in serum albumin below baseline and no increase in LDL-C above baseline observed. Treatment-emergent adverse events were observed to be mild or moderate in severity. IMVT-1402 was delivered subcutaneously in seconds to participants in this cohort as a simple 2 mL injection at a concentration of 150 mg/mL.

Conference Call & Webcast:
Immunovant will host a conference call with accompanying slides and a simultaneous webcast today, September 26, 2023 at 8:00 a.m. EDT to discuss the initial single-ascending dose and 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 volunteers, 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 and results of Immunovant’s clinical trials of IMVT-1402; and the potential benefits of IMVT-1402’s unique product attributes and its best-in-class potential. 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 candidates, 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 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 August 10, 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.

Contact:
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Vice President, Investor Relations
Immunovant, Inc.
info@immunovant.com

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Targeted science, Tailored solutions

for people with autoimmune disease

IMVT-1402 Initial First-in-human Data Presentation

September 26, 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 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 beliefs regarding the potential benefits of IMVT-1402's unique product attributes; 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 and resumption of current trials; Immunovant's scientific approach, clinical trial design, indication selection, and general development progress; future clinical trials may not confirm any safety, potency, or other product characteristics described or assumed in this presentation; any product candidate that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; Immunovant's 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 the ongoing COVID-19 pandemic, 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 June 30, 2023, filed with the SEC on August 10, 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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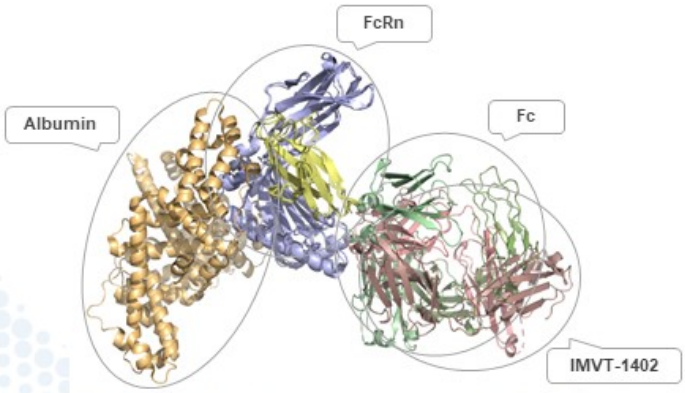
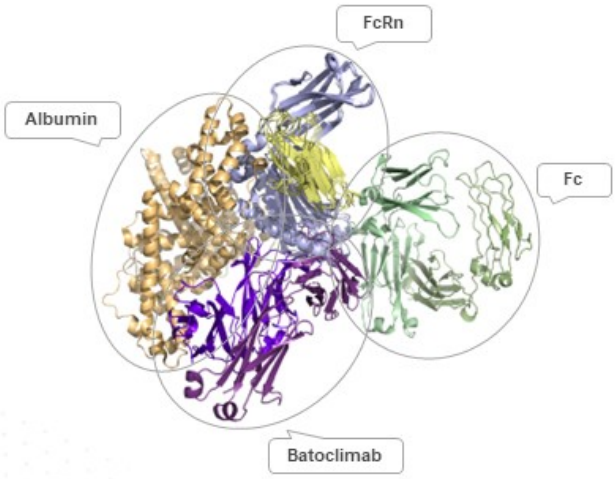
IMVT-1402 Was Selected to Deliver Maximum IgG Reduction While Minimizing Interference with Albumin Recycling

IMVT-1402: overlay with albumin and Fc



Batoclimab: overlay with albumin and Fc



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Note: Ribbon representations generated from X-Ray crystal structure.
Batoclimab solved at 2.4Å resolution. IMVT-1402 solved at 2.6Å resolution.

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.

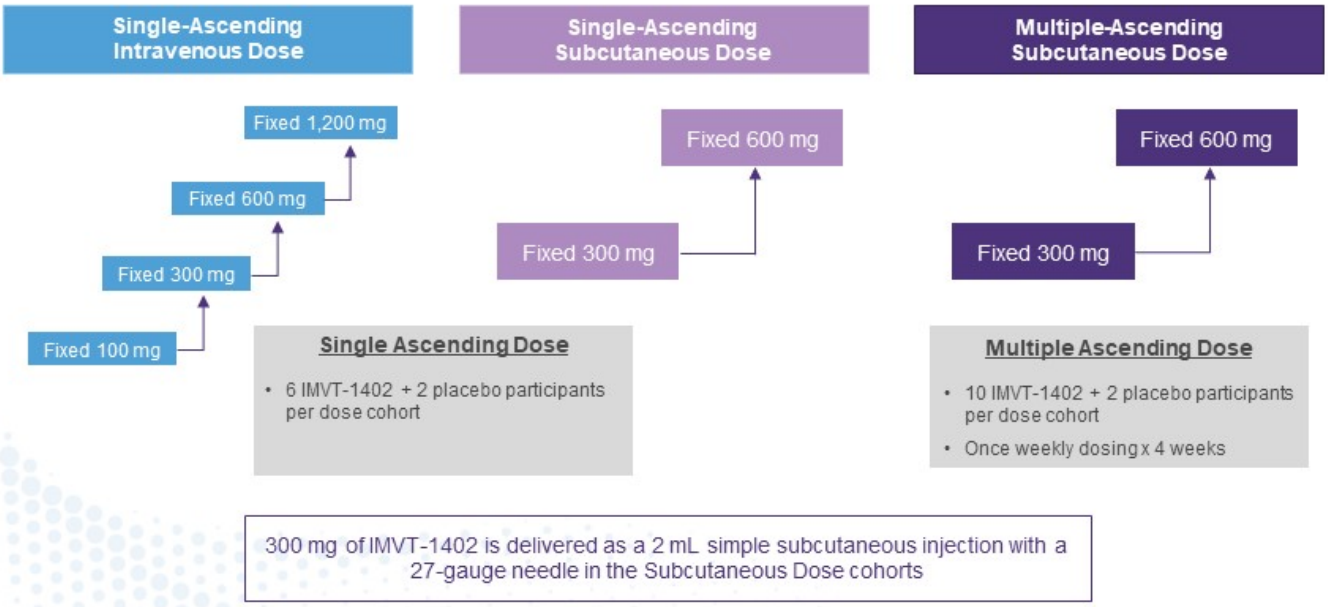
Best-in-Class Potential for IMVT-1402 as FcRn Inhibitor Highlighted by Initial Phase 1 Safety and Pharmacodynamic Data

- Initial SAD and 300 mg MAD data demonstrated deep and rapid IgG reduction, similar to batoclimab, with 63% mean IgG reduction in the 300 mg MAD cohort after four doses
- Initial 300 mg MAD data after four doses showed a favorable analyte profile of no decrease in albumin and no increase in LDL relative to baseline levels
- Simple subcutaneous formulation designed to enable patient self-administration and provide additional differentiation beyond depth of IgG reduction

IMVT-1402 Phase 1 Clinical Trial Objectives

1. Expeditiously evaluate safety, pharmacokinetic & pharmacodynamic profile
2. Validate the IMVT-1402 dose that achieves FcRn saturation
3. Confirm doses for future studies

Study Design for IMVT-1402 Phase 1 Clinical Trial in Healthy Volunteers*



300 mg of IMVT-1402 is delivered as a 2 mL simple subcutaneous injection with a 27-gauge needle in the Subcutaneous Dose cohorts

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* 1,200 mg IV SAD cohort and 600 mg SC MAD cohort remain to be completed

Single-Ascending Subcutaneous Doses

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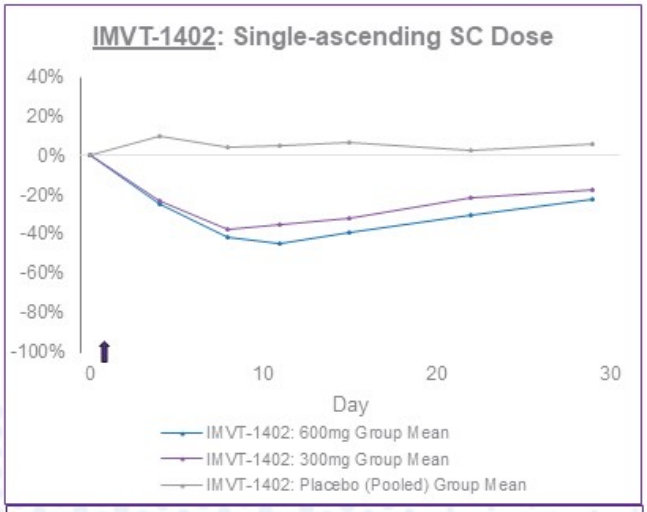
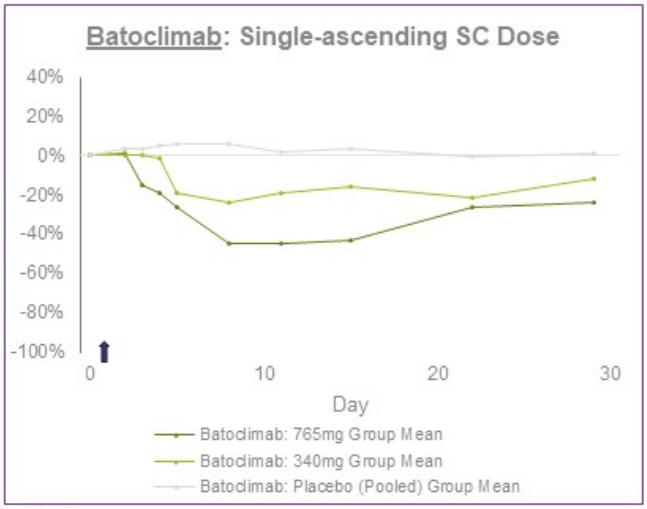
IMVT-1402 SAD Data Suggests Potential Best-in-Class IgG Reduction Similar to Batoclimab

IgG % change from baseline*



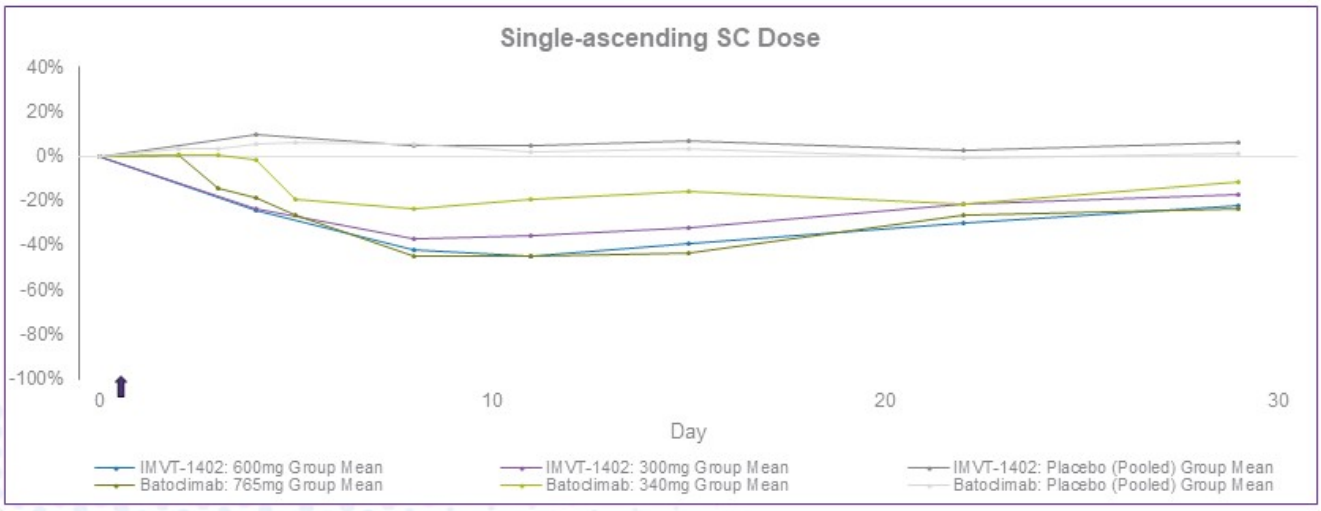


All IgG values in the IMVT-1402 arms showed a significant decrease from baseline (all p-values < 0.05)

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

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

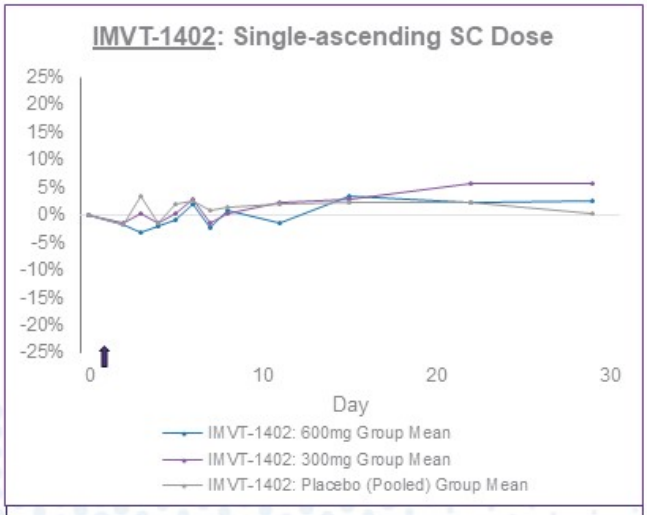
IgG % change from baseline*

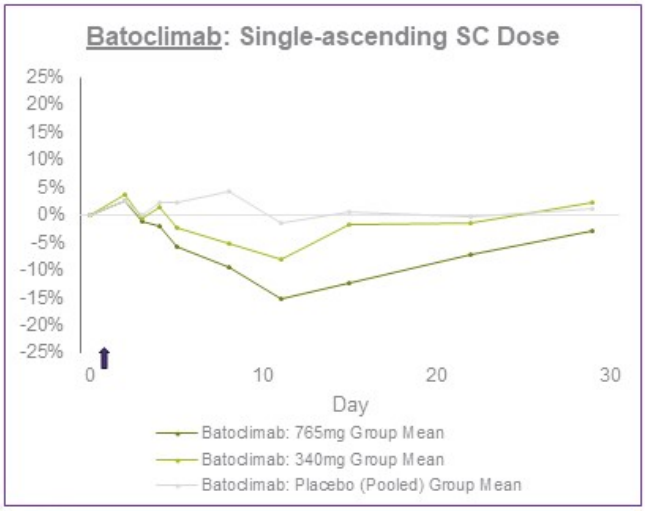


IMMUNOVANT ⬆ Dose administration * Data presented are from separate clinical trials, not a head-to-head study, conducted by Immunovant.

IMVT-1402 Produced a Similar Effect on Albumin as Placebo

Albumin % change from baseline*



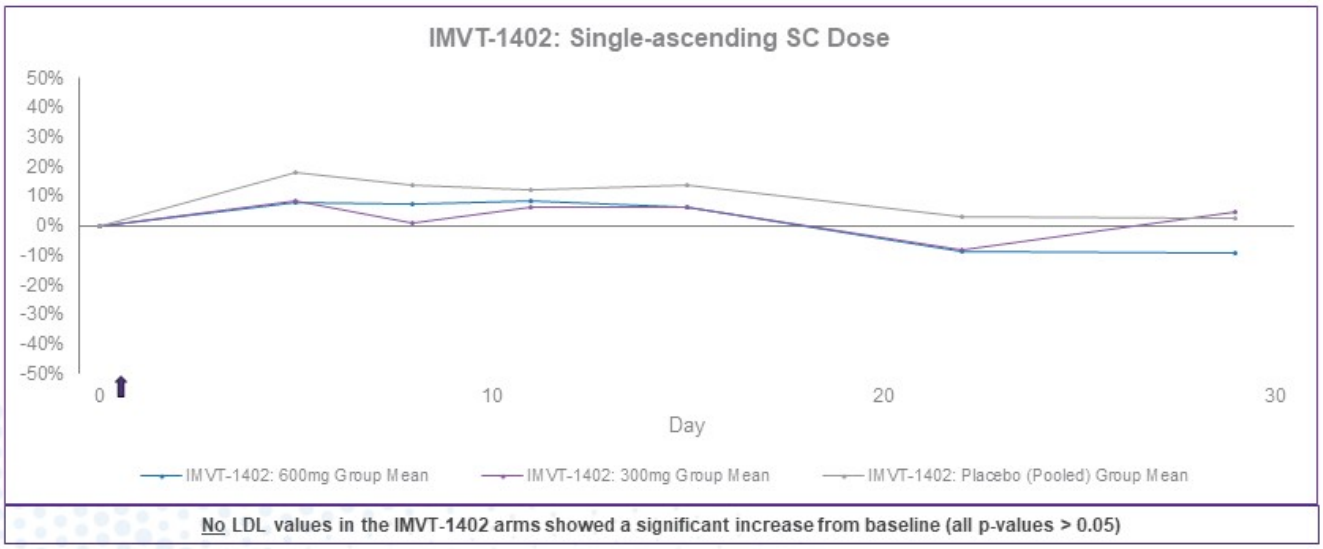


No albumin values in the IMVT-1402 arms showed a significant decrease from baseline (all p-values > 0.05)

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

IMVT-1402 Produced a Similar Effect on LDL as Placebo

LDL % change from baseline*



No LDL values in the IMVT-1402 arms showed a significant increase from baseline (all p-values > 0.05)

IMMUNOVANT ⬆ Dose administration * Batoclimab phase 1 study did not measure LDL, so no comparison provided

Multiple-Ascending Subcutaneous Doses

(Once-weekly dosing x 4 weeks)

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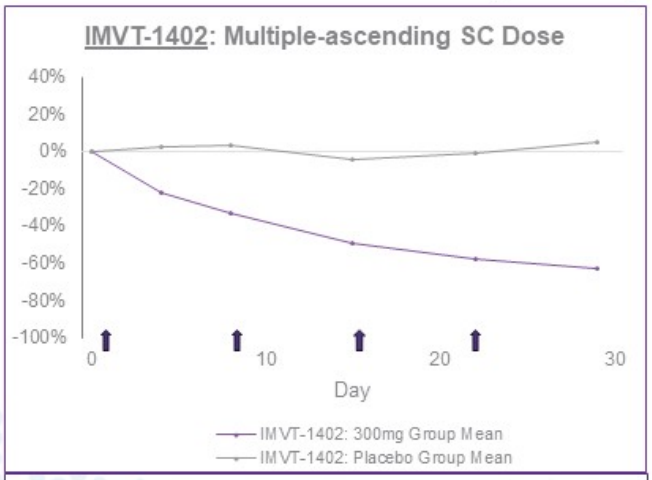
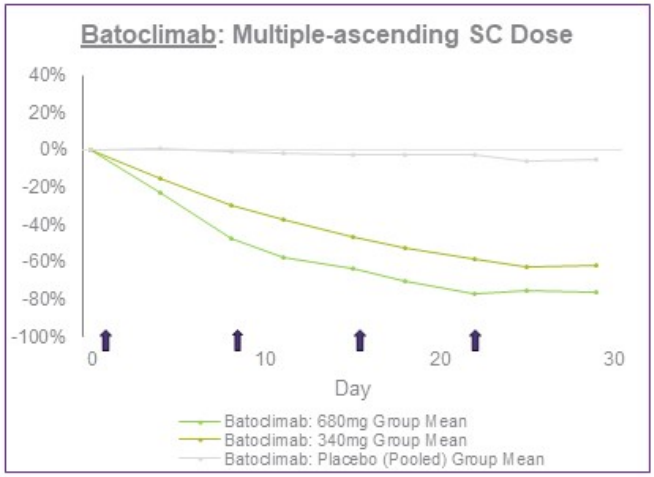
IMVT-1402 300 mg MAD Data Suggests Potential Best-in-Class IgG Reduction Similar to Batoclimab

IgG % change from baseline*





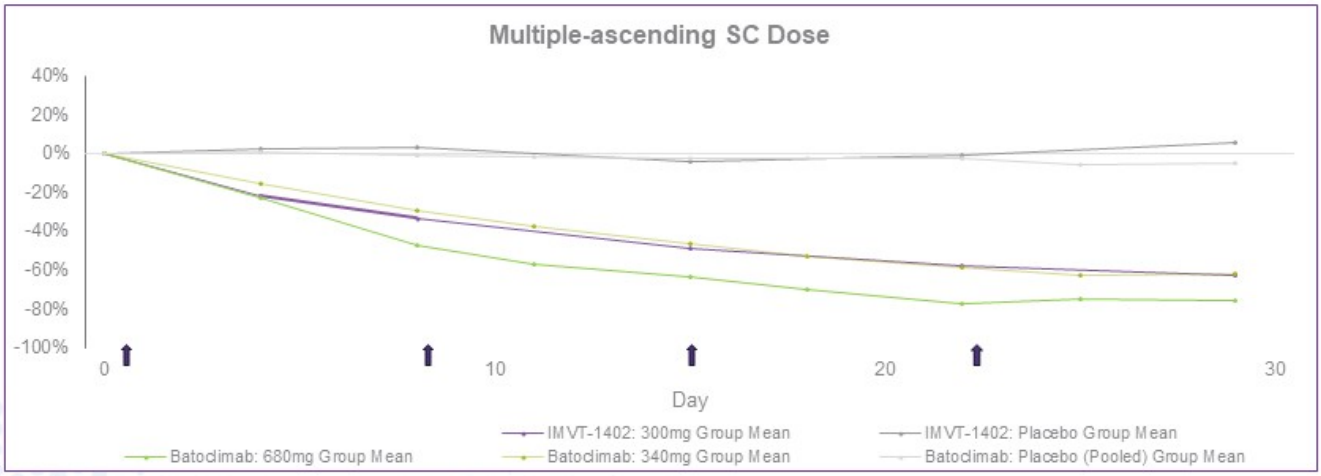
All IgG values in the IMVT-1402 arms showed a significant decrease from baseline (all p-values < 0.05)

IMVT-1402 MAD 600 mg data on track for November 2023

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

IMVT-1402 300 mg MAD Data Suggests Potential Best-in-Class IgG Reduction Similar to Batoclimab

IgG % change from baseline*

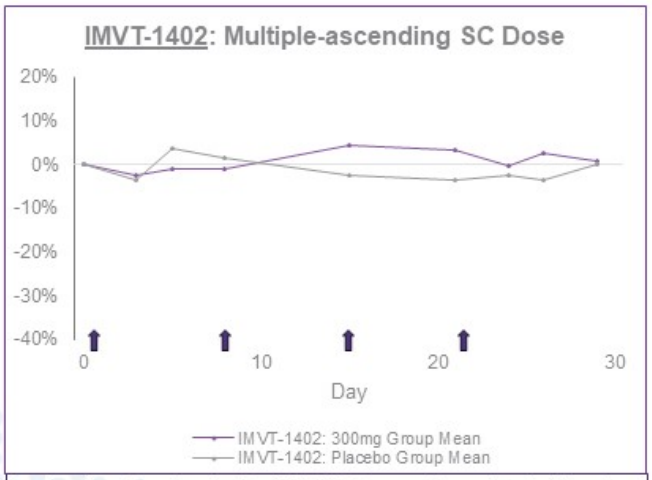


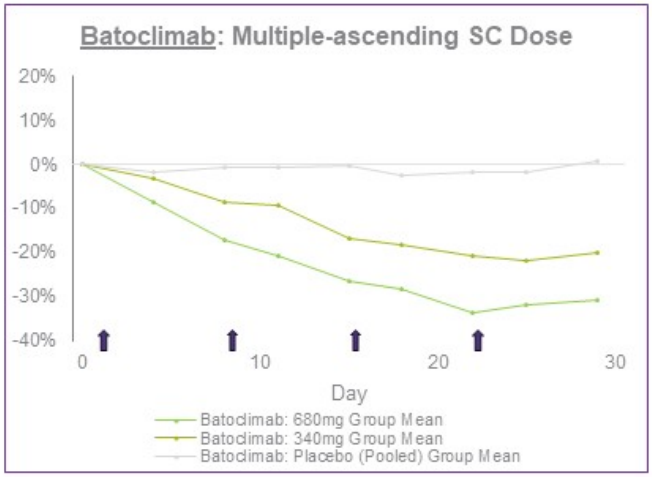
IMVT-1402 MAD 600 mg data on track for November 2023

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

IMVT-1402 300 mg MAD Data: No Albumin Reduction Compared to Baseline After Four Weeks of Dosing

Albumin % change from baseline*





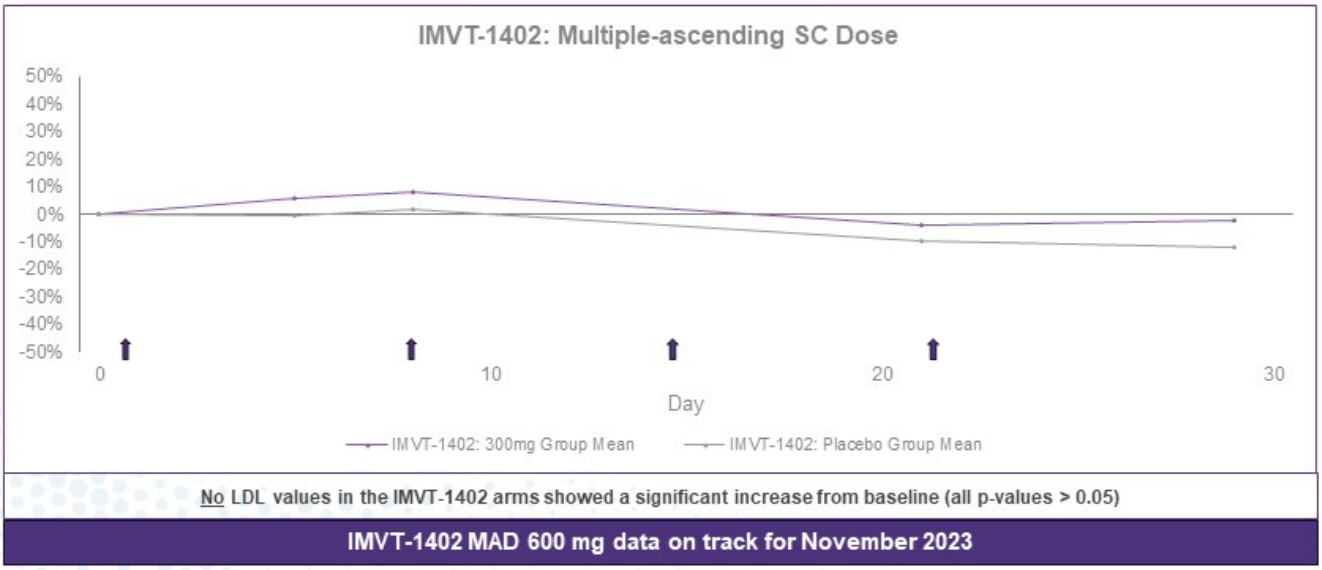
No albumin values in the IMVT-1402 arms showed a significant decrease from baseline (all p-values > 0.05)

IMVT-1402 MAD 600 mg data on track for November 2023

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

IMVT-1402 300 mg MAD Data: No LDL Increase Compared to Baseline After Four Weeks of Dosing

LDL % change from baseline*



No LDL values in the IMVT-1402 arms showed a significant increase from baseline (all p-values > 0.05)

IMVT-1402 MAD 600 mg data on track for November 2023

IMMUNOVANT ⬆ Dose administration * Batoclimab phase 1 study did not measure LDL, so no comparison provided

IMVT-1402 Showed a Favorable Safety Profile in SAD / MAD Initial Data Set

	IV SAD				SC SAD			SC MAD	
	Placebo	100mg	300mg	600mg	Placebo	300mg	600mg	Placebo	300mg
	N = 6 n (%)	N = 6 n (%)	N = 6 n (%)	N = 6 n (%)	N = 4 n (%)	N = 6 n (%)	N = 6 n (%)	N = 2 n (%)	N = 10 n (%)
Participants with at least one TEAE	4 (67)	4 (67)	3 (50)	3 (50)	3 (75)	4 (67)	5 (83)	2 (100)	7 (70)
Participants with at least one TESAE	0	0	0	0	0	0	0	0	0
Participants discontinued study due to TEAEs	0	0	0	0	0	0	0	0	1 (10)*
Participants with dose reduced or temporary discontinuation due to TEAEs**	0	0	0	0	0	0	0	0	0
Deaths	0	0	0	0	0	0	0	0	0
TEAE (≥ 2 Instances)									
Upper Respiratory Tract Infections	2 (33)	3 (50)	0	0	0	1 (17)	0	1 (50)	0
Headache	3 (50)	1 (17)	1 (17)	0	0	1 (17)	0	0	1 (10)
Catheter Site Pain***	1 (17)	0	0	0	1 (25)	0	0	0	2 (20)

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

* Participant who discontinued experienced a Mild TEAE. The event was considered not related to study treatment.
** Participant in the 1200 mg IV SAD had an infusion reaction without change in vital signs. The event resolved and the subject remained on-study.
*** Catheter site pain refers to pain at the site of the catheter used for blood draws
TEAE = treatment emergent adverse event; TESAE = treatment emergent serious adverse event

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Concluding Thoughts

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Summary of IMVT-1402 SAD/MAD Data Reviewed

IMVT-1402 SAD/MAD data to date suggest potential for best-in-class IgG lowering with IMVT-1402

IMVT-1402 data appeared similarly potent as batoclimab in both the SAD and 300 mg MAD data with robust, predictable, dose-dependent IgG lowering

IMVT-1402 SAD/MAD data to date suggest potential best-case profile with respect to albumin and LDL impact

No reduction in albumin and no increase in LDL compared to baseline observed, including after the full four weeks of dosing in the MAD 300 mg cohort

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

Based on SAD / MAD data to date, IMVT-1402 has a potential best-in-class profile

MAD 600mg SC cohort just starting with data expected in November 2023

Anti-FcRn market offers many attractive opportunities and a favorable development path