

# Immunovant 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, Nov. 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](http://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.

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