September 26, 2023

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, Sept. 26, 2023 (GLOBE NEWSWIRE) -- **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 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 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.

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Source: Immunovant Inc.