

Immunovant Announces Positive Clinical Results from Ongoing Phase 2a Proof-of-Concept Study of IMVT-1401, A Novel Investigational Anti-FcRn Antibody Delivered by Subcutaneous Injection, in Thyroid Eye Disease

Company to Host Conference Call on March 30, 2020 at 8:30am EDT

- 65% mean reduction in total IgG was observed from baseline to end of treatment, with a pharmacodynamic (PD) response nearly identical to modeled predictions for dosing regimen tested in trial
- IMVT-1401 was safe and generally well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs), and no headaches
- 4/7 patients (57%) improved by ≥ 2 points on the Clinical Activity Score (CAS) and 3/7 patients (43%) achieved a proptosis response
- Results establish first proof of concept for an anti-FcRn antibody in Thyroid Eye Disease

NEW YORK, March 30, 2020 (GLOBE NEWSWIRE) -- Immunovant, Inc. (NASDAQ: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune disease, today announced initial results from the treatment phase of its ongoing Phase 2a study of IMVT-1401 (ASCEND GO-1) in patients with Thyroid Eye Disease (TED), also known as Graves' ophthalmopathy.

The multi-center, open-label, single-arm clinical trial evaluated two weekly 680mg subcutaneous doses of IMVT-1401 followed by four weekly 340mg subcutaneous doses of IMVT-1401 in seven adult patients with moderate-to-severe active TED. A planned eighth patient enrolled in ASCEND GO-2 instead of ASCEND GO-1. All patients in the trial have completed IMVT-1401 treatment and have entered the follow-up phase of the trial. Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, 4/7 patients (57%) improved by ≥ 2 points on the Clinical Activity Score (CAS). Of six patients with baseline diplopia, 4/6 patients (67%) demonstrated improvement in diplopia. 3/7 patients (43%) were proptosis responders. The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. All AEs were mild or moderate and there were no headaches reported.

"We are very excited by the initial results of this trial," said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. "These results provide an early proof-of-concept of the potential for IMVT-1401 to ultimately become a safe and effective treatment for patients suffering from Thyroid Eye Disease. Importantly, IMVT-1401 was delivered by

subcutaneous injection, opening the possibility of at-home treatment rather than infusion center-based treatment, for patients with Thyroid Eye Disease. We look forward to reporting the study's full results, including detailed lab observations and 12 weeks of follow up data, at an upcoming medical meeting."

"I am encouraged by IMVT-1401's early results showing promising efficacy and safety with a subcutaneous route of administration. If validated by additional data and approved by regulatory agencies, this drug could really benefit our patients suffering from active Thyroid Eye Disease," said Peter Dolman, M.D., Oculoplastics Division Head, Department of Ophthalmology and Visual Sciences at the University of British Columbia. Dr. Dolman serves as principal investigator for the ASCEND GO-1 trial. "Even in this small study population, the response across multiple measures is notable," he added.

Immunovant will host a conference call on Monday, March 30 at 8:30am EDT. Following prepared remarks, the call will include a live question-and-answer session for the investment community. To access the webcast, please visit Immunovant's website at www.immunovant.com. Participants may also dial in using the numbers provided below:

Toll Free: 1-877-407-9039

Toll/International: 1-201-689-8470

An archived webcast recording will be available on the Immunovant's website for a limited time.

About Immunovant, Inc.

Immunovant, Inc is a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. Immunovant is developing IMVT-1401, a novel, fully human anti-FcRn monoclonal antibody, as a subcutaneous injection for the treatment of autoimmune diseases mediated by pathogenic IgG antibodies.

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 "may," "might," "will," "would," "should," "expect," "believe," "estimate," and other similar expressions are intended to identify forward-looking statements. For example, all statements Immunovant makes regarding Immunovant's progress towards its vision of enabling normal lives for patients with autoimmune diseases; the timing, progress and reporting of results of its clinical programs; and the potential of IMVT-1401 to become a treatment option for patients suffering from TED are forward-looking. 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 availability of data from clinical trials; the expectations for regulatory submissions and approvals; the continued development of Immunovant's product candidates; Immunovant's scientific approach and general development progress; the availability and commercial potential of Immunovant's product candidates including the size

of potentially addressable markets and degree of market acceptance; and the potential impact of the recent COVID-19 pandemic on Immunovant's clinical development plans and timelines. These statements are also subject to a number of material risks and uncertainties that are described under the section titled "Risk Factors" in Immunovant's Form 10-Q filed with the Securities and Exchange Commission (SEC) on February 14, 2020, 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:

John Strumbos, PhD, MBA
Vice President, Finance
Immunovant, Inc.
info@immunovant.com



Source: Immunovant