February 2, 2021

Immunovant Announces Voluntary Pause in Clinical Dosing of IMVT-1401

NEW YORK, Feb. 02, 2021 (GLOBE NEWSWIRE) -- Immunovant (Nasdaq: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases, today announced a voluntary pause of dosing in its ongoing clinical trials for IMVT-1401.

The Company has become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease (TED). Cholesterol levels were not measured in prior clinical trials of IMVT-1401 in Myasthenia Gravis (MG) and in healthy subjects. Out of an abundance of caution, the Company has decided to voluntarily pause dosing in ongoing clinical studies in both TED and in Warm Autoimmune Hemolytic Anemia, in order to inform patients, investigators, and regulators as well as to modify the monitoring program.

ASCEND GO-2 is a randomized, placebo-controlled trial in TED evaluating different doses, each given weekly for 12 weeks. In this study, cholesterol parameters are assessed at baseline, at twelve weeks, and at week 20 following eight weeks off drug. Based on preliminary, unblinded data from about 40 patients through week 12, mean LDL cholesterol at week 12 was increased by approximately 65% in the 680mg dose group, by approximately 40% in the 340mg dose group, and did not increase in the control group. Average HDL and triglyceride levels increased to a much lesser degree. For context, commercially available statins report a reduction in LDL cholesterol between 27-60%. At the twenty-week timepoint, average LDL levels had declined to baseline or lower in the 680mg dose group, in the 340mg dose group, and in the control group. No serious cardiovascular events have been reported to date in IMVT-1401 clinical trials.

Harbour BioMed, the license holder for 1401 in Greater China, has informed Immunovant that based on their preliminary review of blinded data in their ongoing clinical studies in Chinese patients with MG and Idiopathic Thrombocytopenic Purpura, similar increases in cholesterol have not been observed. The Company is not aware whether trials involving other anti-FcRn agents in development have performed detailed assessments of lipid parameters.

The Company will work closely with regulators and scientific experts to characterize the detailed profile of these lipid changes and to understand the mechanism of these changes across indications. After discussion and agreement with regulators regarding protocol modifications, the Company intends to continue to pursue development of IMVT-1401.

Immunovant will host a conference call on Tuesday, February 2 at 8:00am EST. 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 period of time.

About Immunovant
Immunovant 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. Examples of these forward-looking statements include statements concerning Immunovant's intent to continue the development of IMVT-1401 after discussion and agreement with regulators, the ability of Immunovant to identify new opportunities, the potential efficacy and success of IMVT-1401 and the potential of IMVT-1401 to become a best-in-class treatment for multiple autoimmune diseases and to improve the quality of life for patients suffering from these conditions. 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; the potential impact of the recent COVID-19 pandemic on Immunovant's clinical development plans and timelines; and actions by regulatory authorities with respect to Immunovant's product candidates. 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 filed with the SEC on November 12, 2020. 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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