Immunovant Announces Positive Topline Results from Multi-Center, Placebo-Controlled Phase 2a Trial of IMVT-1401, A Novel Investigational Anti-FcRn Antibody Delivered by Subcutaneous Injection, in Myasthenia Gravis

August 25, 2020

Company to Host Conference Call on August 25, 2020 at 8:30am EDT

- 3.8-point mean improvement on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale was statistically significant vs. placebo (p = 0.029)
- 8.0-point mean improvement on Myasthenia Gravis Composite (MGC) scale was highly statistically significant vs. placebo (p = 0.006)
- Mean reductions in total IgG from baseline for the 340 mg and 680 mg cohorts were 59% and 76%, respectively
- IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs) and no withdrawals due to adverse events (AEs)
- Registration-enabling Phase 3 MG trial is expected to initiate in the first half of 2021

NEW YORK, Aug. 25, 2020 (GLOBE NEWSWIRE) -- Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases, today announced positive topline results from ASCEND MG, a Phase 2a study of IMVT-1401 in patients with myasthenia gravis (MG).

The multi-center, randomized, placebo-controlled trial was designed to evaluate the safety, tolerability, pharmacodynamics, and efficacy of IMVT-1401 in patients with moderate-to-severe generalized MG. Results from the six-week treatment period included three arms: 340 mg IMVT-1401 weekly (N=5), 680 mg IMVT-1401 weekly (N=5), and placebo (N=5).

As evaluated in a pre-specified, pooled analysis of 15 patients who completed Day 42, IMVT-1401-treated patients (N=10) showed a mean 3.8-point improvement on the MG-ADL scale vs. a mean decline of +0.6 for placebo, a result that was statistically significant (p = 0.029). IMVT-1401-treated patients also showed a highly statistically significant improvement on the MGC scale, with an average improvement of 8.0 points vs. a mean decline of +1.4 for placebo (p = 0.006).

MG-ADL responder rates, defined as the percentage of patients showing a > 2-point improvement, were 60% for IMVT-1401-treated patients vs. 20% for placebo. MG-ADL deep responder rates, defined in the study as the percentage of patients showing a > 6-point improvement, were 40% for IMVT-1401-treated patients vs. 0% for placebo. MGC deep responder rates, defined in the study as the percentage of patients showing a > 10-point improvement, were 40% for IMVT-1401-treated patients vs. 0% for placebo.

Consistent with previously reported Phase 1 results, IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs), and no imbalance in headaches. Mean reductions in total serum IgG from baseline for the 340 mg and 680 mg cohorts were 59% and 76%, respectively.

“We are absolutely thrilled with the results of this trial,” said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. “The clinical benefits we observed in this trial provide strong support that IMVT-1401 might ultimately become a best-in-class anti-FcRn agent for MG patients. Importantly, IMVT-1401 was delivered by subcutaneous injection, opening the future possibility of at-home, self-administered treatment rather than infusion center-based treatment. We look forward to engaging with the FDA later this year on the design of our Phase 3 registrational program in MG.”

After taking into consideration the impact of COVID-19 and the validation of the anti-FcRn mechanism in MG as discussed in its June 29th press release, Immunovant elected to unblind the study after 15 of an anticipated 21 patients had completed the six-week treatment course.

“Although this small Phase 2a study was designed principally to evaluate safety and tolerability, as well as changes in IgG antibody levels, it is extremely encouraging to see such promising early results on a range of MG outcome measures,” said Michael Benatar, M.D., M.S., Ph.D., Chief of the Neuromuscular Division at the University of Miami. “Results of this study will provide critical insights for the design and implementation of a pivotal phase 3 study,” he added.

Immunovant will host a conference call on Tuesday, August 25 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 potential of IMVT-1401 to become a best-in-class treatment option for patients suffering from MG; and the design and implementation of a pivotal Phase 3 study of IMVT-1401 for the treatment of MG 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 of final trial results or of the results of later clinical trials; future clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release; any product candidates 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 the ongoing COVID-19 pandemic on Immunovant’s clinical development plans and timelines; Immunovant’s business is heavily dependent on the successful development, regulatory approval and commercialization of its sole product candidate, IMVT-1401; and Immunovant will require additional capital to fund its operations and advance IMVT-1401 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 Form 10-Q filed with the SEC on August 12, 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 and Strategy
Immunovant, Inc.
info@immunovant.com

IMMUNOVANT

Source: Immunovant