

# Immunovant Announces Two New Development Programs for Batoclimab

- Plan to initiate a Pivotal Phase 2b trial in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in the second half of 2022<sup>1</sup> with initial results from open-label period 1 expected in the first half of 2024
- Plan to initiate a Phase 2 trial in Graves' Disease in early 2023 with initial results expected in the second half of 2023
- Immunovant expects a robust cadence of data every half year beginning in the second half of 2023 through the first half of 2025, including multiple clinical readouts in CIDP, Graves' Disease, Myasthenia Gravis (MG), and Thyroid Eye Disease (TED)
- Company management will host an investor webcast today at 8 AM ET that can be accessed [here](#).

NEW YORK, Sept. 07, 2022 (GLOBE NEWSWIRE) --**Immunovant, Inc.** (Nasdaq: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for people with autoimmune diseases, today announced plans to develop batoclimab in Chronic Inflammatory Demyelinating Polyneuropathy and Graves' Disease.

"We are excited to announce the addition of two new target indications for batoclimab, one of which will be a pivotal program, confirming our confidence in the broad development opportunity for batoclimab," said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. "Evidence suggests that both CIDP and Graves' Disease are caused by autoantibodies and that targeting FcRn is a compelling therapeutic strategy. We believe both indications present promising opportunities ripe for innovation."

"CIDP represents a multibillion-dollar market for IVIG and a compelling opportunity for the anti-FcRn class, as current therapies for this complex disease have meaningful safety, tolerability and logistical limitations. We have designed our pivotal Phase 2b study leveraging learnings from historical and ongoing clinical trials in this disease, with a goal to improve probability of success and effect size, while studying multiple doses for optimal differentiation," added Bill Macias, M.D., Chief Medical Officer at Immunovant.

"With regard to Graves' Disease, current treatments leave a meaningful proportion of patients unable to achieve normal thyroid hormone function and many remain symptomatic even when on current therapies", said Dr Salzmann. "As a classic autoantibody condition, the straightforward biology of Graves' Disease, from pathogenic autoantibody to altered hormones, provides solid scientific rationale for the indication, supported by anecdotal data from our Thyroid Eye Disease Phase 2b trial. By further defining the dose-response for batoclimab in Graves' Disease, we believe our Graves' Phase 2 trial, if successful, can meaningfully inform and de-risk a future Phase 3 trial and help bring a novel therapy to a large patient population that requires additional treatment."

With the addition of these development programs, Immunovant is now pursuing batoclimab's clinical development in five indications, including MG and TED that have previously disclosed

data readouts. Immunovant plans to finalize its trial design in Warm Autoimmune Hemolytic Anemia following interactions with regulators later in 2022.

## **Investor Webcast**

Immunovant will host an investor webcast today at 8 AM ET. The webcast will feature prepared remarks by company management and external key opinion leaders and will highlight the current treatment landscape for CIDP and Graves' Disease, as well as plans to study batoclimab's potential to address the unmet needs in its target patient populations. A live question-and-answer session with company management will follow the formal presentations.

Featured speakers will include:

- George Kahaly, MD, PhD, Professor of Medicine and Endocrinology / Metabolism at the Johannes Gutenberg University (JGU) Medical Center
- Jonathan Katz, MD, Director, Neuromuscular Clinic, California Pacific Medical Center
- Todd Levine, MD, Medical Director, Neurology Department, Honor Health Scottsdale, Arizona

To access the webcast, please register [here](#). An archived recording of the webcast will be available on Immunovant's website for a limited time following its conclusion.

## **About Immunovant, Inc.**

Immunovant, Inc. is a clinical-stage biopharmaceutical company dedicated to enabling normal lives for people with autoimmune diseases. As a leader in FcRn inhibitor technology, the Company is boldly developing innovative therapies for a range of debilitating autoimmune diseases with significant unmet patient needs. The Company's investigational compound, batoclimab, is a novel, fully human, monoclonal antibody targeting the neonatal Fc receptor (FcRn). For additional information on the Company, please visit [www.immunovant.com](http://www.immunovant.com).

## **Forward Looking Statement**

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 plan to initiate a Phase 2b clinical trial for batoclimab in CIDP in the second half of calendar year 2022 with initial results from open-label period 1 expected in the first half of calendar year 2024; Immunovant's plan to initiate a Phase 2 clinical trial for batoclimab in Graves' Disease in early calendar year 2023 with initial results expected in the second half of calendar year 2023; Immunovant's plan to finalize its trial design in Warm Autoimmune Hemolytic Anemia following expected interactions with regulators later in calendar year 2022; Immunovant's plan to develop batoclimab across a broad range of other autoimmune indications; the timing of discussions with regulatory agencies; the size and growth of the potential markets for Immunovant's product candidate and indication selections; Immunovant's expectations regarding timing, the design and results of clinical trials of its product candidates and indication selections; and the potential benefits of batoclimab's unique product attributes. 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 candidate, 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 candidate may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic, geopolitical tensions, and adverse macroeconomic conditions 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, batoclimab; Immunovant is at an early stage in development of batoclimab; and Immunovant will require additional capital to fund its operations and advance batoclimab 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 Annual Report on Form 10-K, its Form 10-Q filed with the SEC on August 5, 2022, 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:**

Tom Dorney, MS, MBA  
Director, Investor Relations & Strategy  
Immunovant, Inc.  
[info@immunovant.com](mailto:info@immunovant.com)

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1. All dates refer to calendar year



Source: Immunovant