June 8, 2022

Immunovant Achieves Alignment with FDA on Plans for Phase 3 Clinical Trials of Batoclimab in Thyroid Eye Disease and Reports Financial Results for the Fourth Quarter and Fiscal Year Ended March 31, 2022

- Immunovant plans to initiate two placebo-controlled Phase 3 clinical trials of batoclimab in thyroid eye disease (TED) in the second half of calendar year 2022 with top-line data expected for both in the first half of calendar year 2025
- Immunovant estimates annual addressable U.S. TED population for a new mechanism of action to be 8,000-18,000 patients
- Immunovant on track to initiate pivotal Phase 3 clinical trial of batoclimab in myasthenia gravis (MG), by the end of June 2022
- Cash balance of $494 million as of March 31, 2022 expected to provide cash runway into calendar year 2025

NEW YORK, June 08, 2022 (GLOBE NEWSWIRE) -- Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for people with autoimmune diseases, today announced that it has achieved alignment with the United States Food and Drug Administration (FDA) Division of Ophthalmology on plans to initiate two placebo-controlled Phase 3 clinical trials to evaluate batoclimab in TED. Immunovant expects to initiate its Phase 3 TED program in the second half of calendar year 2022.

“TED represents a unique opportunity with meaningful unmet need despite recent therapeutic innovation. As a heterogeneous disease with varied symptom presentation, we believe this indication lends itself well to new mechanistic approaches,” said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. “In our TED Phase 2 program, we observed batoclimab’s potential to provide deep reductions of stimulating anti-TSHR autoantibodies and we are enthusiastic about the potential of this first-in-class program in TED,” continued Dr. Salzmann.

Immunovant’s Phase 3 development program for TED will include two placebo-controlled trials (run in-parallel) followed by an open label extension that will enroll subjects from both Phase 3 studies. The Phase 3 trials will have the same design and are expected to enroll about 100 subjects for each trial. After randomization to either treatment or placebo, the standard 24-week treatment period will include 12 weeks of 680 mg of batoclimab followed by 12 weeks of 340 mg of batoclimab. Batoclimab and placebo will be delivered weekly by a simple subcutaneous injection. The primary efficacy endpoint will be a responder analysis versus placebo, where responders are defined as patients with a ≥ 2 mm reduction from baseline in proptosis.

If successful, Immunovant believes these trials can support registration of batoclimab for TED. Top-line results from both trials are expected in the first half of calendar year 2025. Additional details of Immunovant's clinical program in TED will be presented in an investor call described below.

Immunovant's upcoming Phase 3 TED trials represent the Company's second pivotal program, with a Phase 3 pivotal trial in MG expected to initiate by the end of June 2022, and a top-line readout expected in the second half of calendar year 2024. The Company continues to make meaningful progress on additional strategic priorities for batoclimab's broad development and expects to announce two new indications by August 2022.

The Company also reported today its financial results for its fiscal fourth quarter and fiscal year ended March 31, 2022.

Financial Highlights for Fiscal Fourth Quarter ended March 31, 2022 and Fiscal Year ended March 31, 2022:

Cash Position: As of March 31, 2022, Immunovant's cash balance was $493.8 million. Based on its existing cash balance as of March 31, 2022 of $493.8 million, its research and development plans and the timing expectations related to its development programs for batoclimab, the Company expects to be able to fund its operating expenses and capital expenditure requirements into calendar year 2025.

R&D Expenses: Research and development expenses were $32.0 million for the three months ended March 31, 2022, compared to $18.6 million for the three months ended March 31, 2021. Research and development expenses were $101.8 million for the year ended March 31, 2022, compared to $68.6 million for the year ended March 31, 2021. The year-over-year increase was primarily due to increases in cross-indication clinical studies and clinical research costs, an increase in contract manufacturing costs, and higher personnel-related expenses primarily reflecting the enhancement of Immunovant's capabilities to support its strategic objectives as the Company prepares to resume its clinical activities.

G&A Expenses: General and administrative expenses were $15.2 million for the three months ended March 31, 2022, compared to $10.3 million for the three months ended March 31, 2021. General and administrative expenses were $54.2 million for the year ended March 31, 2022, compared to $39.5 million for the year ended March 31, 2021. The year-over-year increase was primarily due to higher personnel-related costs, as well as financial advisory, legal and other professional costs.

Net Loss: Net loss was $47.2 million ($0.41 per common share) for the three months ended March 31, 2022, compared to $28.2 million ($0.29 per common share) for the three months ended March 31, 2021. Net loss was $156.7 million ($1.43 per common share) for the year ended March 31, 2022, compared to $107.4 million ($1.22 per common share) for the year ended March 31, 2021. Net loss for the year ended March 31, 2022 and 2021 included $34.2 million and $18.8 million, respectively, related to non-cash stock-based compensation expense.

Common Stock: As of March 31, 2022, there were 116,482,899 shares of common stock issued and outstanding.

Conference Call Information:

Immunovant will hold a live conference call and webcast today, June 8, 2022 at 8:00 AM ET to discuss its clinical development plan updates. Following prepared remarks, the call will include a live question-and-answer session for the investment community. To access the webcast and the presentation being shared on the call, please visit Immunovant's website at https://www.immunovant.com/investors/news-events.

Participants may also dial in using the numbers provided below:
Toll Free: 1-877-407-9039
Toll/International: 1-201-689-8470

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.

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," "intend," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant's plan to initiate two Phase 3 clinical trials for batoclimab in TED in the second half of calendar year 2022 with expected topline data readouts in the first half of calendar year 2025; Immunovant's plan to initiate a Phase 3 clinical trial in MG by the end of June 2022, with an expected topline data readout in the second half of calendar year 2024; the timing of the announcement of additional indications; Immunovant's expected cash runway; and Immunovant's plan to develop batoclimab across a broad range of autoimmune indications. 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 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 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 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 Quarterly Report on Form 10-Q, its Annual Report on Form 10-K for the year ended March 31, 2022 to be filed with the SEC on June 8, 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.

IMMUNOVANT, INC.

Consolidated Statements of Operations

(In thousands, except share and per share data)

	Three Months Ended March 31,		Years Ended March 31,	
	2022	**2021**	**2022**	**2021**
	(Unaudited)	**(Unaudited)**		
Operating expenses:				
Research and development (includes $5,606 and $3,008 of stock-based compensation expense for the three months ended March 31, 2022 and 2021, respectively, and $14,308 and $7,033 of stock-based compensation expense for the years ended March 31, 2022 and 2021, respectively)[(1)]	$ 31,986	$ 18,615	$ 101,808	$ 68,604

General and administrative (includes $6,258 and $2,480 of stock-based compensation expense for the three months ended March 31, 2022 and 2021, respectively, and $19,936 and $11,789 of stock-based compensation expense for the years ended March 31, 2022 and 2021, respectively)[2]	15,241	10,302	54,225	39,513
Total operating expenses	47,227	28,917	156,033	108,117
Other expense (income), net	(44)	(680)	781	(328)
Loss before benefit for income taxes	(47,183)	(28,237)	(156,814)	(107,789)
Benefit for income taxes	(12)	(79)	(84)	(358)
Net loss	**$ (47,171)**	**$ (28,158)**	**$ (156,730)**	**$ (107,431)**
Net loss per common share - basic and diluted	$ (0.41)	$ (0.29)	$ (1.43)	$ (1.22)
Weighted average shares outstanding - basic and diluted	116,337,733	97,971,243	109,679,256	87,756,513

(1) Includes $59 and $164 of costs allocated from Roivant Sciences Ltd. for the three months ended March 31, 2022 and 2021, respectively, and $312 and $340 for the years ended March 31, 2022 and 2021, respectively.

(2) Includes $289 and $658 of costs allocated from Roivant Sciences Ltd. for the three months ended March 31, 2022 and 2021, respectively, and $1,299 and $1,180 for the years ended March 31, 2022 and 2021, respectively.

IMMUNOVANT, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31,	
	2022	**2021**
Assets		
Current assets:		
Cash	$ 493,817	$ 400,146
Accounts receivable	12,229	596
Prepaid expenses and other current assets	6,253	7,716
Income tax receivable	632	548

Total current assets	512,931	409,006
Operating lease right-of-use assets	2,303	3,282
Property and equipment, net	330	201
Total assets	**$ 515,564**	**$ 412,489**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,629	$ 2,432
Accrued expenses	24,575	15,160
Current portion of operating lease liabilities	1,145	1,179
Due to Roivant Sciences Ltd.	171	—
Total current liabilities	44,520	18,771
Operating lease liabilities, net of current portion	1,219	2,238
Total liabilities	45,739	21,009
Commitments and contingencies		
Stockholders' equity:		
Series A preferred stock, par value $0.0001 per share, 10,000 shares authorized, issued and outstanding at March 31, 2022 and March 31, 2021	—	—
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2022 and March 31, 2021	—	—
Common stock, par value $0.0001 per share, 500,000,000 shares authorized, 116,482,899 shares issued and outstanding at March 31, 2022 and 500,000,000 shares authorized, 97,971,243 shares issued and outstanding at March 31, 2021	12	10
Additional paid-in capital	824,796	590,425
Accumulated other comprehensive income (loss)	404	(298)
Accumulated deficit	(355,387)	(198,657)
Total stockholders' equity	469,825	391,480
Total liabilities and stockholders' equity	**$ 515,564**	**$ 412,489**

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Source: Immunovant