

Immunovant Provides Corporate Updates and Reports Financial Results for the Fourth Quarter and Fiscal Year Ended March 31, 2023

- Investigational New Drug (IND) application and Clinical Trial Application (CTA) for IMVT-1402 cleared by the FDA and MEDSAFE, respectively
- Phase 1 clinical trial in healthy subjects initiated in New Zealand
- Phase 2 proof-of-concept clinical trial of batoclimab in Graves' disease (GD) initiated in Germany
- Global clinical trials of batoclimab are ongoing in myasthenia gravis (MG), thyroid eye disease (TED), and chronic inflammatory demyelinating polyneuropathy (CIDP)

NEW YORK, May 22, 2023 (GLOBE NEWSWIRE) -- **Immunovant, Inc. (Nasdaq: IMVT)**, a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today reported corporate updates and financial results for its fiscal fourth quarter and fiscal year ended March 31, 2023.

"During the past quarter, we made significant progress with IMVT-1402, including receiving the IND clearance by the FDA, and the initiation of a Phase 1 clinical trial following the approval by MEDSAFE to proceed," said Pete Salzmann, M.D., chief executive officer at Immunovant. "This is an important step as we seek to expeditiously generate Phase 1 data and accelerate a global development program for IMVT-1402."

Clinical Development Updates: IMVT-1402:

Immunovant received IND clearance for IMVT-1402 from the U.S. Food and Drug Administration (FDA) and initiated a Phase 1 clinical trial of IMVT-1402 in healthy volunteers in New Zealand after approval of the CTA by the regulatory authority, MEDSAFE. The clinical trial will evaluate the safety, tolerability and pharmacodynamic profiles of IMVT-1402, a subcutaneously administered, FcRn inhibitor. In the multiple-ascending dose (MAD) portion of the study, Immunovant plans to evaluate subcutaneous doses of 300 mg and 600 mg, at a concentration of 150 mg/mL vs. placebo.

Initial data from single-ascending dose cohorts are expected in August/September 2023 and initial data from MAD cohorts are expected in October/November 2023. In a head-to-head, placebo-controlled nonclinical study, IMVT-1402 has been observed to achieve similarly deep IgG reduction as batoclimab and have minimal or no impact on levels of albumin and low-density lipoprotein cholesterol at doses well above the anticipated human effective dose. Immunovant believes this profile could be best in class.

Batoclimab:

A Phase 2 proof-of-concept clinical trial of batoclimab in GD was initiated in Germany, with initial results expected in the fourth quarter of calendar year 2023.

As previously disclosed, Immunovant expects to have initial results from period 1 of the Phase 2b clinical trial in CIDP in the first half of calendar year 2024 and expects to have top-line results from the Phase 3 MG clinical trial and the Phase 3 TED program in the second half of calendar year 2024 and the first half of calendar year 2025, respectively.

Financial Highlights for Fiscal Fourth Quarter Ended March 31, 2023:

Cash Position: As of March 31, 2023, Immunovant's cash and cash equivalents totaled \$376.5 million, which is expected to fund operations into the second half of calendar year 2025.

R&D Expenses: Research and development expenses were \$51.8 million for the three months ended March 31, 2023, compared to \$32.0 million for the three months ended March 31, 2022. The increase was primarily due to higher batoclimab program-specific research and development costs (including contract manufacturing costs), cross-indication clinical studies and clinical research costs and personnel-related costs. These increases were partially offset by lower contract manufacturing costs related to the development of IMVT-1402, which were initiated in the prior-year period.

G&A Expenses: General and administrative expenses were \$12.4 million for the three months ended March 31, 2023, compared to \$15.2 million for the three months ended March 31, 2022. The decrease was primarily due to lower personnel-related expenses and financial advisory, legal, and other professional fees.

Net Loss: Net loss was \$59.4 million (\$0.46 per common share) for the three months ended March 31, 2023, compared to \$47.2 million (\$0.41 per common share) for the three months ended March 31, 2022. Net loss for the three months ended March 31, 2023 and 2022 included \$7.5 million and \$11.9 million, respectively, related to non-cash stock-based compensation expense.

Common Stock: As of March 31, 2023, there were 130,329,863 shares of common stock issued and outstanding.

Financial Highlights for Fiscal Year Ended March 31, 2023:

R&D Expenses: Research and development expenses were \$160.3 million for the fiscal year ended March 31, 2023, compared to \$101.8 million for the fiscal year ended March 31, 2022. The increase was primarily due to higher batoclimab program-specific research and development costs (including contract manufacturing costs), increased personnel-related expenses and higher costs related to cross-indication clinical studies and clinical research.

IPR&D Expenses: Acquired in-process research and development expenses were \$10.0 million for the fiscal year ended March 31, 2023, related to the achievement of a development and regulatory milestone for batoclimab in MG as required under the HanAll inlicense agreement. There were no acquired in-process research and development expenses for the fiscal year ended March 31, 2022.

G&A Expenses: General and administrative expenses were \$48.0 million for the fiscal year

ended March 31, 2023, compared to \$54.2 million for the fiscal year ended March 31, 2022. The decrease was primarily due to lower financial advisory, legal, and other professional fees, as well as personnel-related expenses, partially offset by higher market research and information technology costs.

Net Loss: Net loss was \$211.0 million (\$1.71 per common share) for the fiscal year ended March 31, 2023, compared to \$156.7 million (\$1.43 per common share) for the fiscal year ended March 31, 2022. Net loss for the fiscal year ended March 31, 2023 and 2022 included \$32.3 million and \$34.2 million, respectively, related to non-cash stock-based compensation expense.

About Immunovant, Inc.

Immunovant, Inc. is a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases. As a trailblazer in anti-FcRn technology, the Company is developing innovative, targeted therapies to meet the complex and variable needs of people with autoimmune diseases. 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 "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 expectations regarding the timing, design, and results of clinical trials of its product candidates; Immunovant's plan to develop batoclimab and IMVT-1402 across a broad range of autoimmune indications; Immunovant's beliefs regarding its cash runway; and the potential benefits of batoclimab's and IMVT-1402's unique product attributes. All forwardlooking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forwardlooking 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; results of animal studies may not be predictive of results in humans; 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 candidates, 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 candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of global factors, such as the COVID-19 pandemic, geopolitical tensions, and adverse macroeconomic conditions on Immunovant's business operations and supply chain, including its clinical development plans and timelines; Immunovant's business is heavily dependent on the successful development, regulatory approval and commercialization of batoclimab and

IMVT-1402; Immunovant is at an early stage in development of for IMVT-1402 and in various stages of clinical development for batoclimab; and Immunovant will require additional capital to fund its operations and advance batoclimab and IMVT-1402 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 for the fiscal year ended March 31, 2023, to be filed with the SEC on May 22, 2023, 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,		
	2023	2022	2023	2022	
Operating expenses:					
Research and development	\$ 51,837	\$ 31,986	\$ 160,257	\$ 101,808	
Acquired in-process					
research and development	_	_	10,000	_	
General and administrative	12,422	15,241	48,019	54,225	
Total operating expenses	64,259	47,227	218,276	156,033	
Interest income, net	(3,480)	_	(7,578)	_	
Other expense (income), net	(356)	(44)	253	781	
Loss before provision (benefit)					
for income taxes	(60,423)	(47,183)	(210,951)	(156,814)	
Provision (benefit) for income					
taxes	(992)	(12)	9	(84)	
Net loss	\$ (59,431)	\$ (47,171)	\$ (210,960)	\$ (156,730)	
Net loss per common share —					
basic and diluted	\$ (0.46)	\$ (0.41)	\$ (1.71)	\$ (1.43)	
Weighted average common shares outstanding — basic and diluted	129,632,592	116,337,733	123,075,329	109,679,256	
and undied	123,032,332	110,331,133	123,013,329	103,073,230	

IMMUNOVANT, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2023		March 31, 2022	
Assets				
Current assets:				
Cash and cash equivalents	\$	376,532	\$	493,817
Accounts receivable		700		12,229
Prepaid expenses and other current assets		26,916		6,253
Income tax receivable		185		632
Total current assets		404,333		512,931
Operating lease right-of-use assets		1,172		2,303
Property and equipment, net		333		330
Total assets	\$	405,838	\$	515,564
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	1,353	\$	18,629
Accrued expenses		40,421		24,575
Current portion of operating lease liabilities		1,173		1,145
Due to Roivant Sciences Ltd.		350		171
Total current liabilities		43,297		44,520
Operating lease liabilities, net of current portion		47		1,219
Total liabilities		43,344		45,739
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, 2023 and March 31, 2022		_		_
Preferred stock, par value \$0.0001 per share, 10,000,000				
shares authorized, no shares issued and outstanding at				
March 31, 2023 and March 31, 2022		_		_
Common stock, par value \$0.0001 per share, 500,000,000				
shares authorized, 130,329,863 shares issued and outstanding at March 31, 2023 and 500,000,000 shares				
authorized, 116,482,899 shares issued and outstanding at				
March 31, 2022		13		12
Additional paid-in capital		927,976		824,796
Accumulated other comprehensive income		852		404
Accumulated deficit		(566,347)		(355,387)
Total stockholders' equity		362,494		469,825
Total liabilities and stockholders' equity	\$	405,838	\$	515,564

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Source: Immunovant Inc.