November 7, 2024

Immunovant Provides Development Updates and Reports Financial Results for the Quarter Ended September 30, 2024

- Five Investigational New Drug (IND) applications cleared across a range of therapeutic areas and FDA divisions for lead asset, IMVT-1402
- Proof of concept data from batoclimab trial in Graves' disease (GD) demonstrate potential of deeper IgG reduction with potent FcRn inhibition to transform treatment for GD patients who are not well controlled on antithyroid drugs (ATDs); initiation of potentially registrational trial to evaluate IMVT-1402 in GD expected by year end
- IND cleared for IMVT-1402 in rheumatoid arthritis (RA), with potential best-in-class profile in difficult-to-treat (D2T) RA; initiation of potentially registrational trial to evaluate IMVT-1402 in D2T RA expected by March 31, 2025
- On track to initiate potentially registrational trials with IMVT-1402 in four to five indications, inclusive of GD and D2T RA, by March 31, 2025
- Batoclimab trials in myasthenia gravis (MG) and chronic inflammatory demyelinating polyneuropathy (CIDP) fully enrolled to support data disclosures by March 31, 2025; data from batoclimab trials in thyroid eye disease (TED) now expected in the second half of calendar year 2025; all batoclimab data will inform future trials with IMVT-1402
- Immunovant to host development update call today, November 7, at 8 a.m. ET

NEW YORK, Nov. 07, 2024 (GLOBE NEWSWIRE) -- **Immunovant, Inc. (Nasdaq: IMVT)**, a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today reported development updates and financial results for its fiscal second quarter ended September 30, 2024.

Immunovant continues to focus on moving rapidly to unlock the full potential of its lead asset, IMVT-1402, for the benefit of people with underserved autoantibody-driven diseases. With five IND applications now cleared, the company remains on course to initiate four to five potentially registrational clinical development programs by March 31, 2025. These INDs are expected to support evaluation of IMVT-1402 in a variety of indications and therapeutic areas. As previously announced, Immunovant anticipates initiating clinical trials evaluating IMVT-1402 in a total of ten indications by March 31, 2026.

"Since announcing the Phase 1 data for IMVT-1402 a year ago, we have made tremendous progress in advancing IMVT-1402 towards multiple potentially registrational study initiations. We're ahead of our goal to activate three INDs by calendar year end and we are very excited about all five cleared INDs – both those that have been announced and those that have not yet been announced. In terms of announced indications, we believe our first-in-class program with IMVT-1402 in GD has the potential to transform the treatment of GD patients who respond poorly to ATDs," said Pete Salzmann, M.D., chief executive officer of

Immunovant.

“We are also excited to announce expansion of our IMVT-1402 development program into Rheumatology. Our first program in Rheumatology will be a potentially registrational study in patients with D2T RA where we believe that deeper IgG reduction has the potential to deliver better clinical outcomes in an important subset of patients with elevated RA-specific autoantibodies (ACPA). People living with D2T RA have already exhausted multiple therapeutic options yet continue to suffer from active disease, persistent disability and pain,” Salzmann continued. “We believe IMVT-1402 can deliver meaningful clinical benefit in ACPA-positive (ACPA+) D2T RA patients, with a potentially best-in-class profile driven by deeper IgG reduction.”

FcRn inhibition represents an attractive mechanism as a potential treatment for the approximately 70,000 US patients with D2T, ACPA+ RA. Recently disclosed in-class data demonstrated that both higher baseline ACPA levels and deeper ACPA reduction correlated with better clinical improvement in ACPA+ RA patients treated with an FcRn inhibitor. Having received FDA clearance of the IND for IMVT-1402 in RA, Immunovant plans to initiate a potentially registrational trial in ACPA+ D2T RA by March 31, 2025. The trial builds on in-class learning in terms of its target population (enriched for above-normal ACPA levels) and trial design (open-label lead-in followed by randomized withdrawal). The trial will leverage IMVT-1402’s higher dose (600 mg) during the open-label induction phase of the clinical trial to maximize reduction in ACPA levels.

Recent Highlights and Upcoming Milestones

Endocrinology Program

In September 2024, Immunovant provided a GD program update consisting of new epidemiologic data characterizing unmet need in GD patients who are relapsed, uncontrolled or intolerant of ATDs, additional results from the batoclimab GD study, and an overview of the IMVT-1402 development program in GD. In November 2024, additional data on the efficacy and safety of batoclimab in Graves’ thyroidal and extrathyroidal disease were presented in an oral presentation at the American Thyroid Association (ATA) 2024 Annual Meeting. These data showed that a 60% response rate (defined as T3 and T4 falling below the upper limit of normal (ULN) without increasing the ATD dose) was achieved by Week 2, demonstrating the rapidity of response to batoclimab 680mg dosed weekly. Meaningful improvements in proptosis and lid aperture were also observed at both Week 12 and Week 24. Pronounced improvements in multiple Thyroid-Related Patient-Reported Outcomes (ThyPRO-39) measurement scales were also observed, with ATD-Free Responders (defined as T3 and T4 falling below the ULN and ceasing all ATD medications) reporting greater improvements than other participants.

The batoclimab data in Graves’ disease support the potential for deep IgG reduction to modify the underlying pathophysiology of the disease, which could enable a transformation of the treatment of Graves’ disease for patients not well controlled on ATDs. Immunovant remains on track to initiate the first potentially registrational trial of IMVT-1402 in GD by calendar year end.

Competition for clinical trial participants with acute, active TED has increased over the course of the company’s Phase 3 program to evaluate batoclimab for the treatment of

thyroid eye disease (TED). As a result, top-line results are now expected to be available in the second half of calendar year 2025, along with a decision on whether to advance batoclimab to registration in TED. Data from this trial will be leveraged to inform the overall program in GD for the Company's lead asset, IMVT-1402.

Neurology Program

As previously reported, Immunovant completed enrollment of the batoclimab pivotal trial in MG, with top-line results expected to be reported by March 31, 2025. Results from this trial are expected to inform a decision regarding next steps for batoclimab in MG and the design of the MG program for IMVT-1402, which Immunovant expects to initiate by March 31, 2025.

Enrollment of study participants has completed in the Phase 2b trial evaluating batoclimab in chronic inflammatory demyelinating polyneuropathy (CIDP) for those patients to be included in the period 1 data readout expected by March 31, 2025. A decision to enroll additional patients in the batoclimab CIDP study will be made following the readout of period 1 data. Those results, as well as observations drawn from public disclosures of other studies in CIDP, will be used to inform the trial design for a potentially registrational program for IMVT-1402 in CIDP.

Corporate Update

Immunovant also announced today that it appointed Melanie Gloria as Chief Operating Officer, effective November 18, 2024. Ms. Gloria brings over 20 years of experience in the biotechnology industry, including leadership roles at Acelyrin, Horizon Therapeutics and AbbVie. At AbbVie and Horizon she led teams to achieve global approvals of HUMIRA®, Viekera Pak®, Mavyret®, Skyrizi®, Rinvoq®, TEPEZZA®, and ORILISSA®. "I am thrilled to welcome Melanie to Immunovant where her success in driving late-stage drug development will be incredibly valuable," said Salzmann. "Melanie's proven drug development capabilities are a great fit for Immunovant's portfolio."

Webcast Details

Immunovant will host a webcast at 8:00 a.m. ET today to discuss these updates**Please click register here to register for the event.** The live webcast will also be available under the News & Events section of Immunovant's website. A replay of the event and presentation will be available immediately following the event.

Financial Highlights for Fiscal Second Quarter Ended September 30, 2024:

Cash Position: As of September 30, 2024, Immunovant's cash and cash equivalents totaled approximately $472.9 million.

R&D Expenses: Research and development expenses were $97.3 million for the three months ended September 30, 2024, compared to $48.0 million for the three months ended September 30, 2023. The increase was primarily due to activities in preparation for potential future clinical trials of IMVT-1402, including contract manufacturing costs for drug substance, higher overall clinical trial costs related to our batoclimab pivotal clinical trials, and elevated personnel-related expenses. The increase was partially offset by lower overall costs related to our IMVT-1402 Phase 1 trial and nonclinical studies.

G&A Expenses: General and administrative expenses were $18.5 million for the three months ended September 30, 2024, compared to $13.8 million for the three months ended September 30, 2023. The increase was primarily due to higher personnel-related expenses, legal and other professional fees, and information technology costs.

Net Loss: Net loss was $109.1 million ($0.74 per common share) for the three months ended September 30, 2024, compared to $58.7 million ($0.45 per common share) for the three months ended September 30, 2023. Net loss for the three months ended September 30, 2024 and September 30, 2023 included $12.7 million and $10.5 million, respectively, related to non-cash stock-based compensation expense.

Common Stock: As of September 30, 2024, there were 146,565,049 shares of common stock issued and outstanding.

Financial Highlights for Fiscal Six Months Ended September 30, 2024:

R&D Expenses: Research and development expenses were $172.7 million for the six months ended September 30, 2024, compared to $98.5 million for the six months ended September 30, 2023. The increase was primarily due to activities in preparation for potential future clinical trials of IMVT-1402, including contract manufacturing costs for drug substance, higher overall clinical trial costs related to our batoclimab pivotal clinical trials, and elevated personnel-related expenses. The increase was partially offset by lower overall costs related to our IMVT-1402 Phase 1 trial and nonclinical studies.

IPR&D Expenses: There were no acquired in-process research and development expenses for the six months ended September 30, 2024. During the six months ended September 30, 2023, acquired in-process research and development expenses were $12.5 million related to the achievement of development and regulatory milestones for batoclimab under the terms of the HanAll in-license agreement.

G&A Expenses: General and administrative expenses were $37.3 million for the six months ended September 30, 2024, compared to $29.2 million for the six months ended September 30, 2023. The increase was primarily due to higher personnel-related expenses, legal and other professional fees, and information technology costs.

Net Loss: Net loss was $196.3 million ($1.34 per common share) for the six months ended September 30, 2024, compared to $132.6 million ($1.01 per common share) for the six months ended September 30, 2023. Net loss for the six months ended September 30, 2024 and September 30, 2023 included $26.1 million and $21.2 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 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,” “anticipate,” “intend,” and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include statements regarding Immunovant’s expectations regarding the timing, design, and results of clinical trials of IMVT-1402 and batoclimab, including the number and timing of (a) FDA clearance with respect to IND applications, (b) potential registrational programs and clinical trials of IMVT-1402, (c) expected data readouts from batoclimab trials in MG and CIDP, and (d) estimates of the target populations for IMVT-1402, including in RA; Immunovant’s plan to develop IMVT-1402 and batoclimab across a broad range of indications; and potential benefits of IMVT-1402’s unique product attributes and potential best-in-class profile. 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: Immunovant may not be able to protect or enforce its intellectual property rights; 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; 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 number and 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 candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of macroeconomic and geopolitical factors 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 IMVT-1402 and/or batoclimab; Immunovant is at various stages of clinical development for IMVT-1402 and batoclimab; and Immunovant will require additional capital to fund its operations and advance IMVT-1402 and 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 Form 10-Q to be filed with the SEC on November 7, 2024, 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
(Unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 97,272	$ 47,959	$ 172,745	$ 98,534
Acquired in-process research and development	—	—	—	12,500
General and administrative	18,471	13,841	37,279	29,243
Total operating expenses	115,743	61,800	210,024	140,277
Interest income	(6,073)	(3,572)	(13,254)	(7,637)
Other income, net	(629)	(20)	(657)	(484)
Loss before provision for income taxes	(109,041)	(58,208)	(196,113)	(132,156)
Provision for income taxes	78	454	156	443
Net loss	**$ (109,119)**	**$ (58,662)**	**$ (196,269)**	**$ (132,599)**
Net loss per common share – basic and diluted	$ (0.74)	$ (0.45)	$ (1.34)	$ (1.01)
Weighted-average common shares outstanding – basic and diluted	146,468,991	131,155,642	146,313,696	130,872,717

IMMUNOVANT, INC.
Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share data)

	September 30, 2024	March 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 472,941	$ 635,365
Accounts receivable	1,876	5,337
Prepaid expenses and other current assets	32,555	25,068
Total current assets	507,372	665,770
Operating lease right-of-use assets	45	133
Other assets	7,619	—
Property and equipment, net	671	462
Total assets	**$ 515,707**	**$ 666,365**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 20,727	$ 7,155
Accrued expenses	45,879	41,315

Current portion of operating lease liabilities	47	138
Total current liabilities	66,653	48,608
Total liabilities	66,653	48,608
Commitments and contingencies		
Stockholders' equity:		
Series A preferred stock, par value $0.0001 per share, 10,000 shares authorized, issued and outstanding at September 30, 2024 and March 31, 2024	—	—
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2024 and March 31, 2024	—	—
Common stock, par value $0.0001 per share, 500,000,000 shares authorized, 146,565,049 shares issued and outstanding at September 30, 2024 and 500,000,000 shares authorized, 145,582,999 shares issued and outstanding at March 31, 2024	14	14
Additional paid-in capital	1,469,082	1,441,518
Accumulated other comprehensive income	1,910	1,908
Accumulated deficit	(1,021,952)	(825,683)
Total stockholders' equity	449,054	617,757
Total liabilities and stockholders' equity	**$ 515,707**	**$ 666,365**

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Source: Immunovant Inc.