– Initial Results From Ongoing Part C of Phase 1 Clinical Trial of IMU-856 in Celiac Disease Expected Mid-2023 –

– Interim Results From Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis Expected in the Second Half of 2023 –

– $116.4 Million in Cash, Cash Equivalents and Investments Expected to Fund Immunic Into the Fourth Quarter of 2024 –

– Webcast to be Held Today, February 23, 2023, at 8:00 am ET –

NEW YORK, Feb. 23, 2023 /PRNewswire/ -- **Immunic, Inc. (NASDAQ: IMUX),** a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, today announced financial results for the year ended December 31, 2022, and provided a corporate update.

"We made significant progress throughout the year in advancing our lead asset, vidofludimus calcium, for the treatment of multiple sclerosis (MS). Our next MS-related data inflection point, expected in the second half of 2023, is an interim analysis of our phase 2 CALLIPER trial in progressive MS, which will provide selected biomarker data to guide study progress," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "As previously announced, the CALLIPER trial is designed to corroborate the neuroprotective potential of vidofludimus calcium, which, if confirmed, would provide an additional key differentiator for the drug in the MS market. Furthermore, we look forward to reporting data from the interim analysis of the phase 3 ENSURE program late next year and to read-out the first of our identical, twin phase 3 ENSURE trials in relapsing MS at the end of 2025. Considering the promising clinical activity observed, thus far, along with vidofludimus calcium's established safety and tolerability profile, we believe that the design of the ENSURE program gives us a straightforward path toward potential regulatory approval in relapsing MS. Vidofludimus calcium has the potential to be a unique treatment option targeted to the biology of MS, differentiated by its combined anti-inflammatory, antiviral and neuroprotective effects."

"Our second clinical asset, IMU-935, recently received the proposed International Nonproprietary Name (INN), izumerogant, from the World Health Organization. We plan to provide further updates and guidance on potential next steps for our phase 1b clinical trial in patients with moderate-to-severe psoriasis towards the end of the first quarter of 2023."

Dr. Vitt continued, "During our recently held celiac disease R&D webcast, we shared that IMU-856 appears to influence the tightly regulated network of genes and proteins associated with intestinal epithelial cell interaction and adhesion, restoring intestinal barrier function while maintaining immunocompetency. These characteristics indicate that IMU-856 could possibly present an entirely new and innovative approach for the treatment of a number of gastrointestinal diseases, including celiac disease, without the serious consequences associated with immunosuppressive therapies. We believe IMU-856 has the potential to be a first-in-class oral celiac disease therapy. We expect to report data from the ongoing Part C of our phase 1 clinical trial in celiac disease patients mid this year."

Fourth Quarter 2022 and Subsequent Highlights

- February 2023: Announced that Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio, presents data from the blinded and open-label extension parts of the phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting MS at the eighth annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2023.
- February 2023: Hosted a celiac disease R&D webcast. Management was joined by two renowned key opinion leaders to discuss the dynamics of this multifactorial, complex autoimmune disease, immune stimulation and its connection to clinical symptoms, the role of the epithelial barrier in the pathogenesis of the disease, current and potential treatment options and the continued unmet medical need for effective therapeutics, which is driving an increased focus within the industry.
- November 2022: Reported new data from the phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting MS. The data was highly encouraging, showing that long-term open-label treatment with vidofludimus calcium was associated with a low rate of confirmed disability worsening over time, which compares favorably to historical trial data for currently available MS medications.
- October 2022: Reported a pre-planned interim group-level data analysis of the phase1b clinical trial of izumerogant in patients with moderate-to-severe psoriasis. Group averages for Psoriasis Area and Severity Index (PASI) reductions in the first two active arms did not separate from placebo at four weeks due to an unexpectedly high placebo rate. Although these active arms performed in line with expectations, based on similarly designed trials, the trial experienced a greater decrease than expected in PASI in the placebo arm. Administration of izumerogant and placebo were demonstrated to be safe and well-tolerated, and no new safety signals were observed.
- October 2022: Closed a $60 million private placement with participation from new and existing institutional investors.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:** As previously announced, data from the interim analysis of the phase 2 CALLIPER trial of vidofludimus calcium in progressive MS is expected to be available in the second half of 2023 and top-line data at the end of 2024. Moreover, data from the interim analysis of the ENSURE program is expected in late 2024, with the read-out of the first of the ENSURE trials at the end of 2025.
- **Izumerogant (IMU-935) phase 1 program in psoriasis:** Immunic plans to provide further updates and guidance on potential next steps for the phase 1 clinical trial of izumerogant in patients with moderate-to-severe psoriasis towards the end of the first quarter of 2023.
- **IMU-856 phase 1 program in celiac disease**: The ongoing Part C of the phase 1 program is a double-blind, randomized, placebo-controlled trial designed to assess the safety and tolerability of IMU-856 during 28 days of treatment with 80 and 160 mg of IMU-856 or placebo, once daily, in patients with celiac disease during periods of gluten-free diet and gluten challenge. Secondary objectives include pharmacokinetic as well as acute and chronic disease markers, including those evaluating acute response on the biomarker interleukin-2 (IL-2) and gastrointestinal architecture and inflammation. Initial results are expected to be available in mid-2023.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $71.3 million for the twelve months ended December 31, 2022, as compared to $61.1 million for the twelve months ended December 31, 2021. The $10.1 million increase reflects (i) a $18.4 million increase in external development costs related to the ongoing clinical programs of vidofludimus calcium in relapsing and progressive MS, as well as izumerogant and IMU-856, and (ii) a $2.5 million increase in personnel expense in research and development, $1.5 million of which is related to non-cash stock compensation expense. The increases were partially offset by (i) a decrease of $10.1 million in external development costs related to the clinical trials of vidofludimus calcium in ulcerative colitis, COVID-19 and relapsing-remitting MS, and (ii) a decrease of $0.7 million in external development costs across numerous categories.

- **General and Administrative (G&A) Expenses** were $15.3 million for the twelve months ended December 31, 2022, as compared to $13.3 million for the same period ended December 31, 2021. The $2.0 million increase was primarily due to (i) a $1.6 million increase in personnel expense in general and administrative, $0.5 million of which is related to non-cash stock compensation expense, (ii) a $0.3 million increase in travel expenses, and (iii) a $0.1 million net increase across numerous categories.

- **Other Income (Expense)** was ($0.9 million) for the twelve months ended December 31, 2022, as compared to ($1.3 million) for the same period ended December 31, 2021. The $0.4 million decrease in expense was primarily attributable to (i) a $1.0 million increase in interest income as a result of higher interest rates, and (ii) a $0.5 million increase in research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia. This was offset by a $1.1 million decrease in grants.

- **Impairment of Goodwill:** The company recorded a non-cash, goodwill impairment of approximately $33.0 million in the fourth quarter of 2022, which represents a full write down of its previous goodwill balance. The impairment resulted from the announcement of the interim group-level data of the phase 1b clinical trial of izumerogant in psoriasis on October 20, 2022, the company's stock price experienced a significant decline from the prices preceding the announcement. The company considered this to be a triggering event, indicating that it is more likely than not that goodwill is impaired.

- **Net Loss** for the twelve months ended December 31, 2022, was approximately $120.4 million, or $3.78 per basic and diluted share, based on 31,819,006 weighted average common shares outstanding, compared to a net loss of approximately $92.9 million, or $3.93 per basic and diluted share, based on 23,652,779 weighted average common shares outstanding for the same period ended December 31, 2021.

- **Cash, Cash Equivalents and Investments** as of December 31, 2022, were $116.4 million. With these funds, Immunic expects to be able to fund its operations into the fourth quarter of 2024.

Webcast Information

Immunic will host a webcast today at 8:00 am ET. To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_Gfg-b_qaSWugtw_SM5Gt-A or on the "Events and Presentations" section of Immunic's website at: ir.imux.com/events-and-presentations. Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.

An archived replay of the webcast will be available approximately one hour after completion on Immunic's website at: ir.imux.com/events-and-presentations.

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases. The company's lead development program, vidofludimus calcium (IMU-838), currently in phase 3 clinical trials for the treatment of multiple sclerosis, selectively inhibits activated immune cells and shows combined anti-inflammatory, anti-viral and neuroprotective effects. Izumerogant (IMU-935) is a selective inverse agonist of RORγ/RORγt, which inhibits the IL-17 pathway, and is currently being studied in clinical proof-of-concept trials in psoriasis and castration-resistant prostate cancer. IMU-856 is targeted to restore intestinal barrier function and regenerate bowel epithelium, which would be applicable in numerous gastrointestinal diseases, such as celiac disease, where it is currently being evaluated in a clinical proof-of-concept trial. For further information, please visit: www.imux.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, sufficiency of cash, expected development, timing and results of clinical trials, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Immunic's three development programs and the targeted diseases; the potential for Immunic's development programs to safely and effectively target diseases; preclinical and clinical data for Immunic's development programs; the timing of current and future clinical trials and anticipated clinical milestones; the nature, strategy and focus of the company and further updates with respect thereto; the development and commercial potential of any product candidates of the company; and the company's expected cash runway. Immunic may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management's current expectations and involve substantial risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the COVID-19 pandemic, increasing inflation, impacts of the Ukraine – Russia conflict on planned and ongoing clinical trials, risks and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient financial and other resources to meet business objectives and operational requirements, the fact that the results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results, the protection and market exclusivity provided by Immunic's intellectual property, risks related to the drug development and the regulatory approval process and the impact of competitive products and technological changes. A further list and descriptions of these risks, uncertainties and other factors can be found in the section captioned "Risk Factors," in the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC onFebruary 24, 2022, and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or ir.imux.com/sec-filings. Any forward-looking statement made in this release speaks only as of the date of this release. Immunic disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made. Immunic expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.

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Financials

Immunic, Inc.
Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(Unaudited)

	Years Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 71,255	$ 61,115
General and administrative	15,263	13,300
Goodwill impairment	32,970	—
4SC Royalty Settlement	—	17,250
Total operating expenses	119,488	91,665
Loss from operations	(119,488)	(91,665)
Other income (expense):		
Interest income	1,041	66
Other expense, net	(1,960)	(1,346)
Total other expense, net	(919)	(1,280)
Net loss	$ (120,407)	$ (92,945)
Net loss per share, basic and diluted	$ (3.78)	$ (3.93)
Weighted-average common shares outstanding, basic and diluted	31,819,006	23,652,779

Immunic, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 106,745	$ 86,863
Investments - other	9,629	—
Other current assets and prepaid expenses	9,490	18,125
Total current assets	125,864	104,988
Property and equipment, net	294	152
Goodwill	—	32,970
Right of use asset, net	1,552	948
Other long-term assets	43	42
Total assets	$ 127,753	$ 139,100
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,281	$ 3,745
Accrued expenses	7,986	7,071
Other current liabilities	810	585
Total current liabilities	13,077	11,401
Long-term liabilities:		
Operating lease liabilities	992	584
Total long-term liabilities	992	584
Total liabilities	14,069	11,985
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 39,307,286 and 26,335,418 shares issued and outstanding at December 31, 2022 and 2021, respectively	4	3
Additional paid-in capital	427,925	324,237
Accumulated other comprehensive income (loss)	3,035	(252)
Accumulated deficit	(317,280)	(196,873)
Total stockholders' equity	113,684	127,115

Total liabilities and stockholders' equity	$ 127,753	$ 139,100

SOURCE Immunic, Inc.

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https://ir.imux.com/2023-02-23-Immunic,-Inc-Reports-Year-End-2022-Financial-Results-and-Provides-Corporate-Update