Immunic, Inc. Reports First Quarter 2023 Financial Results and Provides Corporate Update

– Positive Results From Phase 1b Clinical Trial of IMU-856 in Celiac Disease Provide Proof-of-Concept for a New Therapeutic Approach to Treat Gastrointestinal Diseases by Promoting Regeneration of Bowel Architecture –

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

– $97.1 Million in Cash, Cash Equivalents and Investments Expected to Fund Immunic Into the Fourth Quarter of 2024 –

– Webcast to be Held Today, May 11, 2023, at 8:00 am ET –

NEW YORK, May 11, 2023 – 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 first quarter ended March 31, 2023, and provided a corporate update.

"In the first quarter of 2023, we reported outstanding results from two key clinical programs. First, we reported positive data from the maintenance phase of our phase 2b CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe ulcerative colitis (UC), and, most recently, announced positive results from our phase 1b clinical trial of IMU-856 in patients with celiac disease, which far exceeded our expectations," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "In the phase 1b trial, IMU-856, designed to restore a healthy gut without suppressing the immune system, demonstrated consistent and meaningful improvements over placebo in four key dimensions of celiac disease pathophysiology: histology, disease symptoms, biomarkers and nutrient absorption. The impressive data set provides first clinical proof-of-concept for IMU-856 and demonstrates its potential to treat gastrointestinal diseases with an entirely new therapeutic approach. Based on this data, we are now preparing for a phase 2b clinical trial of IMU-856 in ongoing active celiac disease patients, while also considering further potential clinical applications in other gastrointestinal disorders. Importantly, during a recent presentation at Digestive Disease Week, we unveiled IMU-856's mode of action as a potent modulator of SIRT6 (Sirtuin 6), through which it restores and regenerates bowel wall architecture."

Dr. Vitt continued, "Data from the maintenance phase of our phase 2b CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe UC were also extremely encouraging, as they demonstrated statistically significant activity of vidofludimus calcium as compared to placebo, while confirming the very favorable safety and tolerability profile observed in other trials. Based on this positive outcome, we are exploring a variety of value creating options for the UC program and other inflammatory bowel disease indications."

"Additionally, during the quarter, we continued to progress vidofludimus calcium for the treatment of multiple sclerosis (MS). Our next value inflection point will be a second half 2023 interim biomarker analysis of our phase 2 CALLIPER trial in progressive MS, which is designed to corroborate the neuroprotective potential of vidofludimus calcium and could therefore be an additional differentiator for

the drug in the MS market. Based on the strong clinical activity observed thus far and the solidly established safety and tolerability profile, to date, we continue to believe that vidofludimus calcium has the potential to be a unique treatment option targeted to the complex pathophysiology of MS," concluded Dr. Vitt.

First Quarter 2023 and Subsequent Highlights

- May 2023: Presented clinical and preclinical data for IMU-856, including its molecular mode of action as a highly selective and potent small molecule modulator of SIRT6, a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium, in a virtual e-poster at Digestive Disease Week (DDW) 2023.
- May 2023: Announced positive results from the phase 1b clinical trial of IMU-856 in patients with celiac disease. The data demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well-tolerated in this trial. The data provides first clinical evidence that IMU-856's ability, observed in preclinical studies, to re-establish proper gut cell renewal, translates into clinical benefits for patients with celiac disease. Most importantly, the observed protection of intestinal villi from gluten-induced destruction, independent of targeting immune mechanisms involved specifically in celiac disease, appears to be unique among proposed therapeutic approaches and may be applicable to other gastrointestinal disorders.
- April 2023: Strengthened Board of Directors with the addition of Richard Rudick, M.D., a thought-leader in multiple sclerosis with decades of experience in the clinic, academia and industry, effective April 26, 2023. Also announced that Vincent Ossipow, Ph.D., will step down from the Board, effective June 28, 2023, the date of Immunic's 2023 Annual Meeting of Stockholders.
- April 2023: Reported positive data from the maintenance phase of the phase 2b CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe ulcerative colitis. Data showed a dose-linear increase in clinical remission as compared to placebo at week 50. An exploratory statistical analysis confirmed the 30 mg dose of vidofludimus calcium to be statistically superior (p=0.0358) in achieving clinical remission at week 50, with a 33.7% absolute improvement over placebo. Moreover, a dose-linear increase in endoscopic healing was observed, with the 30 mg dose of vidofludimus calcium being associated with a 37.8% absolute improvement over placebo and also achieving statistical significance in an exploratory statistical analysis (p=0.0259). Administration of vidofludimus calcium was observed to be safe and well-tolerated.
- 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, presented 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, Joseph A. Murray, M.D., from the Mayo Clinic in Rochester and Michael Schumann, M.D., from the Charité Berlin, 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.

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.
- **IMU-856 in celiac disease**: Based on positive data from the phase 1b clinical trial, testing IMU-856 in celiac disease patients during periods of gluten-free diet and gluten challenge, the company is actively preparing for clinical phase 2b testing of IMU-856 in ongoing active celiac disease.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $23.0 million for the three months ended March 31, 2023, as compared to $17.4 million for the three months ended March 31, 2022. The $5.5 million increase reflects (i) a $5.8 million increase in external development costs related to the ongoing clinical programs of vidofludimus calcium in relapsing and progressive MS, as well as IMU-856, (ii) a $0.4 million increase in personnel expense in research and development related to an increase in headcount, $0.1 million of which was due to non-cash stock based compensation and (iii) a $0.2 million increase related costs across numerous categories. The increases were partially offset by a decrease of $0.9 million in external development costs related to the phase 2 clinical trial of vidofludimus calcium in ulcerative colitis and the IMU-935 program.

- **General and Administrative (G&A) Expenses** were $4.3 million for the three months ended March 31, 2023, as compared to $4.0 million for the same period ended March 31, 2022. The $0.3 million increase was primarily due to (i) a $0.2 million increase in travel expense and (ii) a $0.3 million increase across numerous categories. The increases were partially offset by a decrease of $0.2 million in non-cash stock based compensation expense.

- **Other Income** was $2.0 million for the three months ended March 31, 2023, as compared to $0.6 million for the same period ended March 31, 2022. The $1.4 million increase was primarily attributable to (i) a $1.1 million research allowance attributable for tax year 2021 from the German Federal Ministry of Finance and (ii) a $0.8 million increase in interest income as a result of higher interest rates. The increase was partially offset by (i) a $0.3 million decrease in foreign exchange gains and (ii) a $0.2 million decrease in research and development tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia.

- **Net Loss** for the three months ended March 31, 2023, was approximately $25.3 million, or $0.58 per basic and diluted share, based on 43,664,783 weighted average common shares outstanding, compared to a net loss of approximately $20.8 million, or $0.74 per basic and diluted share, based on 28,127,288 weighted average common shares outstanding for the same period ended March 31, 2022.

- **Cash, Cash Equivalents and Investments** as of March 31, 2023 were $97.1 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_ab5Mb3dMSBCsDvygg-RyAA 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 and which has shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis and moderate-to-severe ulcerative colitis, selectively inhibits activated immune cells and shows combined anti-inflammatory, anti-viral and neuroprotective effects. 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 in preparations for a phase 2 clinical 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 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, 2022, filed with the SEC on February 23, 2023, 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.

Contact Information

Immunic, Inc.
Jessica Breu
Head of Investor Relations and Communications
+49 89 2080 477 09
jessica.breu@imux.com

US IR Contact
Rx Communications Group
Paula Schwartz
+1 917 633 7790
immunic@rxir.com

US Media Contact
KOGS Communication
Edna Kaplan
+1 617 974 8659
kaplan@kogspr.com

Financials

Immunic, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 22,963	$ 17,445
General and administrative	4,288	3,990
Total operating expenses	27,251	21,435
Loss from operations	(27,251)	(21,435)
Other income (expense):		
Interest income	800	7
Other income (expense), net	1,179	620
Total other income	1,979	627
Net loss	$ (25,272)	$ (20,808)
Net loss per share, basic and diluted	$ (0.58)	$ (0.74)
Weighted-average common shares outstanding, basic and diluted	43,664,783	28,127,288

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

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 92,761	$ 106,745
Investments - other	4,351	9,629
Other current assets and prepaid expenses	9,470	9,490
Total current assets	106,582	125,864
Property and equipment, net	288	294
Right-of-use assets, net	1,959	1,552
Other long-term assets	43	43
Total assets	$ 108,872	$ 127,753
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,241	$ 4,281
Accrued expenses	10,183	7,986
Other current liabilities	878	810
Total current liabilities	16,302	13,077
Long-term liabilities		
Operating lease liabilities	1,352	992
Total long-term liabilities	1,352	992
Total liabilities	17,654	14,069
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding as of March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 44,403,838 and 39,307,286 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	429,955	427,925
Accumulated other comprehensive income (loss)	3,811	3,035
Accumulated deficit	(342,552)	(317,280)
Total stockholders' equity	91,218	113,684
Total liabilities and stockholders' equity	$ 108,872	$ 127,753