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

– Preclinical Data Published in the Journal of Medicinal Chemistry Identifies Vidofludimus Calcium as a Potent Nurr1 Activator, Reinforcing Neuroprotective Potential in Multiple Sclerosis –

– 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 Fall of 2023 –

– $77.3 Million in Cash, Cash Equivalents and Investments Expected to Fund Immunic Into the Fourth Quarter of 2024 –

– Webcast to be Held Today, August 3, 2023, at 8:00 am ET –

NEW YORK, August 3, 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 second quarter ended June 30, 2023, and provided a corporate update.

"During the second quarter, we reported important clinical and preclinical data from our two, lead pipeline programs, including the most advanced drug candidate, vidofludimus calcium (IMU-838), as well as IMU-856," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Importantly, we announced publication, in the peer-reviewed Journal of Medicinal Chemistry, of preclinical evidence showing that vidofludimus calcium acts as a potent nuclear receptor related 1 (Nurr1) activator, which may be associated with both its hypothesized neuroprotective effects and the reduced disability-worsening events observed in multiple sclerosis (MS) patients. In the fall of this year, we expect to report an interim biomarker analysis of our phase 2 CALLIPER trial in progressive MS, designed to corroborate the neuroprotective potential of vidofludimus calcium, which could become a distinguishing factor in the MS market. Based on the substantial clinical activity seen thus far, along with the already known favorable safety and tolerability profile, we remain confident that vidofludimus calcium can potentially be a unique therapeutic approach for managing the multifaceted pathophysiology of MS."

Dr. Vitt continued, "In May, we reported stronger than expected positive results from the part C portion of our phase 1 clinical trial of IMU-856 in patients with celiac disease, showing the first clinical evidence of its ability, as observed preclinically, to regenerate the gut wall. In particular, the phase 1b data showed that IMU-856 was effective compared to placebo in improving four crucial aspects of celiac disease: histology, disease symptoms, biomarkers and nutrient absorption. This was followed by our announcement, at Digestive Disease Week, of the molecular mode of action of IMU-856 as a potent modulator of Sirtuin 6 (SIRT6), which works to restore and regenerate the architecture of the intestinal wall. As a result, we now have clinical evidence to suggest IMU-856's activity and its potential to treat various gastrointestinal disorders with a novel therapeutic approach. Based on these findings, preparations for a phase 2 clinical trial in ongoing active celiac disease (OACD) are currently underway."

"The maintenance phase of our CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe ulcerative colitis (UC) patients, announced during the quarter, delivered very promising results, demonstrating statistically significant activity in comparison to placebo. Moreover, this data reconfirmed the excellent safety and tolerability profile for vidofludimus calcium found in prior trials," concluded Dr. Vitt.

Second Quarter 2023 and Subsequent Highlights

- July 2023: Hosted a virtual celiac disease expert roundtable to discuss the substantial unmet medical need for new therapeutic solutions. Immunic's management also provided an overview of the company's IMU-856 program, including the recently announced, positive phase 1b trial results in celiac disease patients.
- May 2023: Published preclinical data in the peer-reviewed, high impact Journal of Medicinal Chemistry, confirming that vidofludimus calcium acts as a potent Nurr1 activator, in addition to its known mode of action as a dihydroorotate dehydrogenase (DHODH) inhibitor, in a paper entitled, "Development of a potent Nurr1 agonist tool for in vivo applications." Data showed that activation of Nurr1 could be responsible for the drug's postulated neuroprotective effects and may contribute to the previously reported reduction of confirmed disability worsening events in MS patients.
- May 2023: Presented clinical and preclinical data for IMU-856, including, for the first time, 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 part C portion of the phase 1 clinical trial of IMU-856 in patients with celiac disease. 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. Immunic believes this data provides initial clinical proof-of-concept for an entirely new therapeutic approach to gastrointestinal disorders by promoting regeneration of bowel architecture. The data also 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., would step down from the Board, effective June 28, 2023.
- 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 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 while also achieving statistical significance in an exploratory statistical analysis (p=0.0259). Administration of vidofludimus calcium was observed to be safe and well-tolerated.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:** Data from the interim analysis of the phase 2 CALLIPER trial of vidofludimus calcium in progressive MS, previously guided for the second half of 2023, is now expected to be available in the fall of 2023. The top-line data read-out for the trial is expected at the end of 2024. 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 the 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 2 testing of IMU-856 in OACD patients.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $21.2 million for the three months ended June 30, 2023, as compared to $16.5 million for the three months ended June 30, 2022. The $4.7 million increase reflects (i) a $6.1 million increase in external development costs related to the ongoing clinical programs of vidofludimus calcium in relapsing and progressive MS, as well as the IMU-856 program, (ii) a $0.6 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 $0.7 million increase related costs across numerous categories. The increases were partially offset by (i) a decrease of $1.4 million in external development costs related to the phase 2 clinical trial of vidofludimus calcium in ulcerative colitis and (ii) a decrease of $1.3 million related to the IMU-935 psoriasis program.

  For the six months ended June 30, 2023, R&D expenses were $44.1 million, as compared to $34.0 million for the same period ended June 30, 2022. The $10.1 million increase reflects (i) a $12.1 million increase in external development costs related to the ongoing clinical programs of vidofludimus calcium in relapsing and progressive MS, as well as the IMU-856 program, (ii) a $1.1 million increase in personnel expense in research and development related to an increase in headcount, $0.2 million of which was due to non-cash stock based compensation and (iii) a $0.5 million increase related costs across numerous categories. The increases were partially offset by (i) a decrease of $2.0 million in external development costs related to the phase 2 clinical trial of vidofludimus calcium in ulcerative colitis and (ii) a decrease of $1.6 million related to the IMU-935 psoriasis program.

- **General and Administrative (G&A) Expenses** were $3.8 million for the three months ended June 30, 2023, as compared to $4.1 million for the same period ended June 30, 2022. The $0.3 million decrease was primarily due to a $0.4 million decrease for non-cash stock-based compensation, which was offset by increased costs across numerous categories.

  For the six months ended June 30, 2023, G&A expenses were $8.1 million, as compared to $8.0 million for the same period ended June 30, 2022. The $0.1 million increase was primarily due to (i) a $0.6 million increase across numerous categories, partially offset by a decrease of $0.5 million in personnel expense in general and administrative which was primarily due to non-cash stock-based compensation decrease.

- **Other Income (Expense)** was $1.0 million for the three months ended June 30, 2023, as compared to ($1.3 million) for the same period ended June 30, 2022. The $2.3 million increase was primarily attributable to (i) a $1.7 million decrease in foreign exchange losses, (ii) a $0.9 million increase in interest income as a result of higher interest rates and (iii) a $0.1 million increase for grants received. The increase was partially offset by a $0.4 million decrease in research and development tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia.

  For the six months ended June 30, 2023, other income was $3.0 million, as compared to ($0.7 million) for the same period ended June 30, 2022. The $3.7 million increase was primarily attributable to (i) a $1.7 million increase in interest income as a result of higher interest rates, (ii) a $1.4 million decrease in foreign exchange losses and (iii) a $1.1 million research allowance attributable for tax year 2021 from the German Federal Ministry of Finance. The increase was partially offset by a $0.5 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 June 30, 2023, was approximately $24.0 million, or $0.54 per basic and diluted share, based on 44,432,955 weighted average common shares outstanding, compared to a net loss of approximately $21.9 million, or $0.72 per basic and diluted share, based on 30,248,767 weighted average common shares outstanding for the same period ended June 30, 2022.

  Net loss for the six months ended June 30, 2023, was approximately $49.3 million, or $1.12 per basic and diluted share, based on 44,036,352 weighted average common shares outstanding, compared to a net loss of approximately $42.7 million, or $1.49 per basic and diluted share, based on 28,686,910 weighted average common shares outstanding for the same period ended June 30, 2022.

- **Cash, Cash Equivalents and Investments** as of June 30, 2023 were $77.3 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_p1SCneOlThmUfjhnJ3AZ4g 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), is currently in phase 3 and phase 2 clinical trials for the treatment of relapsing and progressive multiple sclerosis, respectively, and has shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple

sclerosis and moderate-to-severe ulcerative colitis. Vidofludimus calcium combines neuroprotective effects, through its mechanism as a first-in-class nuclear receptor related 1 (Nurr1) activator, with additional anti-inflammatory and anti-viral effects, by selectively inhibiting the enzyme dihydroorotate dehydrogenase (DHODH). IMU-856, which targets the protein Sirtuin 6 (SIRT6), is intended to restore intestinal barrier function and regenerate bowel epithelium, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, where it is currently in preparations for a phase 2 clinical trial. IMU-381, which currently is in preclinical testing, is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases. 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 timing, development 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 21,172	$ 16,538	$ 44,135	$ 33,983
General and administrative	3,849	4,072	8,137	8,062
Total operating expenses	25,021	20,610	52,272	42,045
Loss from operations	(25,021)	(20,610)	(52,272)	(42,045)
Other income (expense):				
Interest income	968	106	1,768	113
Other income (expense), net	54	(1,397)	1,233	(777)
Total other income (expense)	1,022	(1,291)	3,001	(664)
Net loss	$ (23,999)	$ (21,901)	$ (49,271)	$ (42,709)
Net loss per share, basic and diluted	$ (0.54)	$ (0.72)	$ (1.12)	$ (1.49)
Weighted-average common shares outstanding, basic and diluted	44,432,955	30,248,767	44,036,352	28,686,910

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

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 77,294	$ 106,745
Investments - other	—	9,629
Other current assets and prepaid expenses	9,257	9,490
Total current assets	86,551	125,864
Property and equipment, net	290	294
Right-of-use assets, net	1,855	1,552
Other long-term assets	43	43
Total assets	$ 88,739	$ 127,753
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,700	$ 4,281
Accrued expenses	12,613	7,986
Other current liabilities	928	810
Total current liabilities	18,241	13,077
Long term liabilities		
Operating lease liabilities	1,214	992
Total long-term liabilities	1,214	992
Total liabilities	19,455	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 June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 44,488,371 and 39,307,286 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	431,849	427,925
Accumulated other comprehensive income	3,982	3,035
Accumulated deficit	(366,551)	(317,280)
Total stockholders' equity	69,284	113,684
Total liabilities and stockholders' equity	$ 88,739	$ 127,753