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

– Positive Interim Analysis from Phase 2 CALLIPER Trial Showed Improvements in Serum Neurofilament Light Chain for Vidofludimus Calcium, Consistent Throughout the Overall Progressive Multiple Sclerosis Population and All Subtypes –

– Notice of Allowance for United States Patent Protecting the Treatment of Relapsing Multiple Sclerosis with Vidofludimus and Its Salts Bolsters Multilayered Intellectual Property Position –

– $59.7 Million in Cash and Cash Equivalents as of September 30, 2023 Expected to Fund Immunic Into September of 2024 –

– Webcast to be Held Today, November 14, 2023, at 8:00 am ET –

NEW YORK, November 14, 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 third quarter ended September 30, 2023, and provided a corporate update.

"We have continued to make tangible progress on the clinical development of our lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium (IMU-838). Of particular importance, we completed enrollment of our phase 2 CALLIPER trial in patients with progressive multiple sclerosis (PMS) and most recently reported a stronger than expected, positive interim biomarker analysis of this trial. Notably, the clear separation observed in serum neurofilament light chain (NfL) over placebo in this patient population represents another key milestone for what could potentially be a first-in-class Nurr1 activator for PMS," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Serum NfL responses were consistently observed for vidofludimus calcium across progressive MS disease as well as all subpopulations and even in non-active SPMS, a population where the medical need for new therapies is particularly high. We believe that the data set provides biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, further reinforcing its neuroprotective potential and bolstering our view that it may be associated with the reduced disability-worsening events we already observed in multiple sclerosis (MS) patients."

"Assuming that the top-line CALLIPER data, which we plan to report in April 2025, continues to show a neuroprotective effect, we may be able to position vidofludimus calcium as the first oral treatment for non-active secondary progressive MS. We also think that the drug's potential first-in-class ability to activate Nurr1 may meaningfully benefit our ongoing phase 3 ENSURE program in relapsing MS (RMS). To that end, we continue to enroll patients in our twin phase 3 ENSURE trials and currently expect to report an interim futility analysis in late 2024, with the read-out of the first of the ENSURE trials expected at the end of 2025. If ultimately approved, we continue to believe that vidofludimus calcium, with combined neuroprotective, anti-inflammatory, and antiviral effects, could potentially offer a unique treatment option targeted to the complex pathophysiology of MS."

Dr. Vitt continued, “In October and November, respectively, we presented the previously reported positive results from our phase 1b clinical trial of our second key program, IMU-856, an orally available and systemically acting small molecule modulator that targets SIRT6 (Sirtuin 6), in patients with celiac disease, at two prestigious medical conferences. The results, gathered during periods of gluten-free diet and gluten challenge, 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. We believe that this highly encouraging data provides initial clinical proof-of-concept for a potential new therapeutic approach to gastrointestinal disorders by promoting regeneration of bowel architecture. That said, we are currently preparing for clinical phase 2 testing of IMU-856 in ongoing active celiac disease (OACD), while also considering further potential clinical applications in other gastrointestinal disorders.”

Third Quarter 2023 and Subsequent Highlights

- November 2023: Received a Notice of Allowance from the United States Patent and Trademark Office for patent application 17/391,442, entitled, “Treatment of Multiple Sclerosis Comprising DHODH Inhibitors,” covering a daily dose of about 10 mg to 45 mg of vidofludimus calcium and other salt as well as free acid forms for the treatment of RMS. The claims are expected to provide protection into 2041, unless extended further.
- November 2023: Presented data from the company’s phase 1b clinical trial of IMU-856 in patients with celiac disease in a poster presentation at the Association of European Coeliac Societies (AOECS) 35th General Assembly Conference 2023.
- October 2023: Presented data from the phase 1b clinical trial of IMU-856 in patients with celiac disease in a moderated poster session; along with data from the company’s phase 2 CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe ulcerative colitis (UC) in an oral presentation, both at the United European Gastroenterology Week (UEGW) 2023.
- October 2023: Presented data from the company’s phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting MS in an ePoster at MSMilan2023: The 9th Joint ECTRIMS-ACTRIMS Meeting.
- October 2023: Reported positive interim data from the phase 2 CALLIPER trial of vidofludimus calcium in PMS. Serum NfL responses were consistently observed for vidofludimus calcium across PMS disease and all subtypes, as well as in patients that show or do not show disease and/or magnetic resonance imaging (MRI) activity. The Company believes that this data showed biomarker evidence that vidofludimus calcium’s activity extends beyond the previously observed anti-inflammatory effects, thereby further reinforcing its neuroprotective potential.
- August 2023: Announced the completion of enrollment of the phase 2 CALLIPER trial of vidofludimus calcium in PMS. In total, 467 patients with primary PMS, or active or non-active secondary PMS were randomized to either 45 mg of vidofludimus calcium or placebo.
- 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 positive results from the phase 1b clinical trial in patients with celiac disease.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:** Top-line data from the phase 2 CALLIPER trial of vidofludimus calcium in PMS is expected in April of 2025. An interim futility 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 $19.8 million for the three months ended September 30, 2023, as compared to $16.5 million for the three months ended September 30, 2022. The $3.3 million increase reflects (i) a $2.8 million increase in external development costs related to the phase 3 clinical program of vidofludimus calcium in RMS, (ii) a $1.2 million increase in drug supply costs for vidofludimus calcium to support our ongoing trials, (iii) a $1.0 million increase in external development costs related to the phase 2 clinical trial of vidofludimus calcium in PMS, (iv) a $0.5 million increase in personnel expense in R&D related to an increase in headcount and (v) a $0.9 million increase in related costs across numerous categories. The increases were partially offset by (i) a decrease of $2.5 million resulting from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer and (ii) a $0.6 million decrease in external development costs related to the phase 1 clinical trial of IMU-856.

  For the nine months ended September 30, 2023, R&D expenses were $63.9 million, as compared to $50.5 million for the same period ended September 30, 2022. The $13.4 million increase reflects (i) a $10.1 million increase in external development costs related to the phase 3 clinical program of vidofludimus calcium in RMS, (ii) a $2.9 million increase in external development costs related to the phase 2 clinical trial of vidofludimus calcium in PMS, (iii) a $2.3 million increase in drug supply costs for vidofludimus calcium to support our ongoing trials, (iv) a $1.8 million increase in external development costs related to the phase 1 clinical trial of IMU-856, (v) a $1.6 million increase in personnel expense in R&D related to an increase in headcount, $0.2 million of which was due to non-cash stock based compensation and (vi) a $0.5 million increase in related costs across numerous categories. The increases were partially offset by (i) a decrease of $4.0 million resulting from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer and (ii) a decrease of $1.8 million in external development costs related to the phase 2 clinical trial of vidofludimus calcium in UC.

- **General and Administrative (G&A) Expenses** were $3.8 million for the three months ended September 30, 2023, as compared to $3.6 million for the same period ended September 30, 2022. The $0.2 million increase was spread across numerous categories.

  For the nine months ended September 30, 2023, G&A expenses were $11.9 million, as compared to $11.6 million for the same period ended September 30, 2022. The $0.3 million increase was primarily due to (i) a $0.2 million increase in travel expense, (ii) a $0.2 million increase in legal and consultancy expense and (iii) a $0.5 million increase across numerous categories. The increases were partially offset by a decrease of $0.6 million in personnel expenses in G&A, which was primarily due to non-cash stock-based compensation decrease.

- **Other Income (Expense)** was $0.8 million for the three months ended September 30, 2023, as compared to ($1.1 million) for the same period ended September 30, 2022. The $1.9 million increase was primarily attributable to (i) a $1.8 million decrease in foreign exchange losses and (ii) a $0.5 million increase in interest income as a result of higher interest rates. The increase was partially offset by a $0.4 million decrease in R&D tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia primarily for IMU-856.

  For the nine months ended September 30, 2023, other income was $3.8 million, as compared to ($1.8 million) for the same period ended September 30, 2022. The $5.6 million increase was primarily attributable to (i) a $2.2 million increase in interest income as a result of higher interest rates, (ii) a $3.2 million decrease in foreign exchange losses and (iii) a $1.1 million research allowance attributable to tax year 2021 from the German Federal Ministry of Finance. The increase was partially offset by a $0.9 million decrease in R&D 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 September 30, 2023, was approximately $22.8 million, or $0.51 per basic and diluted share, based on 44,574,377 weighted average common shares outstanding, compared to a net loss of approximately $21.2 million, or $0.69 per basic and diluted share, based on 30,564,995 weighted average common shares outstanding for the same period ended September 30, 2022.

  Net loss for the nine months ended September 30, 2023, was approximately $72.0 million, or $1.63 per basic and diluted share, based on 44,227,264 weighted average common shares outstanding, compared to a net loss of approximately $63.9 million, or $2.16 per basic and diluted share, based on 29,655,946 weighted average common shares outstanding for the same period ended September 30, 2022.

- **Cash, Cash Equivalents and Investments** as of September 30, 2023 were $59.7 million. With these funds Immunic expects to be able to fund its operations into September 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_AxIAE0pCQ12oMZliehNKDg 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, progressive 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 and the conflict in the Middle East 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.

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Financials

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 19,796	$ 16,537	$ 63,931	$ 50,520
General and administrative	3,774	3,579	11,911	11,641
Total operating expenses	23,570	20,116	75,842	62,161
Loss from operations	(23,570)	(20,116)	(75,842)	(62,161)
Other income (expense):				
Interest income	766	230	2,534	343
Other income (expense), net	35	(1,338)	1,268	(2,115)
Total other income (expense)	801	(1,108)	3,802	(1,772)
Net loss	$ (22,769)	$ (21,224)	$ (72,040)	$ (63,933)
Net loss per share, basic and diluted	$ (0.51)	$ (0.69)	$ (1.63)	$ (2.16)
Weighted-average common shares outstanding, basic and diluted	44,574,377	30,564,995	44,227,264	29,655,946

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

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 59,689	$ 106,745
Investments - other	—	9,629
Other current assets and prepaid expenses	5,545	9,490
Total current assets	65,234	125,864
Property and equipment, net	288	294
Right-of-use assets, net	1,412	1,552
Other long-term assets	43	43
Total assets	$ 66,977	$ 127,753
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,199	$ 4,281
Accrued expenses	13,659	7,986
Other current liabilities	923	810
Total current liabilities	17,781	13,077
Long term liabilities		
Operating lease liabilities	789	992
Total long-term liabilities	789	992
Total liabilities	18,570	14,069
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 44,595,383 and 39,307,286 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	433,818	427,925
Accumulated other comprehensive income	3,905	3,035
Accumulated deficit	(389,320)	(317,280)
Total stockholders' equity	48,407	113,684
Total liabilities and stockholders' equity	$ 66,977	$ 127,753