Immunic, Inc. Reports Second Quarter 2022 Financial Results and Provides Corporate Update

– Initial Clinical Activity Results of IMU-935 in Psoriasis Expected in the Fourth Quarter –

– Unblinded Safety Data from the Single and Multiple Ascending Dose Parts of Phase 1 Clinical Trial of IMU-856 in Healthy Human Subjects Expected in the Third Quarter –

– $88.1 Million in Cash and Cash Equivalents Expected to Fund Immunic Into the Fourth Quarter of 2023 –

– Webcast to be Held Today, August 4, 2022, at 8:00 am ET –

NEW YORK, August 4, 2022 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases, today announced financial results for the second quarter ended June 30, 2022 and provided a corporate update.

"The second quarter was a period of continued progress in each of our key clinical programs, setting the stage for important data readouts during the second half of this year, including for IMU-935, a highly potent and selective oral IL-17 inhibitor, and IMU-856, an orally available and systemically acting small molecule shown preclinically to regulate intestinal barrier function and regenerate bowel epithelium," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Most notably, we look forward to reporting initial clinical activity data from part C of our phase 1 clinical trial of IMU-935 in moderate-to-severe psoriasis patients in the fourth quarter of this year. Additionally, during the third quarter, we expect to report unblinded safety data from both the single (SAD) and multiple ascending dose (MAD) parts of our phase 1 clinical trial of IMU-856 in healthy human subjects."

Dr. Vitt continued, "As we reported in June, the top-line data from our phase 2 CALDOSE-1 trial of our selective oral DHODH inhibitor, vidofludimus calcium (IMU-838), in patients with moderate-to-severe ulcerative colitis (UC), did not meet its primary endpoint due to a previously unknown interaction with chronic concurrent steroid use. Based on a post-hoc analysis of our phase 2 EMPhASIS trial in relapsing-remitting multiple sclerosis (RRMS) patients, we do not believe this will be an issue for our ongoing program in multiple sclerosis (MS) as chronic administration of corticosteroids is not generally used in this patient population or permitted in our ongoing MS trials. Based on the totality of data generated thus far, demonstrating an impressive suppression of MRI lesions, evidence for neuroprotective effects and an unrivaled safety and tolerability profile, we remain highly optimistic about the potential for vidofludimus calcium to become a highly differentiated and uniquely valuable treatment option in relapsing multiple sclerosis (RMS)."

Second Quarter 2022 and Subsequent Highlights

- July 2022: Announced the appointment of Maria Törnsén, an industry executive with 20 years of global commercial experience in U.S. and ex-U.S. markets, to the Board of Directors and the resignation of Jan Van den Bossche from the Board, both effective July 5, 2022.

- June 2022: Announced publication of data from the phase 2 EMPhASIS trial of vidofludimus calcium in patients with RRMS, in the peer reviewed journal, *Annals of Clinical and Translational Neurology*.
- June 2022: Reported top-line data from phase 2 CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe UC, revealing an interaction with chronic concurrent steroid use and, therefore, missing the trial's primary endpoint. Consistent with prior data sets in other patient populations, administration of vidofludimus calcium in this trial was observed to be safe and well-tolerated. Also announced that the company's development programs in the inflammatory bowel disease indications will not be continued without a partner.
- May 2022: Announced the start of the celiac disease cohorts in the ongoing phase 1 clinical trial of IMU-856, representing the first time patients are treated with the company's orally available small molecule modulator targeting restoration of intestinal barrier function and regeneration of bowel epithelium.

Clinical Updates

- **Update on the use of steroids in the phase 2 EMPhASIS trial of vidofludimus calcium in RRMS:** Based on the observed interaction between vidofludimus calcium and chronic steroid use in the CALDOSE-1 trial in UC patients, Immunic performed a post-hoc analysis of the phase 2 EMPhASIS data in RRMS patients to explore the potential influence of steroids on these study results. As anticipated, steroid use was rare and among those RRMS patients who received any steroids, the majority received only short steroid courses following relapse events or acute neurological events. Comparing patients who received at least one dose of corticosteroids with those who did not, Immunic does not see any difference in clinical parameters or any evidence that the rare, short-term use of steroids in RRMS patients has any influence on the effectiveness of vidofludimus calcium in this patient population.
- **Results of exploratory phase 1 drug-drug interaction (DDI) study of IMU-935:** An exploratory phase 1 study was completed in 15 evaluable healthy human subjects to assess the DDI potential of IMU-935. No relevant signals for DDI potential were observed and treatment was safe and well-tolerated.
- **Update on phase 1 clinical trial of IMU-935 in metastatic castration-resistant prostate cancer (mCRPC) – initial safety data available:** The first two dose cohorts of the phase 1 clinical trial of IMU-935 in mCRPC have been fully recruited, with 6 patients enrolled in the 300 mg cohort and 6 patients in the 600 mg cohort. Of these patients, all have completed the initial 28-day safety study part without reaching dose limiting toxicity (DLT). The third, 900 mg cohort is expected to start dosing soon. Initial safety data available so far show a promising safety profile of IMU-935 in mCRPC, with only benign adverse events and no dose limiting toxicities. Immunic plans to provide a more comprehensive update on safety and also on potential signs of anti-tumor activity of IMU-935 in this trial as soon as data from the planned dose expansion part are available.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:** Immunic has carefully analyzed the impact that current events in the Ukraine and Russia may have on its ongoing clinical programs. Based on this assessment, the current goal is to report data from the interim analysis of the phase 2 CALLIPER trial of vidofludimus calcium in progressive multiple sclerosis (PMS) in the second half of 2023 and to read-out top-line data at the end of 2024. Moreover, the read-out of the first of the phase 3

ENSURE trials of vidofludimus calcium in RMS is currently targeted for end of 2025. Although Immunic currently believes that each of these goals is achievable, they are each dependent on numerous factors which are not under the company's direct control and can be difficult to predict. Immunic plans to periodically review this assessment and provide updates of material changes as appropriate.

- **IMU-935 phase 1 program in psoriasis:** Recruitment of part C of the phase 1 clinical trial of IMU-935 in patients with moderate-to-severe psoriasis is ongoing in Australia, New Zealand and Bulgaria. Initial results are expected to be available in the fourth quarter of 2022.
- **IMU-856 phase 1 program**: Unblinded safety data from the SAD and MAD parts of the ongoing phase 1 clinical trial of IMU-856 in healthy human subjects are expected to be available in the third quarter of 2022.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $16.5 million for the three months ended June 30, 2022, as compared to $15.7 million for the three months ended June 30, 2021. The $0.8 million increase reflects (i) a $4.0 million increase in external development costs related to the ongoing clinical trials of vidofludimus calcium for the phase 3 program in RMS and the phase 2 trial in PMS and IMU-935, and (ii) a $0.7 million increase in personnel expense in research and development, $0.3 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount. The increases were partially offset by (i) a $3.2 million decrease in external development costs related to clinical trials of vidofludimus calcium related to COVID-19 and UC, and (ii) a decrease of $0.7 million across numerous categories.

  For the six months ended June 30, 2022, R&D expenses were $34.0 million, as compared to $27.3 million for the same period ended June 30, 2021. The $6.7 million increase reflects (i) a $12.1 million increase in external development costs related to the ongoing clinical trials of vidofludimus calcium for the phase 3 program in RMS and the phase 2 trial in PMS, IMU-935 and IMU-856, and (ii) a $1.8 million increase in personnel expense in research and development, $0.7 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount. The increases were partially offset by (i) a $6.3 million decrease in external development costs related to clinical trials of vidofludimus calcium related to COVID-19 and UC, and (ii) a decrease of $0.9 million in external development costs across numerous categories.

- **General and Administrative (G&A) Expenses** were $4.1 million for the three months ended June 30, 2022, as compared to $3.4 million for the same period ended June 30, 2021. The $0.6 million increase was primarily due to a $0.6 million increase in personnel expenses, $0.3 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount.

  For the six months ended June 30 ,2022, G&A expenses were $8.1 million, as compared to $7.1 million for the same period ended June 30, 2021. The $1.0 million increase was primarily due to personnel expenses, $0.3 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount.

- **Other Income (Expense)** was ($1.3 million) for the three months ended June 30, 2022, as compared to $1.2 million for the same period ended June 30, 2021. The $2.5 million decrease was primarily attributable to an increase in the loss on an intercompany loan between Immunic, Inc. and Immunic AG as a result of changes in currency exchange rates.

  For the six months ended June 30, 2022, other expense was ($0.7 million), as compared to ($0.9 million) for the same period ended June 30, 2021. The $0.2 million decrease was primarily attributable to an increase in research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia as well as the impact of foreign exchange rates on loans between Immunic AG and Immunic Australia Pty Ltd, partially offset by an increase in the loss on an intercompany loan between Immunic, Inc. and Immunic AG.

- **Net Loss** for the three months ended June 30, 2022 was approximately $21.9 million, or $0.72 per basic and diluted share, based on 30,248,767 weighted average common shares outstanding, compared to a net loss of approximately $17.9 million, or $0.82 per basic and diluted share, based on 21,749,439 weighted average common shares outstanding for the same period ended June 30, 2021.

  Net loss for the six months ended June 30, 2022, was approximately $42.7 million, or $1.49 per basic and diluted share, based on 28,686,910 weighted average common shares outstanding, compared to a net loss of approximately $52.5 million, or $2.44 per basic and diluted share, based on 21,463,656 weighted average common shares outstanding for the same period ended June 30, 2021.

- **Cash and Cash Equivalents** as of June 30, 2022 were $88.1 million, which management expects to be sufficient to fund operations into the fourth quarter of 2023.

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_alOspcfoRBWZpGzVMIbfFg 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 clinical-stage biopharmaceutical company with a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases. The company is developing three small molecule products: its lead development program, vidofludimus calcium (IMU-838), a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH and exhibits a host-based antiviral effect, is currently being developed as a treatment option for multiple sclerosis, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγ/RORγt, is targeted for development in psoriasis,

and castration-resistant prostate cancer. IMU-856, which targets the restoration of the intestinal barrier function, is targeted for development in diseases involving bowel barrier dysfunction. 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 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, 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 on February 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 16,538	$ 15,738	$ 33,983	$ 27,257
General and administrative	4,072	3,432	8,062	7,050
4SC royalty settlement	—	—	—	17,250
Total operating expenses	20,610	19,170	42,045	51,557
Loss from operations	(20,610)	(19,170)	(42,045)	(51,557)
Other income (expense):				
Interest income	106	13	113	41
Other income (expense), net	(1,397)	1,223	(777)	(952)
Total other income (expense)	(1,291)	1,236	(664)	(911)
Net loss	$ (21,901)	$ (17,934)	$ (42,709)	$ (52,468)
Net loss per share, basic and diluted	$ (0.72)	$ (0.82)	$ (1.49)	$ (2.44)
Weighted-average common shares outstanding, basic and diluted	30,248,767	21,749,439	28,686,910	21,463,656

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

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 88,078	$ 86,863
Other current assets and prepaid expenses	16,683	18,125
Total current assets	104,761	104,988
Property and equipment, net	139	152
Goodwill	32,970	32,970
Right-of-use assets, net	745	948
Other long-term assets	42	42
Total assets	$ 138,657	$ 139,100
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,117	$ 3,745
Accrued expenses	5,741	7,071
Other current liabilities	544	585
Total current liabilities	10,402	11,401
Long term liabilities		
Operating lease liabilities	407	584
Total long-term liabilities	407	584
Total liabilities	10,809	11,985
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, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 21,749,439 and 21,168,240 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	368,087	324,237
Accumulated other comprehensive loss	(660)	(252)
Accumulated deficit	(239,582)	(196,873)
Total stockholders' equity	127,848	127,115
Total liabilities and stockholders' equity	$ 138,657	$ 139,100