Immunic, Inc. Reports Third Quarter 2025 Financial Results and Provides Corporate Update

– Key Data Highlighting Vidofludimus Calcium's Therapeutic Potential in Multiple Sclerosis Presented at 41st Congress of ECTRIMS –

– Phase 2 CALLIPER Data Demonstrated Statistically Significant 24-Week Confirmed Disability Improvement in Progressive Multiple Sclerosis, With Consistent Signals for Slowing Disability Progression Across Subgroups and Endpoints, Supporting Vidofludimus Calcium's Neuroprotective Potential and Nurr1 Activation Mechanism –

– Long-Term Phase 2 EMPhASIS Data in Relapsing-Remitting Multiple Sclerosis Showed High Rates of Patients Remaining Free of Confirmed Disability Worsening and Favorable Long-Term Safety and Tolerability –

– Top-Line Data from Twin Phase 3 ENSURE Trials of Vidofludimus Calcium in Relapsing Multiple Sclerosis Expected by Year-End 2026 –

NEW YORK, November 13, 2025 – Immunic, Inc. (Nasdaq: IMUX), a late-stage biotechnology company pioneering the development of novel oral therapies for neurologic and gastrointestinal diseases, today announced financial results for the three and nine months ended September 30, 2025, and provided a corporate update.

"The third quarter was marked by our strong presence at the 41st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), during which we had the opportunity to highlight the clinical momentum of our lead asset, vidofludimus calcium (IMU-838), an orally available nuclear receptor-related 1 (Nurr1) activator, and its potential to transform the oral multiple sclerosis (MS) therapy landscape," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "The collective data meanwhile available from across our clinical MS trials, including the phase 2 CALLIPER and EMPhASIS trials, highlight vidofludimus calcium's unique promise to slow disability progression in both relapsing and progressive forms of the disease. Notably, new data from our positive phase 2 CALLIPER trial in progressive MS (PMS), also featured in the Best of ECTRIMS 2025 slide deck, showed statistically significant 24-week confirmed disability improvement in the overall patient population and consistent effects across both the primary progressive MS (PPMS) and non-active secondary progressive MS (naSPMS) subgroups, further reinforcing the compound's neuroprotective and anti-inflammatory characteristics."

"We believe the CALLIPER data clearly support advancing vidofludimus calcium into phase 3 development in progressive forms of MS. With only one approved therapy currently available for PPMS, there is a significant opportunity in this underserved, multi-billion-dollar market. By slowing disease progression, vidofludimus calcium could help patients maintain independence, manage symptoms more effectively, and achieve improved long-term outcomes."

Dr. Vitt continued, "Notably, we also presented additional long-term data from the open-label extension (OLE) period of our phase 2 EMPhASIS trial in relapsing-remitting multiple sclerosis (RRMS) at ECTRIMS, which further highlighted the robust efficacy signals and favorable safety and tolerability observed, to

date. Our twin phase 3 ENSURE trials in relapsing MS (RMS) remain on track. Given vidofludimus calcium's unique profile and its potential to become the oral therapy of choice addressing the full spectrum of MS, we look forward to reporting top-line data by the end of 2026."

"We also successfully continued our efforts to meaningfully enhance our strong and multi-layered intellectual property position for vidofludimus calcium. During the quarter, we received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a key patent covering dose strengths of vidofludimus calcium for the treatment of PMS. This newly allowed patent adds another layer of potential exclusivity protection in the United States, with the option for further term extension."

Third Quarter 2025 Highlights

- September 2025: Presented key data at the 41st Congress of ECTRIMS, highlighting vidofludimus calcium's therapeutic potential in MS, in one oral and four poster presentations, including one late-breaking poster. The results from the phase 2 CALLIPER trial in PMS were also selected for the Best of ECTRIMS 2025 slide deck.

  The CALLIPER data underscored vidofludimus calcium's neuroprotective potential across PMS populations and its ability to slow disease progression in patients with or without focal inflammation. Consistent 24-week confirmed disability worsening (24wCDW) outcomes were observed across disability endpoints, patient populations and subgroups (including the overall population and in PPMS and naSPMS), and those without baseline inflammatory gadolinium-enhancing (Gd+) lesions during magnetic resonance imaging (MRI). Newly available data regarding 24-week confirmed disability improvement (24wCDI) demonstrated a greater than two-fold probability for vidofludimus calcium over placebo, statistically significant in the overall PMS population, with consistent trends across subtypes. These findings support clinically measurable neuroprotective effects consistent with vidofludimus calcium's Nurr1 activation mechanism and de-risk a potential phase 3 program, as 24wCDW is an accepted regulatory endpoint to demonstrate clinical benefit in PMS.

  Long-term data from the phase 2 EMPhASIS OLE period reinforced vidofludimus calcium's robust efficacy signals and favorable safety and tolerability profile, demonstrating that it was well-tolerated for treatment durations of up to 5.5 years in patients with RRMS. Among 182 patients remaining on therapy as of January 14, 2025, cumulative exposure totaled ~952 treatment years with an annualized discontinuation rate of only ~6.4%. Most adverse events were mild, with low rates of renal and liver-related events, and no new safety signals observed. Serious adverse events were infrequent, and none were deemed related to treatment.

- September 2025: Received a Notice of Allowance from the USPTO for patent application 18/529,946, entitled, "Treatment of multiple sclerosis comprising DHODH inhibitors." The resulting patent covers dose strengths associated with vidofludimus calcium and other salt forms as well as free acid forms, at a daily dose of about 10 mg to 45 mg, for the treatment of PMS, including the sub-groups PPMS and secondary progressive multiple sclerosis (SPMS). The patent is expected to provide protection into 2041, and potential Patent Term Extension may offer additional market exclusivity in the United States.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:** Top-line data from the twin phase 3 ENSURE-1 and ENSURE-2 trials in RMS is expected by the end of 2026.

- **IMU-856**: The company is preparing for further clinical testing of IMU-856, the orally available and systemically acting small molecule modulator that targets Sirtuin 6 (SIRT6), contingent on financing, licensing or partnering.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $20.0 million for the three months ended September 30, 2025, as compared to $21.4 million for the three months ended September 30, 2024. The $1.4 million decrease reflects (i) a $1.3 million decrease in external development costs related to IMU-856, (ii) a $1.1 million decrease in external development costs related to the completion of the phase 2 CALLIPER trial in the prior year and (iii) a $0.2 million decrease related to costs across numerous categories. The decrease was offset by a $1.2 million increase in personnel expenses for R&D, of which $0.8 million were related to non-cash shared-based compensation.

  For the nine months ended September 30, 2025, R&D expenses were $63.0 million, as compared to $58.4 million for the nine months ended September 30, 2024. The $4.5 million increase reflects (i) a $6.2 million increase in external development costs related to the phase 3 ENSURE trials and (ii) a $1.6 million increase in personnel expenses for R&D, of which $0.4 million was related to non-cash stock compensation. The increase was offset by (i) a $2.7 million decrease in external development costs related to IMU-856 primarily due to the timing of the purchase of drug supply for this program and (ii) a $0.6 million decrease across numerous categories.

- **General and Administrative (G&A) Expenses** were $6.0 million for the three months ended September 30, 2025, as compared to $4.4 million for the same period ended September 30, 2024. The $1.6 million increase was due to (i) a $1.2 million increase in personnel expenses, of which $1.0 million is related to non-cash share-based compensation and (ii) a $0.4 million increase related to costs across numerous categories.

  For the nine months ended September 30, 2025, G&A expenses were $17.0 million, as compared to $14.0 million for the same period ended September 30, 2024. The $3.0 million increase was due to (i) a $1.8 million increase related to personnel expenses, of which $0.8 million was related to non-cash stock compensation, (ii) a $0.6 million increase in legal and consultancy expenses and (iii) a $0.6 million increase related to costs across numerous categories.

- **Interest Income** was $0.4 million for the three months ended September 30, 2025, as compared to $0.8 million for the three months ended September 30, 2024. The $0.4 million decrease was primarily due to a lower average cash balance.

  For the nine months ended September 30, 2025, interest income was $0.8 million, as compared to $3.0 million for the same period ended September 30, 2024. The $2.1 million decrease was due to a lower average cash balance.

- In the nine months ended September 30, 2024, there was a non-cash charge related to the change in value of the tranche rights associated with the January 2024 Financing from January 8, 2024 until March 4, 2024. These tranches were initially classified as a liability, but were reclassified to equity on March 4, 2024, when stockholders approved the increase in the authorized shares from 130 million to 500 million shares of common stock and therefore the tranche 2 and tranche 3 rights needed to be revalued to fair value upon the reclassification to equity. There was no change in fair value of the tranche rights recognized in the nine months ended September 30, 2025.

- **Other Income (Expense)** was negligible for the three months ended September 30, 2025, as compared to $0.6 million for the same period ended September 30, 2024. The $0.6 million decrease was primarily attributable to a decrease in research and development tax incentives for clinical trials in Australia due to lower clinical trial spend in Australia.

  For the nine months ended September 30, 2025, Other Income (Expense) was $1.2 million, as compared to ($1.1 million) for the same period ending September 30, 2024. The $2.3 million increase was primarily attributable to (i) a $1.7 million expense related to the portion of deal costs from the January 2024 Financing related to the tranche rights that were established at the time of the deal closing in 2024, (ii) $1.0 million of grant income from the German Federal Ministry of Finance recognized in the first quarter 2025 and (iii) a $0.3 million increase across numerous categories. The increase was offset by a $0.7 million decrease in research and development tax incentives for clinical trials in Australia due to lower clinical trial spend in Australia.

- **Net Loss** for the three months ended September 30, 2025, was approximately $25.6 million, or $0.13 per basic and diluted share, based on 193,897,764 weighted average common shares outstanding, compared to a net loss of approximately $24.4 million, or $0.24 per basic and diluted share, based on 101,272,580 weighted average common shares outstanding for the same period ended September 30, 2024.

  Net loss for the nine months ended September 30, 2025, was approximately $77.9 million, or $0.55 per basic and diluted share, based on 142,811,489 weighted average common shares outstanding, compared to a net loss of approximately $75.3 million or $0.75 per basic and diluted share, based on 99,998,245 weighted average common shares outstanding for the same period ended September 30, 2024.

- **Cash and Cash Equivalents** as of September 30, 2025 were $35.1 million. With this cash, the company does not have adequate liquidity to fund its operations for at least 12 months from September 30, 2025, without raising additional capital.

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a late-stage biotechnology company pioneering the development of novel oral therapies for neurologic and gastrointestinal diseases. The company's lead development program, vidofludimus calcium (IMU-838), is currently in phase 3 clinical trials for the treatment of relapsing multiple sclerosis, for which top-line data is expected to be available by the end of 2026. It has already shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis and progressive multiple sclerosis. 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 as well as inflammatory bowel disease, Graft-versus-Host-Disease and weight management. 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 and cash runway, 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 feasibility of advancing vidofludimus calcium to a confirmatory phase 3 clinical trial in progressive multiple sclerosis; 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; and the development and commercial potential of any product candidates of the company. 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, increasing inflation, tariffs and macroeconomics trends, 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, and the ability to raise sufficient capital to continue as a going concern, the fact that the results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results, any changes to the size of the target markets for the company's products or product candidates, 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, 2024, filed with the SEC on March 31, 2025, and in the company's subsequent filings with the SEC. 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 of 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,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 20,012	$ 21,370	$ 62,914	$ 58,429
General and administrative	5,981	4,356	16,987	13,992
Total operating expenses	25,993	25,726	79,901	72,421
Loss from operations	(25,993)	(25,726)	(79,901)	(72,421)
Other income (expense):				
Interest income	419	776	843	2,961
Change in fair value of the tranche rights	—	—	—	(4,796)
Other income (expense), net	(5)	582	1,186	(1,076)
Total other income (expense)	414	1,358	2,029	(2,911)
Net loss	$ (25,579)	$ (24,368)	$ (77,872)	$ (75,332)
Net loss per share, basic and diluted	$ (0.13)	$ (0.24)	$ (0.55)	$ (0.75)
Weighted-average common shares outstanding, basic and diluted	193,897,764	101,272,580	142,811,489	99,998,245

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

	September 30, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 35,132	$ 35,668
Other current assets and prepaid expenses	4,141	3,664
Total current assets	39,273	39,332
Property and equipment, net	640	545
Right-of-use assets, net	791	991
Total assets	$ 40,704	$ 40,868
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,918	$ 7,846
Accrued expenses	19,454	12,913
Other current liabilities	2,707	1,416
Total current liabilities	30,079	22,175
Long-term liabilities		
Operating lease liabilities	126	264
Total long-term liabilities	126	264
Total liabilities	30,205	22,439
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding as of September 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of September 30, 2025 and December 31, 2024, and 98,650,590 and 90,150,869 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	9	8
Additional paid-in capital	597,179	525,611
Accumulated other comprehensive income	2,582	4,209
Accumulated deficit	(589,271)	(511,399)
Total stockholders' equity	10,499	18,429
Total liabilities and stockholders' equity	$ 40,704	$ 40,868