Immunic, Inc. Reports Third Quarter 2020 Financial Results and Provides Corporate Update

– Released Very Positive Phase 2 Data for IMU-838 in Relapsing-Remitting Multiple Sclerosis; Company to Submit End-of-Phase 2 Meeting Requests to Regulatory Authorities at the End of Q1 2021 –

– 200 Patients Randomized in Phase 2 Trial of IMU-838 for the Treatment of Moderate COVID-19; Top-Line Data From Main Phase 2 Efficacy Analysis Expected in Q1 2021 –

– Readout of 18 Patients From Phase 2, Investigator-Sponsored Proof-of-Concept Clinical Trial of IMU-838 in Primary Sclerosing Cholangitis, Being Conducted at the Mayo Clinic, Expected During Q4 2020 –

– With Approximately $133 Million in Cash and Cash Equivalents, Immunic is Funded Through Key Value Inflection Points into the Second Half of 2022 –

NEW YORK, November 5, 2020 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, today announced financial results for the third quarter ended September 30, 2020 and provides corporate update.

"The third quarter was marked by a significant achievement for our lead asset, selective oral DHODH inhibitor, IMU-838, with the release of top-line data from our phase 2 EMPhASIS trial in patients with relapsing-remitting multiple sclerosis, and subsequent publication of the full unblinded data set. IMU-838 demonstrated robust efficacy, through the achievement of all primary and key secondary endpoints, combined with an outstanding safety and tolerability profile. We believe that the phase 2 results emphasize the game-changing potential of IMU-838 as a once-daily oral therapy for this indication," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "On the heels of this overwhelmingly positive data, we completed a successful common stock offering, raising $103.5 million in gross proceeds, significantly bolstering our balance sheet. We are currently preparing our end-of-phase 2 submission for IMU-838 in relapsing-remitting multiple sclerosis to regulatory authorities, anticipated in the first quarter of next year, after which we look forward to scheduling our end-of-phase 2 meetings, during which we will have the opportunity to discuss our plans for a phase 3 program."

Dr. Vitt continued, "We have also made notable strides in our development of IMU-838 in patients with moderate COVID-19, most recently securing a financing agreement of up to €24.5 million (approximately $29 million) with the European Investment Bank for the ongoing development of our phase 2 CALVID-1 trial, a potential expansion into a confirmatory phase 3 trial and commercial-scale manufacturing of IMU-838. Additionally, we reported that an Independent Data Monitoring Committee recommended the continuation, without changes, of the CALVID-1 trial after an interim safety analysis. Recruitment has accelerated due to the spread of disease within the countries included in the trial and, at the beginning of November, we reached the enrollment goal of 200 patients, pre-specified in the protocol as sufficient to perform the main efficacy analysis of the phase 2 part of the CALVID-1 trial. The data of this unblinded main analysis of all available efficacy, biomarker and virus titer data is expected to be available in the first quarter of next year."

The company's current cash position of approximately $133.2 million, at September 30, 2020, is expected to fund activities into the second half of 2022, and specifically through key value inflection points including those for the COVID-19 phase 2 trial with IMU-838; preparation for, and initiation of, a phase 3 trial of IMU-838 in relapsing-remitting multiple sclerosis (RRMS); the phase 2 readouts of IMU-838 in patients with ulcerative colitis (UC) and primary sclerosing cholangitis (PSC); as well as completion of the phase 1 trials of IMU-935 and IMU-856, respectively, including pharmacodynamic evaluations in patients for both of these trials.

Third Quarter 2020 and Subsequent Highlights

- November 2020: Announced 200 patients enrolled and randomized in phase 2 CALVID-1 trial of IMU-838 for the treatment of moderate COVID-19, allowing for main phase 2 efficacy analysis to proceed.
- October 2020: Signed financing agreement with the European Investment Bank for up to €24.5 million (approximately $29 million) to support the development of IMU-838 in patients with moderate COVID-19.
- September 2020: Announced results of interim safety analysis from ongoing phase 2 CALVID-1 trial of IMU-838 in patients with moderate COVID-19. Independent Data Monitoring Committee recommended continuation of the trial without changes.
- September 2020: Published full unblinded clinical data set from phase 2 EMPhASIS trial of IMU-838 in patients with RRMS and announced poster presentation at the MSVirtual2020/8th Joint ACTRIMS-ECTRIMS Meeting. Data confirmed and expanded on the previously announced top-line results, which showed achievement of all primary and secondary endpoints.
- August 2020: Dosed first healthy volunteer in phase 1 clinical program of IMU-856, targeting restoration of intestinal barrier function.
- August 2020: Completed a $103.5 million public offering of 5,750,000 shares of common stock, including the full exercise of underwriters' option to purchase an additional 750,000 shares.
- August 2020: Announced positive top-line data from phase 2 EMPhASIS trial of IMU-838 in patients with RRMS. Study met all primary and key secondary endpoints, indicating activity in RRMS patients.
- July 2020: Enrolled first patients in investigator-sponsored phase 2 IONIC trial of IMU-838 in combination with Oseltamivir (Tamiflu®), in collaboration with sponsor and lead site, University Hospitals Coventry and Warwickshire (UHCW) NHS Trust.

Update on Activities Relating to the Preparation of a Phase 3 Program for IMU-838 in RRMS

As previously announced, the full unblinded clinical data set from the company's phase 2 trial of IMU-838 in patients with RRMS showed achievement of all primary and key secondary endpoints, with high statistical significance. Notably, both doses (30 and 45 mg/day) appeared to be equally safe and efficacious, reducing the number of combined unique active (CUA) magnetic resonance imaging (MRI) lesions up to week 24, as compared to placebo. Based on this phase 2 data as well as established regulatory guidance that the lowest effective dose should be considered for future clinical trials, Immunic may propose the dose of 30 mg/day of IMU-838 for investigation in a phase 3 program.

Given the relative equal performance of the two doses tested, however, and to allow for pharmacodynamic modeling of the dose-response relationship, data from a lower dose in the effective dose range would be beneficial to complete a dose-effect assessment of IMU-838 in RRMS. For this reason, Immunic has already started an additional, small Cohort 2 sub-trial to obtain exploratory data on the expanded dose response of IMU-838. This additional, double-blind assessment includes a cohort of 60 patients who receive 10 mg/day of IMU-838 or placebo for 24 weeks. The still-active sites of the phase 2 trial of IMU-838 in RRMS continue to be used and, as a result, the company expects that this assessment can be executed in an accelerated fashion. This additional sub-trial is not expected to change any conclusions for dosing of IMU-838 in a future phase 3 program. Rather, it is expected to provide additional data to address any potential regulatory requests in the context of the design of a phase 3 program. Management believes that this strategy will enable risk reduction for end-of-phase 2 discussions with regulatory agencies.

The company intends to separate formal end-of-phase 2 meeting preparations from regulatory advice for non-clinical phase 3 related topics to be submitted to regulatory authorities in the near future. Subsequently, the company intends to submit formal end-of-phase 2 meeting requests with a sole focus on the phase 2 data, including the Cohort 2 interim data, and a proposed phase 3 program to regulatory authorities at the end of the first quarter 2021. The end-of-phase 2 meetings are expected to be held in or about May 2021.

In parallel to the preparation and execution of the regulatory discussions, Immunic has begun performing formal feasibility activities for a phase 3 program of IMU-838 in RRMS, including country and site selection, as well as other preparatory activities. The company also believes that this feasibility assessment will help ensure an expeditious execution of the development strategy for IMU-838.

Additional Anticipated Clinical Milestones

- **IMU-838 in PSC:** Due to the COVID-19 pandemic, recruitment for the phase 2, investigator-sponsored proof-of-concept clinical trial for IMU-838 in PSC, being conducted at the Mayo Clinic, is currently paused as patients with PSC are considered high risk for COVID-19 infections and were advised by the investigators to avoid travelling to the clinical sites. Together with the investigators, Immunic currently expects a potential data readout during the fourth quarter of 2020 using the 18 patients who were enrolled prior to the COVID-19 pandemic. The overall recruitment target for this open-label study is 30 patients.

- **IMU-838 in COVID-19:** Top-line efficacy, biomarker and virus titer data from the phase 2 CALVID-1 trial of IMU-838 in patients with moderate COVID-19, based on approximately 200 patients treated, is expected to be available in the first quarter of 2021, after which the company will be able to evaluate whether the program may be expanded into a confirmatory phase 3 trial.

- **IMU-838 in UC:** Although the recruitment of the phase 2 clinical trial of IMU-838 for the treatment of UC has continued during the COVID-19 pandemic, the pandemic has affected, among other things, access to endoscopy sites or hospitals in some countries, which has interfered with recruitment speed, new site activations and clinical site access. As a result, top-line data is now expected to be available in the first half of 2022, instead of in the fourth quarter of 2021 as previously announced.

- **IMU-935 phase 1 program:** The current, single ascending dose part of the ongoing phase 1 trial of IMU-935 is planned to be followed by a multiple ascending dose portion in healthy volunteers and a safety evaluation in patients with mild-to-moderate psoriasis. The trial has been resumed after a temporary pause of trials in healthy volunteers imposed by ethics committees in Australia due to COVID-19. Unblinded safety data from the single and multiple ascending dose parts in healthy volunteers is expected to be available in the first half of 2021. Initiation of the third portion in patients with mild-to-moderate psoriasis is expected in the first half of 2021 and is expected to last approximately 12 months.

- **Potential IMU-935 phase 2 trial in an orphan autoimmune disorder:** Upon completion of the single and multiple ascending dose portions of the ongoing phase 1 trial, Immunic anticipates that it may also begin a phase 2 proof-of-concept clinical trial of IMU-935 in an orphan autoimmune indication. This orphan approach may allow for an accelerated path to approval, in parallel to IMU-935's previously planned development in psoriasis. After a thorough review of suitable autoimmune conditions, the company has targeted IMU-935 for further development in Guillain-Barré syndrome, an acute neurological disorder in which the body's immune system attacks its peripheral nervous system, and for which very few therapies exist. The company plans to announce additional details as soon as design and timing of the envisaged trial are defined.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $11.0 million for the three months ended September 30, 2020, as compared to $7.1 million for the same period ended September 30, 2019. The $3.9 million increase was primarily attributable to (i) a $2.9 million increase in external development costs for IMU-838, related to the phase 2 clinical trial in patients with COVID-19, (ii) a $2.2 million increase in license fees, drug supply and phase 1 costs related to IMU-856, (iii) a $0.6 million increase in development costs for the IMU-935 program, and (iv) a $0.5 million increase in personnel costs. The increases were partially offset by a decrease of $2.3 million in costs related to the phase 2 clinical trial of IMU-838 in patients with RRMS.

  For the nine months ended September 30, 2020, R&D expenses were $27.5 million, as compared to $16.5 million for the same period ended September 30, 2019. The $11.0 million increase was primarily attributable to (i) a $4.8 million increase in external development costs for IMU-838, related to the phase 2 clinical trial in patients with COVID-19, (ii) a $4.5 million increase in license fees, drug supply and phase 1 costs related to IMU-856, (iii) a $1.4 million increase in drug supply costs related to IMU-935, (iv) a $1.2 million increase in drug supply costs related to IMU-838, and (v) a $0.6 million increase in personnel costs. The increases were partially offset by a decrease of $1.5 million related to the phase 2 clinical trial of IMU-838 in patients with RRMS.

- **General and Administrative (G&A) Expenses** were $2.5 million for the three months ended September 30, 2020, as compared to $2.1 million for the same period ended September 30, 2019. The $0.4 million increase was primarily due to increased personnel expenses.

For the nine months ended September 30, 2020, G&A expenses were $7.3 million, as compared to $12.4 million for the same period ended September 30, 2019. The $5.0 million decrease was primarily due to (i) non-recurring costs related to the transaction with Vital Therapies including $6.4 million of stock-based compensation for company executives, key employees and members of the board of directors, and (ii) $2.1 million of non-recurring investment banking and legal fees in the first nine months of 2019. The decrease was partially offset by (i) a $2.3 million increase in personnel expenses, (ii) $1.0 million of increased legal, accounting and consultancy costs, and (iii) $0.2 million of increased costs across numerous categories primarily due to becoming a public company and expanding operations in the United States.

- **Other Income** was $0.6 million for the three months ended September 30, 2020, as compared to $0.9 million for the same period ended September 30, 2019. The $0.3 million decrease was primarily attributable to the $0.4 million difference between the face value and fair value of the promissory note collected in full in September 2019 in connection with the sale of certain assets of Vital Therapies (ELAD Assets), partially offset by the $0.1 million write-off of the investment in Vital Therapies (Beijing) Company Limited (VTL China) included in the ELAD Assets sale.

  For the nine months ended September 30, 2020, other income was $1.9 million, as compared to $1.6 million for the same period ended September 30, 2019. The $0.3 million increase was primarily attributable to $0.7 million of R&D tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia, partially offset by a decrease attributable to (i) the $0.4 million difference between the face value and fair value of the promissory note collected in full in September 2019 in connection with the sale of ELAD Assets offset by the $0.1 million write-off of the investment in VTL China included in the ELAD Assets sale, and (ii) a $0.1 million decrease of recognized income attributable to reimbursements of R&D expenses in connection with the option agreement with Daiichi Sankyo Co., Ltd.

- **Net Loss** for the three months ended September 30, 2020 was approximately $12.9 million, or $0.70 per basic and diluted share, based on 18,405,840 weighted average common shares outstanding, compared to a net loss of approximately $8.2 million, or $0.82 per basic and diluted share, based on 10,022,856 weighted average common shares outstanding for the same period ended September 30, 2019.

  Net loss for the nine months ended September 30, 2020 was approximately $32.9 million, or $2.35 per basic and diluted share, based on 13,966,690 weighted average common shares outstanding, compared to a net loss of approximately $27.2 million, or $3.96 per basic and dilutes share, based on 6,880,057 weighted average common shares outstanding for the same period ended September 30, 2019.

- **Cash and Cash Equivalents,** as of September 30, 2020, were $133.2 million, which management expects to be sufficient to fund operations into the second half of 2022.

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company with a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. Immunic is developing three small molecule products: its lead development program, IMU-838, is 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; IMU-935 is an inverse agonist of RORγt; and IMU-856 targets the restoration of the intestinal barrier function. Immunic announced positive results from its phase 2 EMPhASIS trial of IMU-838 in patients with relapsing-remitting multiple sclerosis, reporting achievement of both primary and key secondary endpoints with high statistical significance. IMU-838 is also in phase 2 clinical development for ulcerative colitis and COVID-19, with an additional phase 2 trial considered in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. 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, 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 IMU-838 to safely and effectively target diseases; clinical data for IMU-838; the timing of current and future clinical trials; the potential for IMU-838 as a treatment for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections associated with coronavirus disease 2019 (COVID-19) and any clinical trials, collaborations and approvals relating to such potential treatment; the future use of the EIB venture loan; the nature, strategy and focus of the company; 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 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, 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 resources to meet business objectives and operational requirements, the fact that the results of earlier studies and 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, 2019, filed with the SEC on March 16, 2020, the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 3, 2020, 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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 11,040	$ 7,102	$ 27,461	$ 16,486
General and administrative	2,505	2,075	7,320	12,360
Total operating expenses	13,545	9,177	34,781	28,846
Loss from operations	(13,545)	(9,177)	(34,781)	(28,846)
Other income:				
Interest income	20	58	48	92
Other income, net	612	904	1,875	1,512
Total other income	632	962	1,923	1,604
Net loss	$ (12,913)	$ (8,215)	$ (32,858)	$ (27,242)
Net loss per share, basic and diluted	$ (0.70)	$ (0.82)	$ (2.35)	$ (3.96)
Weighted-average common shares outstanding, basic and diluted	18,405,840	10,022,856	13,966,690	6,880,057

Immunic, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 133,183	$ 29,369
Other current assets and prepaid expenses	4,358	2,861
Total current assets	137,541	32,230
Property and equipment, net	147	80
Goodwill	32,970	32,970
Right-of-use assets, net	940	633
Other long-term assets	42	42
Total assets	$ 171,640	$ 65,955
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,419	$ 2,423
Accrued expenses	4,253	3,298
Other current liabilities	358	1,351
Total current liabilities	8,030	7,072
Long term liabilities		
Operating lease liabilities	735	520
Total long-term liabilities	735	520
Total liabilities	8,765	7,592
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 20,718,340 and 10,744,806 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	257,394	119,646
Accumulated other comprehensive loss	(1,752)	(1,373)
Accumulated deficit	(92,769)	(59,911)
Total stockholders' equity	162,875	58,363
Total liabilities and stockholders' equity	$ 171,640	$ 65,955