Immunic, Inc. Reports Year End 2020 Financial Results and Highlights Recent Activity

– Phase 3 Program of IMU-838 in Relapsing-Remitting Multiple Sclerosis Expected to Begin in the Second Half of 2021–

– Reported Positive Top-Line Data From Investigator-Sponsored Phase 2 Proof-of-Concept Clinical Trial of IMU-838 in Primary Sclerosing Cholangitis –

– Announced Main Analysis of Phase 2 CALVID-1 Trial of IMU-838 Showing Evidence of Clinical Activity in Patients with Moderate COVID-19 –

– Significantly Bolstered Balance Sheet, Raising Approximately $144.4 Million of Cash During 2020 –

– With $127.5 Million in Cash and Cash Equivalents, Immunic is Funded Into the Second Half of 2022 –

NEW YORK, February 26, 2021 – 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 year ended December 31, 2020 and highlighted recent activity.

"2020 was a year marked by significant operational and clinical milestone achievements across our pipeline, culminating most recently in two important data readouts for our lead asset, selective oral DHODH inhibitor, IMU-838," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "The main analysis of our phase 2 CALVID-1 trial showed evidence of clinical activity in hospitalized patients with moderate COVID-19, a highly encouraging result. The trial generated very meaningful clinical data which indicate that IMU-838 may have potential as a more convenient and highly effective therapeutic option for COVID-19. At the same time, we were also pleased to have just reported positive top-line data from the investigator-sponsored phase 2 proof-of-concept trial of IMU-838 in primary sclerosing cholangitis (PSC), which was conducted at Mayo Clinic. Achievement of a therapeutic benefit, combined with a statistically significant decrease in serum alkaline phosphatase in the per-protocol population and the other liver biochemistry parameters showing a stable pattern, is noteworthy and gives real hope to PSC patients, who currently have no treatment options."

"The strength of these results, including confirmation of the safety and tolerability of IMU-838, speaks volumes about its broad potential in numerous indications. Following the excellent efficacy and safety data from our phase 2 EMPhASIS trial in patients with relapsing-remitting multiple sclerosis (RRMS), which we announced in August and September 2020, respectively, we are on track to file our end-of-phase 2 submissions to regulatory authorities around the end of the first quarter and expect the outcome of the meetings, including our plans for a phase 3 program which we intend to begin in the second half of 2021, to be available around May of this year. Data from our fully enrolled 60-subject Cohort 2 sub-trial of IMU-838 in RRMS, intended to obtain dose response data in patients receiving 10 mg/day of IMU-838 or placebo for 24 weeks, is anticipated at the end of March or in early April, and should serve to de-risk our phase 3 discussions with regulatory authorities."

Dr. Vitt continued, “Our ability to measurably bolster our balance sheet in 2020 reflects investors’ belief in the core value of our technology and pipeline potential, and the approximately $127.5 million in cash and cash equivalents at year-end should fund us through significant clinical milestones into the second half of 2022. Given our progress and expectations for each of our clinical programs, during the fourth quarter of 2020, we announced the formation of a Scientific-Medical Advisory Board. The Board’s inaugural members include some of the most highly distinguished authorities in inflammatory and autoimmune diseases, including Drs. Fred D. Lublin, Bruce E. Sands, Jerrold R. Turner and Paul J. Utz. The experience and guidance of these internationally recognized experts will be invaluable as we continue to advance our pipeline going forward.”

Fourth Quarter 2020 and Subsequent Highlights

- February 2021: Reported positive top-line data from the investigator-sponsored phase 2 proof-of-concept clinical trial of IMU-838 in PSC, conducted in collaboration with investigators at Mayo Clinic. Data showed a statistically significant decrease in serum alkaline phosphatase (ALP) levels (p=0.041) in the 11-patient per-protocol (PP) population after 24-weeks of treatment, as compared to baseline. Additionally, the primary objective, a clinically relevant reduction of serum ALP higher than 25% without an increase in liver biochemistry of more than 33%, was achieved in 27.3% of the patients in the PP population at week 24, as compared to baseline. Other liver biochemistry parameters evaluated, including aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total/direct/indirect bilirubin, remained stable in both the ITT and PP populations, and IMU-838’s favorable safety and tolerability profile was confirmed in the patient population.
- February 2021: Announced top-line clinical efficacy, safety, disease marker and virology data from the main analysis of the phase 2 CALVID-1 trial of IMU-838 in hospitalized patients with moderate COVID-19. While primary and key secondary endpoints were not evaluable due to the very low rates of serious complications in the study population of hospitalized patients with moderate COVID-19, the data did show clinical activity based on multiple secondary endpoints, including (1) clinically meaningful improvements in time to clinical recovery and time to clinical improvement; (2) a substantial treatment effect on high-risk patients and those over 65 years of age; (3) an anti-viral effect of IMU-838 on SARS-CoV-2, as observed by viral titers; (4) a robust anti-inflammatory effect, based on a more effective reduction of C-Reactive Protein (CRP) in treated patients, as compared to placebo; and (5) an indication, based on initial data from a post hoc analysis of “Long COVID” symptoms, that IMU-838 may have the potential to contribute to the prevention of long-term fatigue. IMU-838 was also found to be safe and well-tolerated in hospitalized patients with moderate COVID-19.
- December 2020: Announced Immunic’s addition to the Nasdaq Biotechnology Index, which is designed to track the performance of a set of securities listed on The Nasdaq Stock Market® that are classified as either biotechnology or pharmaceutical according to the Industry Classification Benchmark.
- November 2020: Announced the formation of a Scientific-Medical Advisory Board. Initial members include Drs. Fred D. Lublin, Bruce E. Sands, Jerrold R. Turner and Paul J. Utz, all internationally recognized experts in their respective fields of inflammatory and autoimmune diseases.

- 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.

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

As previously announced, the full unblinded clinical data 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, the 30 and 45 mg/day doses of IMU-838 appear 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 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 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 is conducting an additional, small Cohort 2 sub-trial to obtain exploratory data on the expanded dose response of IMU-838, as previously announced. This additional, double-blind assessment, now fully enrolled, includes a cohort of approximately 60 patients who receive 10 mg/day of IMU-838 or placebo for 24 weeks. The results are not expected to change any conclusions for dosing of IMU-838 in a future phase 3 program. Rather, the sub-trial is expected to provide additional data to address any potential regulatory requests in the context of the design of a phase 3 program. An unblinded interim analysis of selected MRI data is planned after all Cohort 2 patients have completed week 12 MRI assessments. The Company expects this data to be available at the end of March or in early April 2021. Immunic believes that the foregoing strategy for IMU-838 in RRMS will enable risk reduction for end-of-phase 2 discussions with regulatory agencies.

Immunic intends to submit formal end-of-phase 2 meeting requests to discuss the proposed phase 3 program with major regulatory authorities around the end of the first quarter of 2021. The outcome of the end-of-phase 2 meetings are expected to be available in or about May 2021. As previously announced, 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. Immunic plans to announce details on the design of the envisaged phase 3 program in RRMS after its end-of-phase 2 meetings with regulatory authorities. The phase 3 program is expected to start in the second half of 2021.

Additional Anticipated Clinical Milestones

- **IMU-838 in COVID-19:** A final analysis of all 223 randomized patients from the phase 2 CALVID-1 trial, which will comprise data on all endpoints, including subgroup and sensitivity analyses, is expected to be available in the second quarter of 2021.

- **IMU-838 in Ulcerative Colitis (UC):** Recruitment of the phase 2 CALDOSE-1 trial of IMU-838 in patients with UC is expected to be completed in the second half of 2021 and top-line data of the induction phase is expected to be available in the first half of 2022, as previously announced.
- **IMU-935 phase 1 program:** The current, single ascending dose (SAD) part of the ongoing phase 1 trial of IMU-935 is planned to be followed by a multiple ascending dose (MAD) portion in healthy volunteers, which is expected to start in the first quarter of 2021. Unblinded safety data from the SAD and MAD parts in healthy volunteers is expected to be available in the second half of 2021. Initiation of the third portion of the phase 1 trial in patients with mild-to-moderate psoriasis is expected around mid-2021 and is expected to last approximately 12 months.
- **Potential IMU-935 phase 2 trial in Guillain-Barré syndrome:** Upon completion of at least the first two cohorts of the MAD portion in healthy volunteers of the ongoing phase 1 trial, Immunic anticipates that it may also begin a phase 2a proof-of-concept clinical trial of IMU-935 in Guillain-Barré syndrome. This orphan approach may allow for an accelerated path to approval, in parallel to IMU-935's previously planned development in psoriasis. The company plans to announce additional details as soon as design and timing of the envisaged trial are defined.
- **IMU-856 phase 1 program**: The current, SAD part of the ongoing phase 1 trial of IMU-856 is planned to be followed by a MAD portion in healthy volunteers, which is expected to start in the first quarter of 2021. Unblinded safety data from the SAD and MAD parts in healthy volunteers is expected to be available in the second half of 2021. Initiation of the third portion of the phase 1 trial in patients with several diseases involving bowel barrier dysfunction is expected in the second half of 2021.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $38.6 million for the twelve months ended December 31, 2020, as compared to $22.5 million for the same period ended December 31, 2019. The $16.1 million increase was primarily due to (i) a $9.6 million increase in external development costs for IMU-838 related to the phase 2 clinical trial in patients with COVID-19 since the trial was started in 2020, (ii) a $5.0 million increase in license fees, drug supply and phase 1 costs related to IMU-856 since this trial ramped up in 2020, (iii) a $2.1 million increase in drug supply, phase 1 and preclinical costs related to IMU-935 since this trial ramped up in 2020, (iv) a $1.5 million increase in personnel costs, (v) a $0.7 million increase in drug supply costs related to IMU-838, and (vi) a $0.7 million increase for a bioequivalence study related to IMU-838. The increases were partially offset by (i) a $2.0 million decrease related to the phase 2 clinical trial of IMU-838 in patients with RRMS as the clinical trial came to an end in 2020, and (ii) a $1.5 million decrease in costs related to a phase 2 clinical trial in patients with Crohn's disease.

- **General and Administrative (G&A) Expenses** were $10.3 million for the twelve months ended December 31, 2020, as compared to $14.5 million for the same period ended December 31, 2019. The $4.2 million decrease was primarily due to (i) $5.1 million lower stock compensation expense as a result of non-recurring costs recorded in 2019 related to the transaction with Vital Therapies, (ii) $0.9 million of decreased legal, accounting and consultancy costs, and (iii) a $0.7 million decrease in travel costs due to worldwide travel restrictions in connection with the COVID-19 pandemic. The decrease was partially offset by (i) a $2.2 million increase in personnel expenses, and (ii) $0.3 million of increased costs across numerous categories.

- **Other Income** was $5.0 million for the twelve months ended December 31, 2020, as compared to $2.1 million for the same period ended December 31, 2019. The $2.9 million increase was primarily attributable to (i) a $2.5 million foreign exchange gain on a $68.0 million intercompany loan between Immunic, Inc. and Immunic AG, and (ii) a $0.9 million increase in R&D tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia. This increase was partially offset by (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 certain assets of Vital Therapies (ELAD Assets), offset by the $0.1 million write-off of the investment in Vital Therapies (Beijing) Company Limited included in the ELAD Assets sale, and (ii) a $0.2 million decrease of recognized income attributable to reimbursements of R&D expenses in connection with the option and licensing agreement with Daiichi Sankyo Co., Ltd.

- **Net Loss** for the twelve months ended December 31, 2020 was approximately $44.0 million, or $2.81 per basic and diluted share, based on 15,663,826 weighted average common shares outstanding, compared to a net loss of approximately $35.0 million, or $4.52 per basic and diluted share, based on 7,722,269 weighted average common shares outstanding for the same period ended December 31, 2019.

- **Cash and Cash Equivalents,** as of December 31, 2020, were $127.5 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. The company is developing three small molecule products: its lead development program, 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, ulcerative colitis, Crohn's disease, COVID-19, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγt, is targeted for development in psoriasis and Guillain-Barré syndrome. 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, 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 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, 2020, filed with the SEC on February 26, 2021, 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.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Years Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 38,637	$ 22,512
General and administrative	10,334	14,520
Total operating expenses	48,971	37,032
Loss from operations	(48,971)	(37,032)
Other income:		
Interest income	58	107
Other income, net	4,896	1,992
Total other income	4,954	2,099
Net loss	$ (44,017)	$ (34,933)
Net loss per share, basic and diluted	$ (2.81)	$ (4.52)
Weighted-average common shares outstanding, basic and diluted	15,663,826	7,722,269

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 127,452	$ 29,369
Other current assets and prepaid expenses	6,293	2,861
Total current assets	133,745	32,230
Property and equipment, net	203	80
Goodwill	32,970	32,970
Right of use asset, net	901	633
Other long-term assets	42	42
Total assets	$ 167,861	$ 65,955
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,700	$ 2,423
Accrued expenses	4,318	3,298
Other current liabilities	379	1,351
Total current liabilities	8,397	7,072
Long-term liabilities:		
Operating lease liabilities	679	520
Total long-term liabilities	679	520
Total liabilities	9,076	7,592
Commitments and contingencies (note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 21,168,240 and 10,744,806 shares issued and outstanding at December 31, 2020 and 2019, respectively	2	1
Additional paid-in capital	266,823	119,646
Accumulated other comprehensive loss	(4,112)	(1,373)
Accumulated deficit	(103,928)	(59,911)
Total stockholders' equity	158,785	58,363
Total liabilities and stockholders' equity	$ 167,861	$ 65,955