Immunic, Inc. Reports First Quarter 2021 Financial Results and Highlights Recent Activity

– EMPhASIS Cohort 2 Interim Analysis Confirmed 30 mg Dose of IMU-838 as Most Appropriate for Planned Phase 3 Program in Relapsing-Remitting Multiple Sclerosis, Expected to Begin in the Second Half of 2021 –

– Secured Full Rights to IMU-838 with Settlement of Remaining Royalty Obligation to 4SC AG for $17.25 Million (50% in Cash and 50% in Shares of Immunic's Common Stock) –

– $114.8 Million in Cash and Cash Equivalents Expected to Fund Immunic Into the Second Half of 2022 –

NEW YORK, May 6, 2021 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company focused on developing best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced financial results for the first quarter ended March 31, 2021 and highlighted recent activity.

"Our clinical program activities have continued unabated, with significant progress having recently been achieved for our lead asset, selective oral DHODH inhibitor, IMU-838," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Last month, we announced key interim data from our phase 2 EMPhASIS Cohort 2 sub-trial of IMU-838 in patients with relapsing-remitting multiple sclerosis (RRMS), confirming 30 mg as the most appropriate dose for our envisaged phase 3 program. We will now move directly to the filing of an Investigational New Drug (IND) application in the United States and are currently working to complete the package, with the expectation of initiating the phase 3 program in the second half of this year."

"Beyond RRMS, during the first quarter, we reported positive top-line data from the investigator-sponsored, open-label phase 2 proof-of-concept trial of IMU-838 in primary sclerosing cholangitis (PSC), conducted in collaboration with the Mayo Clinic. Results confirmed safety and tolerability and provided encouraging activity signals. In order to find the optimized dose for future clinical activities in PSC, we plan to initiate a phase 1 trial in hepatic impaired patients. Backed by the promising results from our phase 2 CALVID-1 trial of IMU-838 which underlined its broad antiviral activity, our phase 2 trial in ulcerative colitis (UC) has seen recent strong recruitment which we expect to be completed in the second half of this year."

Dr. Vitt added, "With the ongoing accumulation of robust data for IMU-838, including repeated confirmation of safety and efficacy across multiple indications, we made a strategic decision during the first quarter to settle our remaining royalty obligation to 4SC AG, giving us full rights to our most advanced asset and securing our ability to unlock its future potential."

First Quarter 2021 and Subsequent Highlights

- April 2021: Announced EMPhASIS interim analysis of 10 mg Cohort 2 confirming IMU-838's dose response in RRMS and supporting phase 3 dose selection. Previously published data from Cohort 1, together with Cohort 2 data from 59 randomized patients who completed week 12 magnetic

resonance imaging assessments, confirmed that 30 mg once daily IMU-838 is the most appropriate dose for the company's planned phase 3 program in RRMS.

- March 2021: Announced the signing of an agreement with 4SC AG to settle the remaining obligation of a 4.4% royalty on net sales of IMU-838, for $17.25 million. The payment was made 50% in cash and 50% in shares of Immunic's common stock. No further payment obligations remain between Immunic and 4SC AG.
- 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, 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. The data showed clinical activity based on multiple secondary endpoints and confirmed IMU-838 to be safe and well-tolerated in this patient population.

  Meanwhile, additional available data from the full analysis of all 223 randomized patients support the conclusions made in the main analysis and have provided data on a few additional endpoints. Notably, the rate and timing of anti-SARS-CoV-2 antibodies patients are developing in response to the infection was found to be identical between the IMU-838 and placebo treatment arms. The full analysis was also able to detect a relationship between drug trough levels in blood plasma and the clinical recovery endpoint.

  With the progressing rollout of vaccines in many countries, however, the company believes that the opportunity to execute a phase 3 program as a monotherapy and to benefit from any potential commercialization in this indication within a reasonable time frame is no longer viable.

Anticipated Clinical Milestones

- **IMU-838 in RRMS:** As previously announced, Immunic remains in discussions with regulatory authorities, including the FDA and the European Medicines Agency, regarding the planned phase 3 program in RRMS. At the FDA's request, the company is proceeding directly to submission of an IND application, instead of holding an end-of-phase 2 meeting. Feasibility and other preparatory activities for the phase 3 program are ongoing and initiation is expected in the second half of 2021.
- **IMU-838 in 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-838 in PSC:** Immunic plans to perform a phase 1 trial in hepatic impaired patients which will allow for dose optimization of IMU-838 for potential future clinical activities in PSC.
- **IMU-935 phase 1 program:** Based on a positive outcome of the single ascending dose (SAD) cohort of the phase 1 trial of IMU-935, the company received approval from the Ethics Committee in Australia, during first quarter of 2021, to proceed with the multiple ascending dose (MAD) portion of the trial and subjects in the first cohort are currently being dosed. Unblinded safety, pharmacodynamics and pharmacokinetics data from the SAD and MAD parts in healthy volunteers is expected to be available in the second half of 2021. Initiation of a third portion of

the phase 1 trial in patients with mild-to-moderate psoriasis is expected in the third quarter of 2021 and is anticipated to last approximately 12 months.

- **IMU-856 phase 1 program**: The SAD part of the ongoing phase 1 trial of IMU-856 has been completed. Based on the favorable data available, the company expects to receive clearance from the Ethics Committee in Australia to proceed to the MAD part in healthy volunteers, in the near future. 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 $11.5 million for the three months ended March 31, 2021, as compared to $6.4 million for the same period ended March 31, 2020. The $5.1 million increase was primarily due to (i) a $1.7 million increase in external development costs related to the phase 2 clinical trial in patients with COVID-19 as trials did not start until the second quarter of 2020, (ii) a $1.4 million increase in drug supply costs related to IMU-838 to support the company's ongoing and future clinical trials, (iii) a $0.9 million increase in preparation costs related to the phase 3 program of IMU-838 in multiple sclerosis, (iv) $0.4 million related to increased cost for the ulcerative colitis trial, and (v) $0.7 million related to increased costs across numerous categories.

- **General and Administrative (G&A) Expenses** were $20.9 million for the three months ended March 31, 2021, as compared to $2.6 million for the same period ended March 31, 2020. The $18.3 million increase was primarily due to (i) a $17.3 million settlement of royalty obligations to 4SC AG, and (ii) a $1.3 million increase in personnel expenses of which $1.2 million is related to non-cash stock compensation expense, partially offset by a $0.3 million decrease in travel related costs.

- **Other Income (Expense)** was $(2.1) million for the three months ended March 31, 2021, as compared to $0.5 million for the same period ended March 31, 2020. The $2.6 million decrease was primarily attributable to (i) a $2.5 million foreign exchange loss on a $52.0 million intercompany loan between Immunic, Inc. and Immunic AG, and (ii) a $0.4 million decrease in recognized deferred income attributable to reimbursements of R&D expenses in connection with the option agreement with Daiichi Sankyo Co., Ltd. realized in the first quarter of 2020. The decrease was partially offset by a $0.2 million increase in R&D tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia.

- **Net Loss** for the three months ended March 31, 2021 was approximately $34.5 million, or $1.63 per basic and diluted share, based on 21,174,698 weighted average common shares outstanding, compared to a net loss of approximately $8.5 million, or $0.79 per basic and diluted share, based on 10,749,460 weighted average common shares outstanding for the same period ended March 31, 2020.

- **Cash and Cash Equivalents** as of March 31, 2021 were $114.8 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 relating to Immunic's three development programs and the targeted diseases; the potential for Immunic's development programs to safely and effectively target diseases; clinical data for Immunic's development programs; the timing of current and future clinical trials; 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 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.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 11,519	$ 6,434
General and administrative	20,868	2,580
Total operating expenses	32,387	9,014
Loss from operations	(32,387)	(9,014)
Other income (expense):		
Interest income	28	24
Other income (expense), net	(2,175)	503
Total other income (expense)	(2,147)	527
Net loss	$ (34,534)	$ (8,487)
Net loss per share, basic and diluted	$ (1.63)	$ (0.79)
Weighted-average common shares outstanding, basic and diluted	21,174,698	10,749,460

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

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 114,839	$127,452
Other current assets and prepaid expenses	5,441	6,293
Total current assets	120,280	133,745
Property and equipment, net	190	203
Goodwill	32,970	32,970
Right-of-use assets, net	1,242	901
Other long-term assets	42	42
Total assets	$ 154,724	$167,861
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,048	$ 3,700
Accrued expenses	5,827	4,318
Other current liabilities	481	379
Total current liabilities	16,356	8,397
Long term liabilities		
Operating lease liabilities	922	679
Total long-term liabilities	922	679
Total liabilities	17,278	9,076
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at March 31, 2021 and December 31, 2020	—	—
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 March 31, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	277,027	266,823
Accumulated other comprehensive loss	(1,121)	(4,112)
Accumulated deficit	(138,462)	(103,928)
Total stockholders' equity	137,446	158,785
Total liabilities and stockholders' equity	$ 154,724	$167,861