- Study Meets Primary and Key Secondary Endpoints with High Statistical Significance Indicating Activity for IMU-838 in Relapsing-Remitting Multiple Sclerosis -

- Statistically Significant Reduction of 62% and 70% in Combined Unique Active Magnetic Resonance Imaging Lesions in 45mg and 30mg Patient Cohorts, As Compared to Placebo -

- Data Supports Previously Observed Favorable Safety Profile of IMU-838 in Relapsing-Remitting Multiple Sclerosis Patient Population -

- Company Also Reports Second Quarter 2020 Financial Results With $48.6 Million in Cash and Cash Equivalents -

- Conference Call and Webcast to be Held on August 3, 2020 at 8:30am ET -

NEW YORK, Aug. 2, 2020 /PRNewswire/ -- **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 positive top-line data from its phase 2 EMPhASIS trial of lead asset, IMU-838, the company's selective oral DHODH inhibitor, in patients with relapsing-remitting multiple sclerosis (RRMS). The study achieved all primary and key secondary endpoints, indicating activity in RRMS patients. In particular, the study met its primary endpoint, demonstrating a statistically significant reduction in the cumulative number of combined unique active (CUA) magnetic resonance imaging (MRI) lesions up to week 24 in patients receiving 45mg of IMU-838 once daily, by 62% (p=0.0002), as compared to placebo. The study also met its key secondary endpoint, showing a statistically significant reduction in the cumulative number of CUA MRI lesions for the 30mg once daily dose, by 70% (p<0.0001), as compared to placebo.

		IMU-838	Placebo	Suppression of CUA MRI Lesions	p-value (1-sided)
Primary Endpoint	45 mg IMU-838 vs. Placebo	N=69	N=69	**62%**	**0.0002**
Key Secondary Endpoint	30 mg IMU-838 vs. Placebo	N=71		**70%**	**<0.0001**

All other secondary endpoints, including those based on other MRI parameters and on clinical endpoints such as relapse events, also provided a noticeable signal and numerical benefit for the IMU-838 treatment groups, as compared to placebo. Given the study's design, sample size and the patient's follow-up duration, full statistical analysis of these secondary endpoints was not deemed appropriate or included in the analysis plan. Nonetheless, we believe data on these endpoints provides useful information for the further development path towards potential approval.

Consistent with prior data sets in other patient populations, administration of IMU-838 in this trial was observed to be safe and well-tolerated, thereby providing evidence of an attractive target product profile for IMU-838 in the RRMS patient population. The rate of treatment-emergent adverse events was 42.9% of IMU-838-treated patients compared with 43.5% of patients on placebo. Likewise, serious treatment-emergent adverse events were rare and only observed in 3 out of 140 IMU-838-treated patients, and in 1 out of 69 patients on placebo. The rate of treatment withdrawals in the 24-week blinded treatment period was only 5.0% in the pooled IMU-838 treatment arms versus 7.2% in the placebo group. In addition, the rate of discontinuations due to adverse events or protocol-specified discontinuation criteria were equivalent between the pooled IMU-838 treatment arms and placebo. There was no increase in liver or renal events for the IMU-838 treatment arms versus placebo. Analysis of the full EMPhASIS data is ongoing and will be presented at an upcoming scientific meeting.

"Patients in the EMPhASIS trial exhibited robust responses across all study endpoints included in the top-line analysis. In addition to showing consistent activity by IMU-838 in RRMS using different measures, the study data also supports the previously observed favorable safety and tolerability profile of IMU-838 in RRMS patients," commented Andreas Muehler, M.D., Chief Medical Officer of Immunic. "We believe this data strongly supports our goal of developing IMU-838 as an easy, safe and convenient oral treatment option for patients with RRMS and other autoimmune diseases. We are extremely encouraged by these results and intend to now focus on the development plan with the goal of eventually making IMU-838 available as a best-in-class, once-daily oral therapy for RRMS."

The phase 2 EMPhASIS trial was an international, multicenter, double-blind, placebo-controlled, randomized, parallel-group study, designed to assess the efficacy and safety of IMU-838 in patients with RRMS. Of the 210 patients randomized in 36 centers across four European countries, 209 patients received at least one dose of IMU-838 or placebo (placebo n=69, 30mg IMU-838 n=71, 45mg IMU-838 n=69), and 197 patients completed the blinded 24-week treatment period. All enrolled patients were required to have shown disease activity based on clinical evidence of relapse and additional MRI criteria. The primary and key secondary endpoints were the cumulative number of CUA MRI lesions, up to week 24, for 45mg and 30mg of IMU-838, respectively. MRI was performed at baseline and at weeks 6, 12, 18 and 24, and was evaluated centrally by an independent, blinded MRI reader. The study includes an optional, extended treatment period for up to 9.5 years to evaluate long-term safety and tolerability of IMU-838.

"These positive phase 2 results impressively show the robust activity of IMU-838 in RRMS and provide further evidence of the favorable safety profile already observed in other patient populations, representing more than 650 human subjects and patients, to date," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "We believe that these phase 2 data of IMU-838 speak volumes about its potential to provide a new, convenient, once daily oral front-line treatment option to patients suffering from RRMS, bolstered by a unique combination of potential efficacy, safety and tolerability. Given the strength of these top-line results, we will continue to prepare a clinical phase 3 program for IMU-838 in RRMS and, after a full review of the data, anticipate providing a further update on development strategy. We are also looking forward to reading out clinical data from the other ongoing phase 2 trials of IMU-838 in COVID-19, primary sclerosing cholangitis and ulcerative colitis in the upcoming months."

Second Quarter 2020 and Subsequent Highlights

- July 2020: Enrolled the first patients in investigator-sponsored phase 2, IONIC clinical trial of IMU-838 in combination with oseltamivir (Tamiflu®) for the treatment of patients with moderate-to-severe COVID-19, in collaboration with sponsor and lead site, University Hospitals Coventry and Warwickshire NHS Trust.
- June 2020: Dosed the first patients in CALVID-1 clinical trial, a prospective, multicenter, randomized, placebo-controlled, double-blind phase 2 trial of IMU-838 in patients with moderate COVID-19.
- June 2020: Completed a $25.0 million public offering of common stock.
- June 2020: Announced company's addition to the Russell 3000® Index.
- May 2020: Held its first R&D Day to discuss current treatment options for, and the unmet medical needs of, chronic inflammatory and autoimmune diseases, as well as clinical progress of the company's development programs. The presentation included preclinical data of IMU-838 against SARS-CoV-2 as well as first pharmacokinetic data from the ongoing single ascending dose part of the phase 1 clinical trial of IMU-935.
- April 2020: Reported several changes to the company's executive team, including the promotion of Glenn Whaley to the position of Vice President Finance, Principal Financial and Accounting Officer and the announcement that Duane Nash, MD, JD, MBA, current Chairman of the Board of Directors, has temporarily assumed the role of Executive Chairman.
- April 2020: Announced that IMU-838 has successfully demonstrated preclinical activity against clinical isolates of SARS-CoV-2 associated with COVID-19.
- April 2020: Completed a $15.0 million registered direct offering led by institutional investor, Altium Capital.

Financial and Operating Results

Research and Development (R&D) Expenses were $10.0 million for the three months ended June 30, 2020, as compared to $6.0 million for the same period ended June 30, 2019. The $4.0 million increase was primarily attributable to (i) a $2.2 million increase in external development costs for lead development program, IMU-838, related to the phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis, ulcerative colitis and COVID-19, (ii) a $1.0 million increase in drug supply costs related to IMU-838, (iii) a $1.0 million increase in preclinical, drug supply and phase 1 preparation costs related to IMU-856, (iv) a $1.0 million increase in costs due to drug supply and the start of the phase 1 trial in September 2019 for the IMU-935 program and (v) $0.3 million of increased employee costs. The increase was partially offset by a contingent payment under the asset purchase agreement with 4SC AG settled in stock valued at $1.5 million at the transaction with Vital Therapies in the second quarter of 2019.

For the six months ended June 30, 2020, R&D expenses were $16.4 million compared to $9.4 million for the same period ended June 30, 2019. The $7.0 million increase was primarily attributable to (i) a $3.2 million increase in external development costs for lead development program, IMU-838, related to the phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis, ulcerative colitis and COVID-19, (ii) a $1.2 million increase in drug supply costs related to IMU-838, (iii) $2.2 million of an increase in license fees, preclinical, drug supply and phase 1 preparation costs related to IMU-856, (iv) $1.2 million in costs for drug supply and the start of the phase 1 trial in September 2019 for the IMU-935 program and (v) $0.7 million of increased employee and other costs. The increase was offset by a contingent payment under the asset purchase agreement with 4SC AG settled in stock valued at $1.5 million at the transaction with Vital Therapies in the second quarter of 2019.

General and Administrative (G&A) Expenses were $2.2 million for the three months ended June 30, 2020, as compared to $9.0 million for the same period ended June 30, 2019. The $6.7 million improvement is primarily due to one-time costs related to the transaction with Vital Therapies including $6.4 million of stock-based compensation for the executives, key employees and members of the board of directors and $1.2 million in investment banking and legal fees in the second quarter of 2019. The decrease was offset by a $0.9 million increase in personnel and other expenses.

For the six months ended June 30, 2020, G&A expenses were $4.8 million compared to $10.3 million for the same period ended June 30, 2019. The $5.5 million improvement was primarily due to one-time costs related to the transaction with Vital Therapies including $6.4 million of stock-based compensation for the executives, key employees and members of the board of directors and $2.1 million in investment banking and legal fees in the first six months of 2019. The decrease was partially offset by (i) a $1.6 million increase in personnel expenses, (ii) $0.8 million of increased legal and consultancy costs and (iii) $0.6 million of increased costs across numerous categories primarily due to becoming a public company and expanding operations into the United States.

Other Income was $0.8 million for the three months ended June 30, 2020, as compared to $0.3 million for the same period ended June 30, 2019. The $0.5 million increase was primarily attributable to (i) $0.2 million of research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia and (ii) $0.3 million recognized deferred income attributable to reimbursements of research and

development expenses in connection with the option and license agreement with Daiichi Sankyo.

For the six months ended June 30, 2020, other income was $1.3 million compared to $0.6 million for the same period ended June 30, 2019. The $0.6 million increase was primarily attributable to (i) $0.3 million of research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia and (ii) $0.3 million recognized deferred income attributable to reimbursements of research and development expenses in connection with the option and license agreement with Daiichi Sankyo.

Net Loss for the three months ended June 30, 2020 was approximately $11.5 million, or $0.90 per basic and diluted share, based on 12,695,989 weighted average common shares outstanding, compared to a net loss of approximately $14.7 million, or $1.52 per basic and diluted share, based on 9,669,129 weighted average common shares outstanding for the same period ended June 30, 2019.

Net loss for the six months ended June 30, 2020 was approximately $19.9 million, or $1.70 per basic and diluted share, based on 11,722,725 weighted average common shares outstanding, compared to a net loss of approximately $19.0 million, or $3.60 per basic and dilutes share, based on 5,282,412 weighted average common shares outstanding for the same period ended June 30, 2019.

Cash and Cash Equivalents, as of June 30, 2020, were $48.6 million, which management expects to be sufficient to fund operations beyond twelve months from the date of the issuance of this earnings release.

Conference Call and Webcast Information

Immunic's management team will host a public conference call and webcast on August 3, 2020 at 8:30 a.m. Eastern Time to provide a corporate update and to discuss the top-line data from the phase 2 EMPhASIS trial of IMU-838 in relapsing-remitting multiple sclerosis.

To participate in the conference call, dial 1-877-870-4263 (USA) or 1-412-317-0790 (International) and ask to be joined into the Immunic, Inc. call. A live, listen-only webcast of the conference call can be accessed at https://www.webcaster4.com/Webcast/Page/2301/35524 or on the "Events and Presentations" section of Immunic's website at ir.imux.com/events-and-presentations.

An archived replay of conference call and webcast will be available approximately one hour after the completion for one year on Immunic's website at: ir.imux.com.

About Relapsing-Remitting Multiple Sclerosis
Multiple sclerosis (MS) is an autoimmune disease that affects the brain, spinal cord and optic nerve. In MS, myelin, the coating that protects the nerves, is attacked and damaged by the immune system. Thus, MS is considered an immune-mediated demyelinating disease of the central nervous system. Relapsing-remitting MS (RRMS) is the most common form of the disease. Approximately 85% of patients with MS are expected to develop RRMS, with some of these patients later developing more progressive forms of the disease. RRMS is characterized by clearly defined attacks of new or increasing neurologic symptoms. These relapses are followed by periods of remission, or partial or complete recovery. During remissions, all symptoms may disappear, or some symptoms may continue and become permanent. MS is a progressive disease which, without effective treatment, leads to severe disability. MS affects more than 700,000 people in the United States, and more than 2.2 million people worldwide. The disease mainly affects young adults of prime working age, although MS can occur at any age. MS is at least two to three times more common in women than in men.

About IMU-838
IMU-838 is an orally available, next-generation selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme dihydroorotate dehydrogenase (DHODH). IMU-838 acts on activated T and B cells while leaving other immune cells largely unaffected and allows the immune system to stay functioning, e.g. in fighting infections. In previous trials, IMU-838 did not show an increased rate of infections compared to placebo. In addition, DHODH inhibitors, such as IMU-838, are known to possess a host-based antiviral effect, which is independent with respect to specific virus proteins and their structure. Therefore, DHODH inhibition may be broadly applicable against multiple viruses. IMU-838 was successfully tested in two phase 1 clinical trials in 2017 and is currently being tested in phase 2 trials in patients with COVID-19, relapsing-remitting multiple sclerosis and ulcerative colitis. Furthermore, Immunic's collaboration partner, the Mayo Clinic, has started an investigator-sponsored proof-of-concept clinical trial testing IMU-838 activity in patients with primary sclerosing cholangitis. To date, IMU-838 has already been tested in about 650 individuals and has shown an attractive pharmacokinetic, safety and tolerability profile. IMU-838 is not yet licensed or approved in any country and has not been demonstrated to be safe or effective for any use.

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. The company is developing three small molecule products: 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. IMU-838 is in phase 2 clinical development for COVID-19, relapsing-remitting multiple sclerosis and ulcerative colitis, 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, including relapsing-remitting multiple sclerosis; preclinical and clinical data for IMU-838; the timing of current and future clinical trials; the availability, safety or efficacy of potential treatment options for patients with relapsing-remitting multiple sclerosis or other conditions, if any, that may be supported by the Company's phase 2 EMPhASIS trial data; future analysis of the EMPhASIS trial data and presentations related thereto; the potential availability and frequency of administration of IMU-838 as a potential treatment for patients with relapsing-remitting multiple sclerosis or for patients with other conditions; the potential for IMU-838 as a treatment for patients with relapsing-remitting multiple sclerosis or for patients with 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 treatments; preparations for a clinical phase 3 program for IMU-838 in relapsing-remitting multiple sclerosis; future readouts of clinical data from phase 2 trials of IMU-838 in COVID-19; 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 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 quarterly period 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 9,987	$ 6,029	$ 16,421	$ 9,384
General and administrative	2,235	8,978	4,815	10,285
Total operating expenses	12,222	15,007	21,236	19,669

Loss from operations	(12,222)	(15,007)	(21,236)	(19,669)
Other income:				
Interest income	4	34	28	34
Other income, net	760	259	1,263	608
Total other income	764	293	1,291	642
Net loss	$ (11,458)	$ (14,714)	$ (19,945)	$ (19,027)
Net loss per share, basic and diluted	$ (0.90)	$ (1.52)	$ (1.70)	$ (3.60)
Weighted-average common shares outstanding, basic and diluted	12,695,989	9,669,129	11,722,725	5,282,412

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

	June 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 48,607	$ 29,369
Other current assets and prepaid expenses	4,416	2,861
Total current assets	53,023	32,230
Property and equipment, net	121	80
Goodwill	32,970	32,970
Right-of-use assets, net	996	633
Other long-term assets	42	42
Total assets	$ 87,152	$ 65,955
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,728	$ 2,423
Accrued expenses	5,450	3,298
Other current liabilities	496	1,351
Total current liabilities	7,674	7,072
Long term liabilities		
Operating lease liabilities	793	520
Total long-term liabilities	793	520
Total liabilities	8,467	7,592
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 14,968,340 and 10,744,806 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	160,148	119,646
Accumulated other comprehensive loss	(1,608)	(1,373)
Accumulated deficit	(79,856)	(59,911)
Total stockholders' equity	78,685	58,363
Total liabilities and stockholders' equity	$ 87,152	$ 65,955

SOURCE Immunic, Inc.