- Received FDA Clearance to Initiate Twin IMU-838 Phase 3 ENSURE Trials in Relapsing-Remitting Multiple Sclerosis and Supportive Phase 2 CALLIPER Trial in Progressive Multiple Sclerosis -

- Reported In Vitro Data Showing That IMU-935 May Inhibit the Generation of Th17 Cells and Production of IL-17 Cytokines Without Impairing RORγt Function Required for Normal Thymocyte Development -

- Reported Preclinical Data Establishing IMU-935 as a Potential Treatment for Castration-Resistant Prostate Cancer; Preparing for a Phase 1 Clinical Trial -

- $87.2 Million in Cash and Cash Equivalents as of June 30, 2021 and the Additional $45.0 Million Raised in July are Expected to Fund Immunic Into 2023 -

NEW YORK, Aug. 6, 2021 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX),** a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases, today announced financial results for the second quarter ended June 30, 2021 and highlighted recent activity.

"So far this year, we have made outstanding progress with both our selective oral DHODH inhibitor, IMU-838, as well as IMU-935, a highly potent and selective inverse agonist of the transcription factor RORγt, enabling what we believe will be an eventful and potentially transformative first half of 2022. In particular, we anticipate five data read-outs from clinical trials within the next twelve months, and expect to begin our first phase 3 program very soon. I want to congratulate our entire team for this remarkable momentum," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "In June, we received U.S. Food and Drug Administration (FDA) clearance for our Investigational New Drug (IND) application for the phase 3 ENSURE program of IMU-838 in patients with relapsing-remitting multiple sclerosis (RRMS), and the supportive phase 2 CALLIPER trial in patients with progressive multiple sclerosis (PMS). Initiation of these trials in the second half of this year will mark a major milestone for our lead program. Additionally, we look forward to completing recruitment of our ongoing phase 2 CALDOSE-1 trial of IMU-838 in patients with ulcerative colitis (UC) during the second half of 2021, and reporting top-line data for this potential second key indication for IMU-838 in the first half of 2022."

"At our virtual R&D Day just last month, we presented very encouraging *in vitro* data showing that IMU-935 may inhibit both the generation of Th17 cells and the production of IL-17 cytokines that are responsible for the development of autoimmune diseases, without impairing thymocyte development, thereby avoiding a potential risk for lymphoma that has complicated third-party programs in this space. We also detailed highly encouraging new preclinical data which suggests that IMU-935 can affect castration-resistant prostate cancer (CRPC) both directly by reducing androgen receptor (AR) expression via RORγ and inhibiting tumor growth, and indirectly by inhibiting tumorigenesis-promoting Th17 and IL-17. Based on the strength of this data, we are preparing a phase 1 trial in metastatic CRPC (mCRPC) patients with Johann Sebastian de Bono, M.D., Ph.D., Regius Professor of Cancer Research and Professor in Experimental Cancer Medicine, The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust, London, United Kingdom, acting as the Principal Investigator. We expect this trial to commence during the fourth quarter of this year and also anticipate availability of initial human data from moderate-to-severe psoriasis patients from our phase 1 trial of IMU-935 during the second quarter of 2022."

Dr. Vitt added, "As previously announced, at the end of the first quarter of 2021, we settled our remaining royalty obligation to 4SC AG for both IMU-838 and IMU-935, for $17.3 million, which was paid 50% in cash and 50% in shares of Immunic's common stock during the second quarter. This strategic decision provides us with 100% of the future sales potential of our two lead programs and should drive significant value for our shareholders. Last month, we were able to offset this payment by bolstering our balance sheet with a $45.0 million financing, providing us with anticipated runway through multiple value inflection points into 2023."

Second Quarter 2021 and Subsequent Highlights

- July 2021: Completed a $45.0 million underwritten public offering of common stock.
- July 2021: Hosted a virtual R&D Day to provide an update on the preclinical and clinical development of IMU-935, including:
    - Based on preclinical studies performed by Immunic, as well as third-party research, the company believes that IMU-935's observed selectivity may enable it to inhibit the generation of Th17 cells and the production of IL-17 cytokines without impairing RORγt function required for normal thymocyte development and may, therefore, avoid the risk of T cell malfunction and potential lymphoma formation seen in third-party RORγt programs.
    - In preclinical studies, IMU-935 was observed to suppress the expression of mutated AR-V7 in prostate cancer cell lines, thus potentially inhibiting tumor growth in CRPC patients who are insensitive to

androgen-targeted therapies. By suppressing the expression of pro-tumorigenic IL-17, IMU-935 may also inhibit tumorigenesis in an indirect fashion. Based on these results, the company is currently preparing an open-label phase 1 dose escalation trial designed to establish a recommended phase 2 dose and to assess safety, tolerability, anti-tumor activity, biomarkers and pharmacokinetics (PK) of IMU-935 in patients with progressive mCRPC.
    - The full PK and blinded safety data from the completed single ascending dose (SAD) part of the phase 1 trial of IMU-935 was made available. The data set revealed dose-linear PK and a blood half-life that may be appropriate for once or twice daily dosing. Although the trial is still blinded, no significant safety findings have been detected in the SAD cohorts, to date.

- June 2021: Announced FDA clearance of the company's IND application to begin the phase 3 ENSURE program, comprised of two multicenter, randomized, double-blind trials designed to evaluate the efficacy, safety, and tolerability of IMU-838 versus placebo in RRMS patients. Additionally, announced FDA clearance of a separate IND application to initiate the supportive, multicenter, randomized, double-blind, placebo-controlled phase 2 CALLIPER trial of IMU-838 in patients with PMS, which will run concurrently with the phase 3 program in RRMS and which is designed to corroborate IMU-838's neuroprotective potential.
- June 2021: Announced the appointment of Inderpal Singh as General Counsel. Mr. Singh is responsible for legal and compliance matters and has become part of the management team of the company.
- April 2021: Announced interim data from the 10 mg Cohort 2 of the EMPhASIS trial of IMU-838 in RRMS confirming, along with previously published data from Cohort 1, that the 30 mg once daily dosing of IMU-838 is the most appropriate dose for the company's phase 3 program in RRMS. The experimental part of double-blind treatment in Cohort 2 has meanwhile been completed.

Anticipated Clinical Milestones

- **IMU-838 in RRMS:** The twin, multicenter, randomized, double-blind, phase 3 ENSURE-1 and ENSURE-2 trials of 30 mg daily IMU-838 or placebo will run concurrently. Dosing of the first patient is expected in the second half of 2021.
- **IMU-838 in PMS:** The multicenter, randomized, double-blind, phase 2 CALLIPER trial of 45 mg daily IMU-838 or placebo is intended to run concurrently with and to complement the phase 3 program in RRMS. Dosing of the first patient is expected in the third quarter 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-935 phase 1 program in healthy volunteers and psoriasis patients:** The multiple ascending dose (MAD) part of the phase 1 trial of IMU-935 is ongoing and progressing. Unblinded safety, pharmacodynamic and PK 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 moderate-to-severe psoriasis is expected in the third quarter of 2021 and initial human data from this patient population is expected to be available in the second quarter of 2022.
- **IMU-935 phase 1 trial in CRPC patients**: An open-label phase 1 dose escalation trial designed to establish a potential recommended phase 2 dose and to assess safety, tolerability, anti-tumor activity, biomarkers and PK of IMU-935 in patients with progressive mCRPC, is expected to commence in the fourth quarter of 2021.
- **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 so far, 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 first quarter of 2022. Initiation of the third portion of the phase 1 trial in patients with several diseases involving bowel barrier dysfunction is expected in the first half of 2022.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $15.7 million for the three months ended June 30, 2021, as compared to $10.0 million for the same period ended June 30, 2020. The $5.7 million increase was primarily due to (i) a $2.6 million increase in preparation costs related to the phase 3 program of IMU-838 in multiple sclerosis, (ii) a $1.8 million increase in external development costs related to the phase 2 clinical trial of IMU-838 in patients with UC, (iii) a $1.7 million increase in preparation costs related to the phase 2 trial of IMU-838 in PMS, (v) a $0.6 million increase in external development costs related to the phase 1 clinical trial of IMU-935, (vi) a $0.5 million increase in external development costs related to the phase 1 clinical trial of IMU-856, (vii) a $0.7 million increase in personnel expenses in research and development and (viii) $0.1 million related to increased costs across numerous categories. The increases were partially offset by a decrease of $2.3 million related to drug supply costs for IMU-838, IMU-935 and IMU-856.

  For the six months ended June 30, 2021, R&D expenses were $27.3 million, as compared to $16.4 million for the same period ended June 30, 2020. The $10.9 million increase was primarily attributable to (i) a $2.9 million increase in preparation costs related to the phase 3 program of IMU-838 in multiple sclerosis, (ii) a $2.4 million increase in preparation costs related to the phase 2 trial of IMU-838 in PMS, (iii) a $2.2 million increase in external development costs related to the phase 2 clinical trial of IMU-838 in patients with UC, (iv) a $1.4 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, (v) a $0.8 million increase in external development costs

related to the phase 1 clinical trial of IMU-856, (vi) a $0.7 million increase in external development costs related to the phase 1 clinical trial of IMU-935, (vii) a $1.0 million increase in personnel expenses in research and development and (viii) $1.0 million related to increased costs across numerous categories. The increases were partially offset by a decrease of $1.5 million in drug supply costs for IMU-856.

- **General and Administrative (G&A) Expenses** were $3.4 million for the three months ended June 30, 2021, as compared to $2.2 million for the same period ended June 30, 2020. The $1.2 million increase was primarily due to (i) a $0.7 million increase related to non-cash stock compensation expense, (ii) a $0.3 million increase of legal and consultancy costs and (iii) a $0.2 million increase across numerous categories.

  For the six months ended June 30, 2021, G&A expenses were $7.1 million, as compared to $4.8 million for the same period ended June 30, 2020. The $2.3 million increase was primarily due to (i) a $1.7 million increase related to non-cash stock compensation expense and (ii) a $0.6 million increase across numerous categories, primarily for legal and consultancy services.

- **4SC Royalty Settlement**: On March 31, 2021, Immunic AG and 4SC AG entered into a Settlement Agreement, pursuant to which Immunic AG settled its 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.

- **Other Income** was $1.2 million for the three months ended June 30, 2021, as compared to $0.8 million for the same period ended June 30, 2020. The $0.4 million increase was primarily attributable to (i) a $0.6 million foreign exchange gain on a $52.0 million intercompany loan between Immunic, Inc. and Immunic AG (the "Intercompany Loan") and (ii) a $0.3 million increase in research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia. The increase was partially offset by a $0.5 million decrease in recognized deferred income attributable to reimbursements of research and development expenses in connection with the option agreement with Daiichi Sankyo Co., Ltd. realized in the second quarter of 2020.

  For the six months ended June 30, 2021, other income was $(1.0) million, as compared to $1.3 million for the same period ended June 30, 2020. The $2.3 million decrease was primarily attributable to (i) a $1.9 million foreign exchange loss on the Intercompany Loan and (ii) a $1.0 million decrease in recognized deferred income attributable to reimbursements of research and development expenses in connection with the Daiichi Sankyo Agreement realized in the first six months of 2020. The decrease was partially offset by a $0.6 million increase in research and development 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 June 30, 2021, was approximately $17.9 million, or $0.82 per basic and diluted share, based on 21,749,439 weighted average common shares outstanding, compared to a net loss of approximately $11.5 million, or $0.90 per basic and diluted share, based on 12,695,989 weighted average common shares outstanding for the same period ended June 30, 2020.

  Net loss for the six months ended June 30, 2021 was approximately $52.5 million, or $2.44 per basic and diluted share, based on 21,463,656 weighted average common shares outstanding, compared to a net loss of approximately $19.9 million, or $1.70 per basic and diluted share, based on 11,722,725 weighted average common shares outstanding for the same period ended June 30, 2020.

- **Cash and Cash Equivalents** as of June 30, 2021, were $87.2 million, which does not include the approximately $42.2 million raised in the equity offering on July 19, 2021. Management expects its current cash and cash equivalents to be sufficient to fund operations into 2023.

About Immunic, Inc.
Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company with a pipeline of selective oral immunology therapies focused on 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, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγt, is targeted for development in psoriasis, castration-resistant prostate cancer 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; preclinical and clinical data for Immunic's development programs; 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; 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 June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 15,738	$ 9,987	$ 27,257	$ 16,421
General and administrative	3,432	2,235	7,050	4,815
4SC Royalty Settlement	—	—	17,250	—
Total operating expenses	19,170	12,222	51,557	21,236
Loss from operations	(19,170)	(12,222)	(51,557)	(21,236)
Other income (expense):				
Interest income	13	4	41	28
Other income (expense), net	1,223	760	(952)	1,263
Total other income (expense)	1,236	764	(911)	1,291
Net loss	$ (17,934)	$ (11,458)	$ (52,468)	$ (19,945)
Net loss per share, basic and diluted	$ (0.82)	$ (0.90)	$ (2.44)	$ (1.70)
Weighted-average common shares outstanding, basic and diluted	21,749,439	12,695,989	21,463,656	11,722,725

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

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 87,175	$ 127,452
Other current assets and prepaid expenses	14,512	6,293
Total current assets	101,687	133,745
Property and equipment, net	194	203
Goodwill	32,970	32,970
Right-of-use assets, net	1,165	901
Other long-term assets	42	42
Total assets	$ 136,058	$ 167,861
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,182	$ 3,700
Accrued expenses	6,175	4,318
Other current liabilities	4,130	379
Total current liabilities	14,487	8,397
Long term liabilities		
Operating lease liabilities	829	679
Total long-term liabilities	829	679
Total liabilities	15,316	9,076
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at June 30, 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 June 30, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	278,534	266,823
Accumulated other comprehensive loss	(1,398)	(4,112)
Accumulated deficit	(156,396)	(103,928)
Total stockholders' equity	120,742	158,785
Total liabilities and stockholders' equity	$ 136,058	$ 167,861

SOURCE Immunic, Inc.

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https://ir.imux.com/2021-08-06-Immunic,-Inc-Reports-Second-Quarter-2021-Financial-Results-and-Highlights-Recent-Activity