Immunic, Inc. Reports Year End 2021 Financial Results and Highlights Recent Activity

– Initiated Enrollment in Phase 3 ENSURE Program of Vidofludimus Calcium for the Treatment of Relapsing Multiple Sclerosis; Final Cohort 2 Data from the Phase 2 EMPhASIS Trial Confirms Phase 3 Dose Selection –

– Completed Enrollment of Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Moderate-to-Severe Ulcerative Colitis; Top-Line Data Expected in June of 2022 –

– Reported Positive Results from the Single and Multiple Ascending Dose Parts of the Phase 1 Clinical Trial of IMU-935; Part C Portion in Psoriasis Patients Ongoing with Data Expected in the Second Half of 2022 –

– Current Cash and Cash Equivalents Expected to Fund Immunic Through the First Quarter of 2023 –

– Webcast to be Held Today, February 24, 2022, at 8:00 am ET –

NEW YORK, February 24, 2022 – 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 fourth quarter and year ended December 31, 2021 and highlighted recent activity.

"2021 was another year of tremendous achievement for Immunic, punctuated by significant clinical progress across our key pipeline programs, including our lead product candidate, selective oral DHODH inhibitor, vidofludimus calcium (IMU-838) and IMU-935, a highly potent and selective oral IL-17 inhibitor. These activities, in particular, clear the way for several important data readouts this year, which are potentially transformative for the company," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Notably, at the end of October, we completed enrollment in our phase 2 CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe ulcerative colitis (UC) and expect top-line data for the induction phase to be available in June of 2022. Additionally, during the fourth quarter, we enrolled the first patients in our phase 3 ENSURE program of vidofludimus calcium in patients with relapsing multiple sclerosis (RMS). Based on the drug's highly significant activity in preventing lesion formation in our phase 2 EMPhASIS trial in RRMS, the consistent correlation observed between lesion formation and clinical relapse in third-party clinical trials, and vidofludimus calcium's outstanding safety and tolerability profile to date, we believe that this program should provide a straightforward path towards possible regulatory approval in RMS."

"We also reported positive unblinded safety, pharmacodynamic and pharmacokinetic (PK) data from the healthy volunteer portions of our ongoing phase 1 clinical trial of IMU-935 and expanded the trial, as planned, to treat patients with moderate-to-severe psoriasis. Based on the strength of preclinical data highlighting the therapeutic potential of IMU-935 to affect metastatic castration-resistant prostate cancer (mCRPC), we initiated an open-label phase 1 dose escalation trial of IMU-935 in mCRPC, for which initial clinical safety data are expected to be available in the third quarter of this year. Most recently, we were successful in expanding and strengthening our intellectual property portfolio for IMU-935 with the receipt

of multiple Notice of Allowances for composition-of-matter patents in the United States, Europe and Australia, providing protection into at least 2038."

Fourth Quarter 2021 and Subsequent Highlights

- February 2022: Presented preclinical data on the potent anti-inflammatory activity of vidofludimus calcium at the 17th Congress of European Crohn's and Colitis Organization. Additionally, announced the blinded baseline characteristics of its phase 2 CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe UC.
- February 2022: Received Notice of Allowances for composition-of-matter patents for IMU-935 in the United States and in Europe, and a notice of grant of the patent in Australia, providing patent protection into at least 2038, with further extension possible through potential Patent Term Extension (PTE) in the United States or Supplementary Protection Certificates (SPC) in Europe, respectively.
- December 2021: Reported positive unblinded safety, tolerability and PK results from Part A (single ascending doses, SAD) and Part B (multiple ascending doses, MAD) of its phase 1 clinical trial of IMU-935, a highly potent and selective inverse agonist of the transcription factor RORγt, in healthy human subjects. Additionally, announced newly available preclinical *in vivo* data showing that IMU-935 maintains normal thymocyte maturation in relevant acute and chronic mouse models.
- December 2021: Enrolled the first patient in the open-label phase 1 clinical trial of IMU-935 in mCRPC.
- November 2021: Enrolled the first patient in the phase 3 ENSURE program of vidofludimus calcium in RMS.
- October 2021: Enrolled and randomized the last patient in the phase 2 CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe UC. At completion of patient recruitment, the trial had randomized a total of 263 patients into four arms: three active dosing arms of 10 mg, 30 mg and 45 mg, as well as placebo.
- October 2021: Dosed the first patient with moderate-to-severe psoriasis in part C of the ongoing phase 1 clinical trial of IMU-935, representing the first-time patients have been treated with the company's potentially best-in-class RORγt inverse agonist.
- October 2021: Appointed Patrick Walsh to the newly created role of Chief Business Officer.

Final Cohort 2 Data from the Phase 2 EMPhASIS Trial of Vidofludimus Calcium in Relapsing-Remitting Multiple Sclerosis (RRMS) Now Available

Final data of Cohort 2 from Immunic's phase 2 EMPhASIS trial of vidofludimus calcium in RRMS are now available. The company believes that this data set provides additional support for the previously determined dose selection for the ongoing ENSURE and CALLPER trials in RMS and PMS, respectively.

Recall that the EMPhASIS trial comprised two cohorts. Cohort 1 compared the efficacy and safety of 30 mg or 45 mg once daily of vidofludimus calcium with placebo in RRMS, while Cohort 2 compared the efficacy and safety of 10 mg once daily of vidofludimus calcium with placebo in RRMS. Full data from Cohort 1 was published in the third quarter of 2020, while 12-week interim data from Cohort 2 was released in the second quarter of 2021.

In the newly available, final Cohort 2 data set, the anti-inflammatory effects of vidofludimus calcium at the 10 mg dose were observed to be lower (13% reduction of gadolinium-enhancing magnetic resonance

imaging lesions up to 24 weeks, as compared to placebo) than those found with the 30 mg vidofludimus calcium dose in the pooled Cohort 1 and 2 data (78% reduction), providing further support for the selection of 30 mg dosing in the ongoing ENSURE trials in RMS. Final Cohort 2 data also provide evidence of dose-proportional neuroprotective activity. For instance, the highest decrease of the biomarker serum neurofilament light chain was observed with the 45 mg dose of vidofludimus calcium versus placebo (-26.0% median of differences between percentage change of serum neurofilament, Hodges-Lehmann estimation), a substantial decrease was seen with the 30 mg dose (-18.0%), while the smallest decrease was observed with the 10 mg dose of Cohort 2 (-9.0%). The 10 mg group in Cohort 2 also showed a signal with respect to improvement in Expanded Disability Status Scale (EDSS), consistent with those signals seen with the higher doses in Cohort 1, although all of these early signals need to be confirmed in a larger patient population with longer follow-up periods. Taken together, these last two observations suggest that higher doses, such as 45 mg vidofludimus calcium, may be preferred doses for clinical trials in which neuroprotective effects are the main mechanism for improvement, such as in PMS.

While Cohort 1 blinded treatment was completed right before the COVID-19 pandemic started, final Cohort 2 data provide additional evidence that ongoing vidofludimus calcium treatment may reduce the risk of COVID-19 infections, presumably related to its known antiviral activity. In the entire Cohort 2 population of 59 patients, who were enrolled during pandemic conditions, incidental COVID-19 infections in the active treatment group were less frequent (8.5%, n=4/47) than in the placebo group (25.0%, n=3/12). Additionally, Immunic recently obtained new preclinical data underlining that vidofludimus calcium shows potent anti-EBV activity. The company also confirmed that vidofludimus calcium can be detected to a noteworthy degree in the cerebrospinal fluid of animals, after oral dosing. Immunic believes that this finding suggests that vidofludimus calcium may be able to act directly within the central nervous system.

Anticipated Clinical Milestones

- **Vidofludimus calcium in UC:** Top-line data of the induction phase of the phase 2 CALDOSE-1 trial in patients with moderate-to-severe UC are expected to be available in June of 2022.
- **IMU-935 phase 1 program in psoriasis patients:** Recruitment of part C of the phase 1 clinical trial of IMU-935 in patients with moderate-to-severe psoriasis depends on several external factors which are not under Immunic's direct control, including, in particular, the relatively restrictive COVID-19-related rules in effect in Australia and New Zealand. This situation has and may further influence Immunic's ability to enroll study participants and/or perform on-site monitoring at clinical sites in those locations. In light of this, Immunic has already initiated remedial measures, including the potential addition of sites outside of Australia and New Zealand, for the ongoing part C of IMU-935 in moderate-to-severe psoriasis patients. As a result, initial results from this third portion of the phase 1 clinical trial are now expected to be available in the second half of 2022, instead of at the end of the second quarter of 2022, as previously announced.
- **IMU-935 phase 1 trial in mCRPC**: Initial clinical safety data from the open-label phase 1 dose escalation trial are expected to be available in the third quarter of 2022.
- **IMU-856 phase 1 program**: The SAD part of the ongoing phase 1 clinical trial of IMU-856 has been completed. Based on the favorable data available so far, the Ethics Committee in Australia has agreed to proceed to the MAD part which is currently being dosed. Unblinded safety data from the SAD and MAD parts in healthy human subjects are expected to be available in the third quarter of 2022. Initiation of the third portion of the phase 1 clinical trial in patients with intestinal barrier function associated diseases is expected in the first half of 2022.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $61.1 million for the twelve months ended December 31, 2021, as compared to $38.6 million for the same period ended December 31, 2020. The $22.5 million increase reflects (i) a $10.2 million increase in external development costs related to the phase 3 program of vidofludimus calcium in RMS, (ii) a $7.4 million increase in external development costs related to the phase 2 trial of vidofludimus calcium in progressive multiple sclerosis, (iii) a $4.7 million increase in external development costs related to the phase 2 clinical trial of vidofludimus calcium in ulcerative colitis, (iv) a $2.4 million increase in personnel expense in research and development, $1.0 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount, (v) a $1.6 million increase in external development costs related to the phase 1 clinical trial of IMU-935, (vi) a $1.8 million increase in external costs for IMU-856, (vii) a $2.1 million increase in preclinical and drug supply costs related to vidofludimus calcium and (viii) $1.1 million related to increased costs across numerous categories. The increases were partially offset by (i) a $6.9 million decrease in external development costs related to the phase 2 clinical trial of vidofludimus calcium in COVID-19 and (ii) a decrease of $1.9 million in drug supply costs for IMU-856.

- **General and Administrative (G&A) Expenses** were $13.3 million for the twelve months ended December 31, 2021, as compared to $10.3 million for the same period ended December 31, 2020. The $3.0 million increase was primarily due to (i) a $2.2 million increase related to non-cash stock compensation expense and (ii) a $0.8 million increase across numerous categories.

- **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 (Expense)** was $(1.3) million for the twelve months ended December 31, 2021, as compared to $5.0 million for the same period ended December 31, 2020. The $6.3 million decrease was primarily attributable to (i) a $6.9 million change in other income (loss) as a result of a $4.3 million foreign exchange loss in 2021 on a $52.0 million intercompany loan between Immunic, Inc. and Immunic AG combined with a $2.6 million foreign exchange gain in 2020 on this 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 option agreement with Daiichi Sankyo Co., Ltd. realized in 2020. The decrease was partially offset by (i) a $1.1 million research allowance received from the German Federal Ministry of Finance and (ii) a $0.5 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 twelve months ended December 31, 2021 was approximately $92.9 million, or $3.93 per basic and diluted share, based on 23,652,779 weighted average common shares outstanding, compared to a net loss of approximately $44.0 million, or $2.81 per basic and diluted share, based on 15,663,826 weighted average common shares outstanding for the same period ended December 31, 2020.

- **Cash and Cash Equivalents** as of December 31, 2021 were $86.9 million, which does not include the approximately $16.2 million of net proceeds raised under the company's at-the-market sales agreement in the first quarter of 2022. Management expects its current cash and cash equivalents to be sufficient to fund operations through the first quarter of 2023.

Webcast Information

Immunic will host a webcast today at 8:00 am ET. To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_d6PSP8F3RCWrEcchTzfi6Q or on the "Events and Presentations" section of Immunic's website at ir.imux.com/events-and-presentations. Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.

An archived replay of the webcast will be available approximately one hour after completion on Immunic's website at ir.imux.com/events-and-presentations.

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, vidofludimus calcium (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 RORγ/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 include, but are not limited to, 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 substantial 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 financial and other resources to meet business objectives and operational requirements, the fact that the results of earlier preclinical studies and clinical 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)

	Years Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 61,115	$ 38,637
General and administrative	13,300	10,334
4SC Royalty Settlement	17,250	—
Total operating expenses	91,665	48,971
Loss from operations	(91,665)	(48,971)
Other income:		
Interest income	66	58
Other income (expense), net	(1,346)	4,896
Total other income (expense)	(1,280)	4,954
Net loss	$ (92,945)	$ (44,017)
Net loss per share, basic and diluted	$ (3.93)	$ (2.81)
Weighted-average common shares outstanding, basic and diluted	23,652,779	15,663,826

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

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 86,863	$ 127,452
Other current assets and prepaid expenses	18,125	6,293
Total current assets	104,988	133,745
Property and equipment, net	152	203
Goodwill	32,970	32,970
Right of use asset, net	948	901
Other long-term assets	42	42
Total assets	$ 139,100	$ 167,861
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,745	$ 3,700
Accrued expenses	7,071	4,318
Other current liabilities	585	379
Total current liabilities	11,401	8,397
Long-term liabilities:		
Operating lease liabilities	584	679
Total long-term liabilities	584	679
Total liabilities	11,985	9,076
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 26,335,418 and 21,168,240 shares issued and outstanding at December 31, 2021 and 2020, respectively	3	2
Additional paid-in capital	324,237	266,823
Accumulated other comprehensive loss	(252)	(4,112)
Accumulated deficit	(196,873)	(103,928)
Total stockholders' equity	127,115	158,785
Total liabilities and stockholders' equity	$ 139,100	$ 167,861