- Unblinded Data Established a Favorable Safety and Tolerability Profile for IMU-935 in Single Dose and 14-Day Multiple Dose Assessments in Healthy Human Subjects -

- Single Daily Dosing up to 400 mg and Multiple Daily Dosing of 300 mg were Found to Be Safe and Well-Tolerated in Healthy Human Subjects (With No Maximum Tolerated Dose Established) and the Investigated Doses are Believed to be Well Within the Potential Therapeutic Window of IMU-935 -

- Newly Available Preclinical in vivo Mouse Model Data Further Corroborates Previously Published in vitro Data Showing That, Compared To Two Known RORγt Inhibitors, Exposure to IMU-935 Allows Normal Thymocyte Maturation -

- Webcast to be Held Today, December 14, 2021, at 8:00 am ET -

NEW YORK, Dec. 14, 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 positive unblinded safety, tolerability and pharmacokinetic (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 in healthy human subjects. In addition, the company announced newly available preclinical *in vivo* data showing that IMU-935 maintains normal thymocyte maturation in relevant acute and chronic mouse models.

In the SAD portion of the phase 1 clinical trial, healthy human subjects were randomized in a double-blinded fashion to either placebo or treatment with single ascending doses of a new powder-in-capsule formulation of IMU-935 at 100 mg, 200 mg, 300 mg and 400 mg. A dose-proportional PK profile was observed across the investigated dose range. Moreover, single ascending doses of IMU-935 were found to be safe and well-tolerated and no maximum tolerated dose was reached. No serious adverse events occurred. These favorable results allowed a smooth transition to the MAD part of the trial using the new formulation.

In the MAD part of this phase 1 clinical trial, healthy human subjects were dosed for 14 days with 150 mg once daily (QD) or 150 mg twice daily (BID) of IMU-935 or placebo in a double-blinded fashion. PK analysis showed that stable steady-state plasma concentrations were achieved within the first week of dosing with an accumulation factor for IMU-935 allowing predictable trough levels during daily dosing. PK parameters in steady-state revealed a T_{max} of 2.4 to 2.8 hours post-dose, a plasma half-life of 29 to 38 hours and dose proportional increases in C_{max} and AUC. The observed average steady-state trough levels in both MAD cohorts exceeded the known IC_{90} values for IL-17F release obtained from *ex vivo* stimulated human lymphocytes. Multiple ascending doses of IMU-935 were found to be safe and well-tolerated and no maximum tolerated dose was reached. Treatment emergent adverse events (TEAEs) were generally mild in severity with moderate TEAEs reported in one of eleven IMUS-935 treated subjects compared with one of four subjects on placebo. No serious adverse events were reported. Finally, no dose-dependent changes in laboratory values (including no effects on liver enzymes or in hematological parameters), vital signs or in electrocardiograph evaluations were found. Taken together, the SAD and MAD parts of this phase 1 clinical trial did not identify any specific adverse events or laboratory abnormalities that require further investigation or special interest in future clinical trials, including no observed evidence of hepatitis's for IMUS-935.

In light of the favorable safety data observed in healthy human subjects, the company has initiated Part C of the ongoing phase 1 clinical trial, where moderate-to-severe psoriasis patients are to be randomized to 28-day treatment with IMU-935 or placebo. Planned assessments include safety, tolerability, PK and pharmacodynamic markers, as well as skin evaluations.

"The unblinded data set from the SAD and MAD parts of our phase 1 clinical trial in healthy human subjects showed a very attractive safety, tolerability and pharmacokinetic profile for IMU-935," stated Andreas Muehler, M.D., Chief Medical Officer of Immunic. "These data are consistent with our preclinical data and support our vision of establishing IMU-935 as the potentially best-in-class RORγt inverse agonist."

In previous preclinical *in vitro* data, it was shown that IMU-935 selectively inhibits Th17 differentiation and IL-17 production, whereas RORγt was unaffected by IMU-935 during thymocyte maturation and, therefore, does not harm normal thymocyte maturation. Newly obtained data from acute and chronic treatment of mice corroborated *in vivo* that IMU-935 is the first molecule observed to impact neither thymus size, thymocyte numbers, nor the maturation status of thymocytes, in contrast to two other known RORγt inhibitors. With these *in vivo* data, Immunic believes that the company may have the first clinical-stage RORγt inverse agonist which circumvents thymocyte maturation issues.

"We are very excited by both these outstanding safety, tolerability and PK results in healthy human subjects and the new preclinical work corroborating selectivity of IMU-935, our selective oral IL-17 inhibitor, *in vivo*," added Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "As expected, the phase 1 clinical trial of IMU-935 was expanded in late October to include a third portion, Part C, comprised of moderate-to-severe psoriasis patients given IMU-935 daily over 28 consecutive days. We look forward to reporting initial results from this Part C portion in psoriasis patients in the second quarter of 2022."

Webcast Information
Immunic's management team will host a webcast today, December 14, 2021, at 8:00 am Eastern Time to discuss the preclinical and clinical phase 1 SAD/MAD data from the company's IMU-935 program.

To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_VF4odmHbR3itlzHBkIRQBQ 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 IMU-935
IMU-935 is a highly potent and selective inverse agonist of RORγt (retinoic acid receptor-related orphan nuclear receptor gamma truncated) with additional activity on DHODH (dihydroorotate dehydrogenase). The nuclear receptor RORγt is believed to be the main driver for the differentiation of Th17 cells and the expression of cytokines involved in various inflammatory and autoimmune diseases. This target is believed to be an attractive alternative to approved antibodies for targets such as IL-23, IL-17 receptor and IL-17, itself. IMU-935 shows strong cytokine inhibition targeting both Th17 and Th1 responses in preclinical testing, as well as indications of activity in animal models for psoriasis and inflammatory bowel disease. Preclinical experiments indicate that, while leading to a potent inhibition of Th17 differentiation and cytokine secretion, IMU-935 did not affect thymocyte maturation. IMU-935 is an investigational drug product that has not been approved in any jurisdiction.

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 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 IMU-935 to safely and effectively target diseases; preclinical and clinical data for IMU-935; the timing of current and future clinical trials; 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, 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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