

– Interim Analysis Revealed Unexpected High Placebo Rate; Two Active Arms Did Not Separate From Placebo –

– No New Safety Signals Observed for IMU-935 in this Trial –

– Company Expects to Continue IMU-935 Development in Psoriasis –

NEW YORK, Oct. 20, 2022 [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 the outcome of a pre-planned interim group-level data analysis of its phase 1b clinical trial of IMU-935 in patients with moderate-to-severe psoriasis. The overall trial is ongoing and remains blinded. The pre-planned interim analysis revealed that the group averages for Psoriasis Area and Severity Index (PASI) reductions in the two active arms did not separate from placebo at four weeks. Although the active arms performed in line with prior expectations, the trial experienced a greater decrease than expected in PASI in the placebo arm based on similarly designed trials.

The trial, conducted in Australia, New Zealand and Bulgaria, was structured as a 28-day, double-blind, placebo-controlled trial. A total of 41 patients were enrolled and the trial evaluated IMU-935 at doses of 150 mg once-daily and 150 mg twice-daily versus placebo (randomized 3:1). The primary objective was the evaluation of the safety and tolerability of IMU-935 in moderate-to-severe psoriasis patients.

At this point, the company only has access to very limited information. The interim analysis only revealed mean values at group-level up to the end of the four-week treatment period. Immunic does not yet have access to unblinded individual patient data. Moreover, pharmacodynamic, biomarker – including skin punches and IL-17 levels in serum – or pharmacokinetic data, at either an individual or group-level, are not yet available. Based on the already available preclinical and clinical safety and tolerability data, Immunic has the flexibility to consider additional higher-dose or longer treatment cohorts. Supported by the broad availability of activity data from *in vitro* and *in vivo* studies in various disease models and settings, the company continues to believe in IMU-935's potential therapeutic activity.

Finally, although the safety data remains blinded, administration of IMU-935 and placebo in this trial were demonstrated to be safe and well-tolerated, and no new safety signals were observed.

"Although we did not see the desired activity signal over placebo in this group-level interim analysis, we retain a high degree of conviction on IMU-935's potential promise in psoriasis and beyond," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Given the proven binding of IMU-935 to the molecular target ROR $\gamma$ t, potent target inhibition as measured by transcription inhibition and secretion of pro-inflammatory cytokines, including IL-17A, IL-17F and IFN $\gamma$  from human peripheral blood mononuclear cells (PBMC), proven inhibition of Th17 cell differentiation, and consistent activity in different animal models, including psoriasis, multiple sclerosis and graft-versus-host disease, we believe IMU-935 holds the potential to provide a safe, efficacious and meaningful treatment option to patients with psoriasis. That said, we look forward to a full and final analysis of data from this trial which hopefully allows us to better understand these early observations to determine the best next steps for this exciting program."

"The unexpected high placebo rates observed in this interim analysis are disappointing and confound the evaluation of activity in the investigated active treatment arms. This requires further investigation throughout the coming weeks and months," stated Andreas Muehler, M.D., Chief Medical Officer of Immunic. "These were the first two dose levels tested in patients. Based on IMU-935's very favorable pharmacokinetic, safety and tolerability profile, to date, including absence of any dose-limiting toxicities in humans at doses exceeding those in this trial, and the preclinical safety and tolerability data, we have significant flexibility to explore higher dosing and longer treatment periods of this promising molecule. Availability of the full, unblinded individual patient data, and in particular the quantitative immunological markers, should help us to further guide the optimal development path for IMU-935."

The company reiterates its prior guidance that current cash, cash equivalents and marketable securities are expected to fund operating and capital expenditures into the fourth quarter of 2024. Regarding the company's upcoming clinical milestones, as previously announced, data from the interim analysis of the phase 2 CALLIPER trial of vidofludimus calcium in progressive multiple sclerosis are expected to be available in the second half of 2023 and top-line data at the end of 2024. Moreover, the read-out of the first of the phase 3 ENSURE trials of vidofludimus calcium in relapsing multiple sclerosis is targeted for end of 2025. Finally, initial clinical efficacy data of the Part C portion of the ongoing phase 1 clinical trial of IMU-856 in celiac disease patients are expected in 2023.

#### **About IMU-935**

IMU-935 is a highly potent and selective inverse agonist of ROR $\gamma$ /ROR $\gamma$ t (retinoic acid receptor-related orphan nuclear receptor gamma / truncated). The nuclear receptor ROR $\gamma$ t is believed to be the main driver for the differentiation of Th17 cells and the release 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, the IL-17 receptor and IL-17 itself. IMU-935

showed strong cytokine inhibition targeting both Th1 and Th17 responses in preclinical testing, as well as indications of activity in animal models for psoriasis, graft-versus-host disease, multiple sclerosis and inflammatory bowel disease. Preclinical experiments indicated that, while leading to a potent inhibition of Th17 differentiation and cytokine secretion, IMU-935 did not affect thymocyte maturation. A phase 1 clinical trial evaluating single and multiple ascending doses in healthy human subjects showed a favorable safety, tolerability and pharmacokinetic profile of IMU-935. 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, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor ROR $\gamma$ /ROR $\gamma$ t, is targeted for development in psoriasis, and castration-resistant prostate cancer. 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](http://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, sufficiency of cash, expected timing and results of clinical trials, 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; interpretation of preclinical and clinical data for IMU-935 and potential effects; plans to continue the phase 1b clinical trial of IMU-935 in patients with moderate-to-severe psoriasis, 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; 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 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, impacts of the Ukraine – Russia conflict on clinical trials, 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, 2021, filed with the SEC on February 24, 2022, and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov) or [ir.imux.com/sec-filings](http://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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