Immunic Announces Positive Results from Single and Multiple Ascending Dose Parts of Its Phase 1 Clinical Trial of IMU-856 in Healthy Human Subjects

– Unblinded Data Revealed a Favorable Safety, Tolerability and Pharmacokinetic Profile for IMU-856 in Single and 14-Day Multiple Dosing –

– No Maximum Tolerated Dose Reached; Investigated Doses Expected to Exceed Required Therapeutic Dosing of IMU-856 –

– Third Portion of Phase 1 Clinical Trial in Patients with Celiac Disease Ongoing –

– Webcast to be Held Today, September 20, 2022, at 8:30 am ET –

NEW YORK, September 20, 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 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-856 in healthy human subjects. IMU-856 is an orally available and systemically acting small molecule modulator that targets a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium.

In the SAD part of the phase 1 clinical trial, healthy human subjects were randomized in a double-blinded manner to either placebo or active treatment with single ascending doses of IMU-856 at 10 mg, 20 mg, 40 mg, 80 mg, 120 mg and 160 mg. Single ascending doses of IMU-856 were found to be safe and well-tolerated and no maximum tolerated dose was reached. No serious adverse events occurred. Moreover, a dose-linear PK profile was observed across the investigated dose range. These favorable results allowed a smooth transition to the MAD part of the trial.

In the MAD part of this phase 1 clinical trial, healthy human subjects were dosed for 14 consecutive days with 40 mg, 80 mg or 160 mg once-daily of IMU-856 or placebo in a double-blinded manner. Multiple ascending doses of IMU-856 were found to be safe and well-tolerated and no maximum tolerated dose was reached. Treatment emergent adverse events (TEAEs) were mostly mild in severity. No Investigational Medicinal Product (IMP)-related serious adverse events were reported. No dose-dependent changes in laboratory parameters (including no effects on liver enzymes or in hematological parameters), vital signs, physical examination or electrocardiographic evaluations were found. PK analysis showed a quick achievement of stable steady-state plasma concentrations within the first week and stable steady-state trough levels over the 14-day treatment period with a low accumulation factor for IMU-856, allowing predictable trough levels during daily dosing. PK parameters in steady-state revealed a T_{max} (time to reach maximum plasma concentration) of 2 to 3 hours post-dose, a plasma half-life of 17.4 to 21.5 hours and dose proportional increases in C_{max} (maximum plasma drug concentration) and AUC (area under the concentration-time curve).

"The unblinded data from the single and multiple ascending dose parts of our phase 1 clinical trial of IMU-856 in healthy human subjects revealed a favorable safety, tolerability and pharmacokinetic profile. In line with our preclinical findings, the data did not show any drug-related adverse events or laboratory abnormalities that would require further investigation. In addition, the pharmacokinetic results indicate that IMU-856 is well suited for a once-daily oral administration," stated Andreas Muehler, M.D., Chief Medical Officer of Immunic. "As expected, our phase 1 clinical trial of IMU-856 was expanded in May 2022 to include a third portion, comprised of well controlled celiac disease patients receiving IMU-856 daily over 28 consecutive days. This portion of the trial is still ongoing. We believe that celiac disease is not only an ideal proof-of-concept indication to investigate IMU-856's acute and chronic impact, as the disease represents a significant unmet need with well characterized surrogate markers of disease activity, but is also an attractive medical target with very few treatment options available."

The ongoing Part C of the phase 1 program includes a double-blind, randomized, placebo-controlled trial designed to assess the safety and tolerability of IMU-856 in patients with celiac disease during periods of gluten-free diet and gluten challenge. A total of approximately 42 patients are planned to be enrolled in two consecutive cohorts with 80 mg or 160 mg of IMU-856 given once-daily over 28 days. Secondary objectives include pharmacokinetics as well as acute and chronic disease markers, including those evaluating gastrointestinal architecture and inflammation. Sites in Australia and New Zealand are participating in Part C.

"We are very excited about the excellent safety, tolerability and pharmacokinetic results of IMU-856, our small molecule modulator targeting restoration of intestinal barrier function and regeneration of bowel epithelium, in healthy human subjects," added Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "These phase 1 results support our ultimate vision of establishing IMU-856 as a potential first-in-class oral celiac disease therapy. Additionally, IMU-856's mechanism could present an entirely new approach to treat a significant number of serious and widely prevalent gastrointestinal diseases, and we believe it could potentially offer a clinical benefit without the serious consequences associated with many immunosuppressive therapies."

Webcast Information

Immunic's management team will host a webcast today, September 20, 2022, at 8:30 am Eastern Time to discuss the clinical phase 1 SAD/MAD data from the company's IMU-856 program.

To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_OMiybBQ0ThmKDGIFW2WCuA 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-856

IMU-856, which Immunic believes to be novel, is an orally available and systemically acting small molecule modulator that targets a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium. Based on preclinical data, the compound may represent a new treatment approach, as the mechanism of action targets the restoration of the intestinal barrier function and bowel wall architecture in patients suffering from gastrointestinal diseases such as celiac disease, inflammatory bowel disease, irritable bowel syndrome with diarrhea and other intestinal barrier function associated diseases. Immunic believes that, because IMU-856 has been shown in preclinical investigations to avoid suppression of immune cells, it may therefore maintain immune surveillance for patients during therapy, an important advantage versus chronic treatment with potentially immunosuppressive medications. IMU-856 is an investigational drug product that has not been approved in any jurisdiction.

IMU-856 was discovered by Daiichi Sankyo Co., Ltd. (Daiichi Sankyo). In November 2018, Immunic and Daiichi Sankyo entered into a global option and license agreement, granting Immunic the exclusive right to license IMU-856. Immunic exercised the option in January 2020.

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 RORγ/RORγt, 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.

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-856 to safely and effectively target diseases; interpretation of preclinical and clinical data for IMU-856 and potential effects; 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 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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