Immunic Announces Publication of Data From Phase 1/1b Clinical Trial of IMU-856 in the Peer Reviewed Journal, *The Lancet Gastroenterology & Hepatology*

– Includes Phase 1 Data in Healthy Human Subjects and Phase 1b Data in Celiac Disease Patients –

NEW YORK, November 13, 2024 – Immunic, Inc. (Nasdaq: IMUX), a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, today announced that the data from its phase 1/1b clinical trial of IMU-856, an orally available and systemically acting small molecule modulator that targets SIRT6 (Sirtuin 6), has been published in the peer reviewed journal, *The Lancet Gastroenterology & Hepatology.* Lead authored by Dr. A. James Daveson, Gastroenterologist, Wesley Research Institute and Coral Sea Clinical Research Institute, Queensland, Australia, the paper is entitled, "*Safety, clinical activity, pharmacodynamics, and pharmacokinetics of IMU-856, a SIRT6 modulator, in coeliac disease: a first-in-human, randomised, double-blind, placebo-controlled, phase 1 trial.*" It can be accessed through the following link: https://www.thelancet.com/journals/langas/article/PIIS2468-1253(24)00248-6/fulltext.

Dr. Daveson stated, "Celiac disease affects approximately 1.4% of the world's population. The only current treatment option is a strict, lifelong gluten-free diet, which poses significant challenges due to dietary and social restrictions and the risk of cross-contamination, which leads to persistent intestinal inflammation with villous atrophy in many patients. IMU-856's potential ability to improve the integrity and function of the intestinal barrier represents a promising, novel approach to treat this condition. Importantly, this phase 1b clinical trial is the first study to show that IMU-856 can mitigate the gluten-related effects in celiac disease patients. Based on this result, in conjunction with the drug's favorable safety and tolerability profile, we have concluded that it warrants further clinical investigation."

"The publication of our phase 1/1b clinical data in healthy human subjects and patients with celiac disease, in such a prestigious peer reviewed journal, confirms that IMU-856's novel mechanism modulating SIRT6, a protein which serves as a transcriptional regulator of intestinal barrier function and physiological regeneration of bowel epithelium, can represent an entirely new approach to treating gastrointestinal diseases," added Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "In our phase 1b clinical trial, IMU-856 showed the first clinical signals of its potential ability to restore a healthy gut by renewal of the gut wall, demonstrating meaningful improvements over placebo in four key dimensions of celiac disease pathophysiology: histology, disease symptoms, biomarkers and nutrient absorption. Together with a favorable safety and tolerability profile, it may set the stage for a potential first-in-class, oral celiac disease therapy. Additionally, we believe that this data provides initial clinical proof-of-concept for a potentially new, oral therapeutic approach to a range of gastrointestinal diseases with high unmet needs, beyond celiac disease."

The first two portions of the phase 1 clinical trial, Parts A and B, were single ascending dose and multiple ascending dose, double-blind, placebo-controlled studies in a total of 71 healthy human subjects. Single and multiple ascending doses of IMU-856 were found to be safe and well-tolerated, with no investigational medicinal product (IMP)-related serious or severe treatment-emergent adverse events. No maximum tolerated dose was reached in either part.

Part C was structured as 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 a 15-day gluten challenge with 6 g of gluten given daily. Further objectives included pharmacokinetics and initial clinical activity assessments, including malabsorption parameters, biomarkers for enterocyte functional mass, such as citrulline, disease-related symptoms as well as histological changes. The trial was conducted at sites in Australia and New Zealand. A total of 43 patients were enrolled in two consecutive cohorts with 80 mg or 160 mg of IMU-856 or placebo given once-daily over 28 days. The data demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response, and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well-tolerated in this trial. There were no IMP-related serious or severe treatment-emergent adverse events, nor was there any dose-dependency in adverse events. Moreover, the rates of treatment-emergent adverse events in non-disease-related parameters were comparable between the active treatment groups and placebo.

About IMU-856

IMU-856 is an orally available and systemically acting small molecule modulator that targets SIRT6 (Sirtuin 6), 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 unique 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 and other intestinal barrier function associated diseases. Based on preclinical investigations demonstrating no suppression of immune cells, IMU-856 may have the potential to maintain immune surveillance for patients during therapy, which would be an important advantage versus immunosuppressive medications. IMU-856 demonstrated positive results in a phase 1b clinical trial in celiac disease patients in four key dimensions of the disease's pathophysiology: histology, disease symptoms, biomarkers and nutrient absorption. Currently, the company is preparing for phase 2 clinical testing. IMU-856 is an investigational drug product that has not been approved in any jurisdiction.

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases. The company's lead development program, vidofludimus calcium (IMU-838), is currently in phase 3 and phase 2 clinical trials for the treatment of relapsing and progressive multiple sclerosis, respectively, and has shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis, progressive multiple sclerosis and moderate-to-severe ulcerative colitis. Vidofludimus calcium combines neuroprotective effects, through its mechanism as a first-in-class nuclear receptor related 1 (Nurr1) activator, with additional anti-inflammatory and anti-viral effects, by selectively inhibiting the enzyme dihydroorotate dehydrogenase (DHODH). IMU-856, which targets the protein Sirtuin 6 (SIRT6), is intended to restore intestinal barrier function and regenerate bowel epithelium, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, for which it is currently in preparations for a phase 2 clinical trial. IMU-381, which currently is in preclinical testing, is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases. 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 and cash runway, expected timing, development 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 development programs and the targeted diseases; the potential for IMU-856 to safely and effectively target diseases; preclinical and clinical data for IMU-856; 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, increasing inflation, impacts of the Ukraine – Russia conflict and the conflict in the Middle East on planned and ongoing 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, including the ability to satisfy the minimum average price and trading volume conditions required to receive funding in tranche 2 and 3 of the January 2024 private placement, 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, 2023, filed with the SEC on February 22, 2024, 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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