– New Data Suggests that IMU-856 Could Be a Potential Oral Treatment Option for Weight Management; Program Is Phase 2 Ready –

– Dose-Dependent Increase of Endogenous GLP-1 Levels Observed in Post Hoc Analysis of Patients From Phase 1b Clinical Trial in Celiac Disease –

– Dose-Dependent Reduction of Body Weight Gain and Food Consumption Observed in Preclinical Study –

– Webcast to be Held Today, February 20 at 8:00 am ET –

NEW YORK, Feb. 20, 2025 /PRNewswire/ -- **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 IMU-856, an orally available and systemically acting small molecule modulator that targets SIRT6 (Sirtuin 6), demonstrated a dose-dependent increase of endogenous glucagon-like peptide-1 (GLP-1) levels in a post hoc analysis of patients from its phase 1b clinical trial in celiac disease. IMU-856 also showed a dose-dependent reduction of body weight gain and food consumption in preclinical *in vivo* testing. These effects may indicate the potential for IMU-856 as an oral treatment option for weight management.

"GLP-1, a hormone that occurs naturally in the gut, is released after eating and helps the body regulate blood sugar and satiety. It plays several critical roles, including triggering insulin release from the pancreas and blocking glucagon, a hormone raising blood sugar. Additionally, GLP-1 affects areas of the brain that process hunger and satiety," noted Hella Kohlhof, Ph.D., Chief Scientific Officer of Immunic. "IMU-856's target, SIRT6, is highly expressed in cells of the bowel wall, including enteroendocrine cells, which produce gastrointestinal hormones such as GLP-1 and gastric inhibitory peptide (GIP). Our phase 1b clinical trial in celiac disease patients demonstrated IMU-856's ability to regenerate epithelial cells, as measured by protection of villous height and improved cellular function. The current observations of increased GLP-1 in these celiac disease patients and the preclinical signs of reduced body weight gain indicate that IMU-856 may also have the effect of activating the function of enteroendocrine cells. These findings corroborate the tissue renewal effects already seen for IMU-856 and warrant continued evaluation, as they may meaningfully expand the potential indications for IMU-856."

New data is available from a post hoc analysis of the company's phase1b clinical trial of IMU-856 in celiac disease patients, where blood concentrations of GLP-1 were measured, between baseline and day 28, in a fasting state. A highly statistically significant (day 29: 80 mg p=0.014; 160 mg p=0.003) and dose-dependent increase of GLP-1 versus placebo control was detectable, even in the small patient population in this phase 1b clinical trial (baseline: N placebo = 11, N 80 mg IMU-856 = 13, N 160 mg IMU-856 = 13). These clinical findings were corroborated by effects observed in a 6-month preclinical *in vivo* study, where IMU-856 was found to reduce body weight gain accompanied by food consumption in a dose-dependent fashion up to -40 %, compared to the control group, which was found to be linked to reduced food intake.

"This newly released clinical and preclinical data demonstrating IMU-856's potential positive effect on GLP-1 and food consumption is an exciting development for Immunic's oral small molecule program," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "Data from our phase 1b clinical trial in celiac disease patients showed, under fasting conditions, a dose-dependent increase of naturally occurring GLP-1 levels of up to 250 % versus placebo. This compares favorably to the typical physiological 2-3 times increase in GLP-1 in healthy humans after a meal, indicating that IMU-856 may replicate the natural effect after eating. While currently available incretin mimetics delivered via subcutaneous injection are focused on one or two enteroendocrine hormones, we hypothesize that the SIRT6 modulation approach may result in a broader, more physiologic activation of enteroendocrine hormones, which we plan to explore further. If the effects reported today can be confirmed in further clinical trials, our convenient, once-daily small molecule tablet may represent an oral treatment option for obesity – a market with millions of people affected worldwide and which is expected to reach more than $170 billion globally by 2031. Our IMU-856 program offers the potential for immediate phase 1b or phase 2 clinical testing. As such, we will continue to analyze the findings and assess any next steps."

Webcast and Presentation Information
Immunic will host a webcast today at8:00 am ET. To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_o9yQAoqtT3yWnjb0049_Dw 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.

Today's update, along with phase1b biomarker data for IMU-856, will also be presented as a digital oral presentation at the 19th Congress of ECCO (European Crohn's and Colitis Organisation). The presentation will be accessible on the

"Events and Presentations" section of Immunic's website at: https://ir.imux.com/events-and-presentations.

- **Presentation Title:** *Promising Effects of IMU-856, an Orally Available Epigenetic Modulator of Barrier Regeneration - Biomarker Findings from a Phase 1 Clinical Study*
- **Presenting Author:** Amelie Schreieck, Ph.D., Senior Manager Biomarker Development, Immunic
- **Abstract Number:** EC25-1515
- **Presentation Number:** DOP012
- **Presentation Time:** 5:57 pm – 6:03 pm CET
- **Session Name:** Digital Oral Presentation (DOP) Session 2: Clinical Trials II
- **Session Date:** February 20, 2025
- **Session Hall:** A8

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. In a post hoc analysis of patients from the phase 1b clinical trial, IMU-856 demonstrated a dose-dependent increase of endogenous glucagon-like peptide-1 (GLP-1) levels and, in preclinical testing, showed a dose-dependent reduction of body weight gain and food consumption, indicating potential as a possible oral treatment option for weight management. The company is currently preparing for further 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 as well as inflammatory bowel disease, Graft-versus-Host-Disease and weight management. 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 or to reduce body weight gain and food consumption; other 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, any changes to the size of the target markets for the Company's products or product candidates, 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 onFebruary 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 of the contents of this press release.

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