NEW YORK, Oct. 15, 2023 /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 the presentation of data from the company's phase 1b clinical trial of IMU-856, an orally available and systemically acting small molecule modulator that targets SIRT6 (Sirtuin 6), in patients with celiac disease in a moderated poster session at the United European Gastroenterology Week (UEGW) 2023, taking place October 14-17 in Copenhagen.

In this phase 1b, double-blind, randomized, placebo-controlled trial in patients with celiac disease, IMU-856 showed positive effects over placebo in four key dimensions of clinical outcome: protection of the gut architecture, improvement of patients' symptoms, biomarker response and enhancement of nutrient absorption. IMU-856 was also found to be safe and well-tolerated with a benign adverse event profile and with pharmacokinetics that allow once-daily dosing. There were no systematic clinically relevant findings relative to safety and tolerability, as assessed by physical examination, clinical laboratory tests, vital signs, and 12-lead electrocardiograms.

"We were delighted to hear that, according to the UEGW, our IMU-856 poster was selected as one of the best among the abstracts submitted," stated Daniel Vitt, Ph.D., Chief Executive Officer and President 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 in patients with celiac disease. These stronger than expected results across histology, disease symptoms, biomarkers and nutrient absorption, along with the drug's clean safety and tolerability profile, may set the stage for a potential first-in-class, oral celiac disease therapy. IMU-856 may also offer extensive potential beyond celiac disease in other gastrointestinal diseases with high unmet needs such as ulcerative colitis, Crohn's disease, or irritable bowel syndrome with diarrhea."

Poster Details:

- **Title:** *First in Human Trial of IMU-856, An Orally Available Epigenetic Modulator of Barrier Regeneration for the Treatment of Celiac Disease*
- **Abstract Number:** AS-UEG-2023-01180
- **Poster Number:** MP147
- **Presenting Author:** Franziska Burianek, M.D., Senior Medical Director, Immunic
- **Poster Session:** Coeliac disease
- **Location:** Moderated Posters, Poster Stage 3
- **Date:** Sunday, October 15, 2023
- **Time:** 5:48 – 5:54 pm CET
- The poster presentation is accessible on the "Events and Presentations" section of Immunic's website at: https://ir.imux.com/events-and-presentations.

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, 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 have the potential to maintain immune surveillance for patients during therapy, 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 in this patient population. 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 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, where 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, 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 vidofludimus calcium to safely and effectively target diseases; preclinical and clinical data for vidofludimus calcium; 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 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, 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, 2022, filed with the SEC on February 23, 2023, 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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