

*- First Time Patients Will be Treated with the Company's Orally Available Small Molecule Modulator Targeting Restoration of Intestinal Barrier Function and Regeneration of Bowel Epithelium -*

NEW YORK, May 5, 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 start of the patient cohorts in its ongoing phase 1 clinical trial of IMU-856, the company's third clinical asset, in patients with celiac disease.

IMU-856 is an orally available and systemically acting small molecule modulator that targets an undisclosed epigenetic regulator. Preclinical studies suggest that IMU-856 can restore barrier function in the gastrointestinal tract and also regenerate intestinal architecture while maintaining immunocompetency. Based on preclinical and early clinical data available to date, the company believes that IMU-856 may represent a novel and potentially ground-breaking approach to the treatment of gastrointestinal diseases.

"Start of Part C of this phase 1 clinical trial in celiac disease patients marks an important milestone in the clinical development of IMU-856, and we hope to be able to confirm its ability to restore intestinal barrier function without affecting the immune system," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Because it represents a significant unmet need with well characterized surrogate markers of disease activity, we believe that celiac disease is an ideal initial clinical indication to provide proof-of-concept of IMU-856's acute and chronic impact. 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 offer a clinical benefit without the serious consequences associated with many autoimmune therapies. Moreover, we look forward to providing the full safety data set from the single and multiple ascending dose portions of this ongoing phase 1 clinical trial in healthy human subjects, currently expected to be available in the third quarter of this year."

"Celiac disease is a life-long and serious autoimmune disease of the small bowel whose pathophysiology is due to gluten-induced damage to the intestinal barrier. Despite adhering to a gluten-free diet, many patients experience ongoing disease activity which may lead to chronic diarrhea, abdominal pain, malabsorption of nutrients and even increased risk of anemia, osteoporosis and certain cancers," stated Andreas Muehler, M.D., Chief Medical Officer of Immunic. "There is an immense need for an effective therapeutic intervention for patients with celiac disease, as the only therapeutic approach today is a strict, life-long gluten-free diet, which is burdensome, often socially restrictive, and regularly fails to stop disease activity. In light of IMU-856's potential to restore intestinal barrier function and intestinal architecture, we believe this compound holds particular promise in improving patients' gastrointestinal health and ability to digest and properly absorb nutrients, thereby reducing possible long-term consequences and improving their quality of life, disease symptoms and potential future complications."

Parts A and B of the ongoing phase 1 clinical trial are evaluating single and multiple ascending doses of IMU-856 in healthy human subjects. The now initiated Part C is structured as a 28-day, double-blind, 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. Approximately 42 patients are planned to be enrolled in two consecutive cohorts with IMU-856 given once-daily over 28 days. Secondary objectives include pharmacokinetics and disease markers, including those evaluating gastrointestinal architecture and inflammation. Approximately 10 sites in Australia and New Zealand are expected to participate in Part C.

The company also reiterates its prior guidance that phase 2 top-line data of vidofludimus calcium (IMU-838) in ulcerative colitis is expected to be available in June of 2022 and that initial clinical efficacy data of the Part C portion of the ongoing phase 1 clinical trial of IMU-935 in psoriasis is expected in the second half of 2022.

### **About IMU-856**

IMU-856, which Immunic believes to be novel, is an orally available 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 and initially developed 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. The license also includes exclusivity on a patent application filed by Daiichi Sankyo, covering IMU-856's composition of matter. Immunic exercised the option in January 2020.

## **About Celiac Disease**

Celiac disease is a chronic autoimmune condition of the small intestine in which ingestion of dietary gluten triggers an inflammatory response in genetically susceptible individuals. Over time, the immune reaction damages the lining of the small intestine and prevents it from absorbing some nutrients (malabsorption). This often causes diarrhea, fatigue, weight loss, bloating and anemia, and can lead to other serious complications. In children, nutrient malabsorption can affect growth and development, in addition to causing the symptoms seen in adults. There is currently no known cure for celiac disease and patients must adhere to a strict, life-long gluten-free diet which can help manage symptoms and avoid disease flareups. Celiac disease is estimated to affect 1 in 100 people, worldwide. In the U.S., alone, it is estimated that 2.5 million people are undiagnosed and are, therefore, at risk for long-term health complications.

## **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, ulcerative colitis, Crohn's disease, 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, castration-resistant prostate cancer and Guillain-Barré syndrome. 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, 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; preclinical and clinical data for IMU-856; the timing of current and future clinical trials; 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, 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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