Immunic, Inc. Announces First Patient Enrolled in Investigator-Sponsored Proof-of-Concept Clinical Trial of IMU-838 for the Treatment of Patients with Primary Sclerosing Cholangitis

– Study Being Conducted in Collaboration with Investigators at Arizona State University and the Mayo Clinic –

SAN DIEGO, August 12, 2019 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company focused on developing potentially best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced enrollment of the first patient in an investigator-sponsored proof-of-concept clinical trial of IMU-838 for the treatment of patients with primary sclerosing cholangitis (PSC). IMU-838 is an orally available, next-generation selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme dihydroorotate dehydrogenase (DHODH). PSC is a progressive disease of the liver with unknown cause and a prevalence of about 4.15 per 100,000 in the United States. Other than liver transplantation, there are currently no approved therapies that have been shown to improve survival in patients with PSC.

Keith Lindor, M.D., Senior Advisor to the Provost and Professor of Medicine, College of Health Solutions, Arizona State University, and Principal Investigator for the trial, was awarded a grant from the National Institutes of Health (NIH) for the study. The study will be sponsored by Elizabeth Carey, M.D., Professor of Medicine, Division of Gastroenterology and Hepatology, Department of Internal Medicine, Mayo Clinic, who has received Investigational New Drug (IND) approval from the U.S. Food & Drug Administration (FDA) and has been granted Institutional Review Board (IRB) approval to conduct the study. The study will be conducted at Mayo Clinic in Arizona (Dr. Carey) and Minnesota (John E. Eaton, M.D.), both of which are tertiary care centers for PSC patients.

The proof-of-concept study, for which Immunic is providing the study medication, is a single-arm, open-label, exploratory study planning to enroll a total of 30 patients with PSC, aged 18 to 75 years, who will receive 30mg IMU-838 once daily for a period of six months. The trial's primary endpoint is the change in serum alkaline phosphatase (ALP) at six months compared to baseline. In previous trials, a biochemical endpoint such as change in serum ALP has been an accepted biomarker of disease progression in PSC patients.

Dr. Keith Lindor commented, "Recent studies indicate that the proinflammatory cytokine interleukin 17, or IL-17, may play a central role in the pathogenesis of PSC, as well as ulcerative colitis. Significant increases in IL-17-expressing lymphocytes are found in the livers of PSC patients. These findings speak to the strong possibility of an overlap in therapeutic approaches to the two diseases. Our goal with this study is to examine the safety, tolerability, and efficacy of daily dosing of IMU-838, an orally available, small molecule inhibitor of DHODH, a target known for its effect on Th17 cells, in order to establish proof-of-concept that IMU-838 shows activity for the treatment of PSC. Establishing such a baseline should enable the design of more comprehensive clinical studies."

"We are honored to be collaborating with such prominent institutions and investigators, including Drs. Lindor, Carey and Eaton on this important clinical trial," noted Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Certainly, the available data, including the mode of action of IMU-838, which already is commercially proven in other indications, compels us to support their work to address the unmet medical need of patients affected by PSC, whose current options include only supportive care or, ultimately, liver transplantation. With the potential for a best-in-class DHODH inhibitor safety profile, and an IND for IMU-838 in inflammatory bowel disease, or IBD, already established, positive data from this investigator-sponsored trial should enable Immunic to approach the regulatory authorities about the possibility of an accelerated regulatory pathway in this orphan indication."

For more information on this clinical trial, please visit: www.clinicaltrials.gov, NCT03722576.

About Primary Sclerosing Cholangitis (PSC)
PSC is a very rare liver disease with a prevalence of about 4.15 per 100,000 in the United States, in which the bile ducts in the liver become inflamed, narrow and prevent bile from flowing properly. The exact cause and disease mechanism are still unknown but an autoimmune mechanism may play a role. There is an association with inflammatory bowel diseases, most often with ulcerative colitis and less commonly with Crohn's disease. PSC is a progressive disease and the estimated time from diagnosis of PSC to death or liver transplant has been shown to be less than 15 years.

About IMU-838
IMU-838 is an orally available, next-generation selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme dihydroorotate dehydrogenase (DHODH). IMU-838 acts on activated T and B cells while leaving other immune cells largely unaffected and allows the immune system to stay functioning, e.g. in fighting infections. In previous trials, IMU-838 did not show an increased rate of infections compared to placebo. In addition, DHODH inhibitors such as IMU-838 are known to possess a direct antiviral effect. IMU-838 was successfully tested in two phase 1 clinical trials in 2017 and is currently being tested in phase 2 trials in patients with relapsing-remitting multiple sclerosis and ulcerative colitis. Immunic intends to initiate an additional phase 2 trial in patients with Crohn's disease later in 2019. Furthermore, Immunic's collaboration partner, Mayo Clinic, has started an investigator-sponsored proof-of-concept clinical trial testing IMU-838 activity in patients with primary sclerosing cholangitis.

About Immunic, Inc.
Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. The company is developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of RORγt; and IMU-856 targets the restoration of the intestinal barrier function. Immunic's lead development program, IMU-838, is in phase 2 clinical development for relapsing-remitting multiple sclerosis and ulcerative colitis, with an additional phase 2 trial in Crohn's disease planned for the second half of 2019. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary

sclerosing cholangitis is ongoing at the Mayo Clinic. For further information, please visit: www.immunic-therapeutics.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 the potential for IMU-838, IMU-935 and IMU-856 to safely and effectively target diseases; the proof-of-concept study of IMU-838 for the treatment of patients with primary sclerosing cholangitis; the potential accelerated regulatory pathway of IMU-838; Immunic's future clinical trials; the nature, strategy and focus of the company; 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 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, 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 resources to meet business objectives and operational requirements, the fact that the results of earlier studies and 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. 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.

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