Immunic, Inc. Announces Dosing of First Healthy Volunteer in Phase 1 Clinical Program of IMU-856, Targeting Restoration of Intestinal Barrier Function

NEW YORK, August 20, 2020 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, today announced dosing of the first healthy volunteer in the company's phase 1 clinical program of IMU-856, an orally available, small molecule modulator that targets a yet undisclosed protein which serves as a transcriptional regulator of intestinal barrier function. Based on preclinical data, the compound appears to represent a novel and paradigm-shifting approach to the treatment of gastrointestinal diseases by potentially restoring intestinal barrier function while maintaining immunocompetency. Immunic's Australian subsidiary, Immunic Australia Pty Ltd., received clearance from the Bellberry Human Research Ethics Committee in Australia to begin a phase 1 trial of IMU-856 under the Clinical Trial Notification (CTN) scheme of the Australian Therapeutic Goods Administration (TGA). The phase 1 clinical program includes single and multiple ascending dose parts in healthy volunteers. Subsequently, Immunic also plans to extend this program to assess biomarker, safety and drug trough levels in patients with diarrhea-predominant irritable bowel syndrome (IBS-D), ulcerative colitis (UC) and Crohn's disease (CD).

"Dosing of the first healthy volunteer in our phase 1 clinical program of IMU-856 brings us one step closer to evaluating whether our approach may eventually translate into a novel treatment option for patients suffering from a range of gastrointestinal diseases, by potentially restoring function of the intestinal barrier without impairing the immune system," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Based on strong preclinical data, IMU-856 shows significant therapeutic potential for diseases that are known to be triggered by the disruption of intestinal barrier function."

The phase 1 study is a double-blind, randomized, placebo-controlled trial comprised of three parts. The first part is a single ascending dose portion in healthy volunteers, which is planned to be followed by a second, multiple ascending dose part in healthy volunteers, with IMU-856 given daily for 14 consecutive days. These first two parts of the phase 1 trial are designed to assess the safety, tolerability and pharmacokinetic properties of IMU-856. In a third part of the phase 1 trial, the study drug would be given daily over 28 consecutive days at two different dose levels in patients with IBS-D, UC and CD who were screened for increased bowel permeability using oral marker tests. The change in bowel permeability, using a 2-sugar test to monitor therapeutic effects, would be evaluated as a pharmacodynamic marker, and include a comparison of two active dose groups to placebo. Additionally, biomarker, safety and trough plasma concentration levels would also be assessed.

Hella Kohlhof, Ph.D., Chief Scientific Officer of Immunic, noted, "Current treatments for many gastrointestinal conditions focus on inhibiting inflammation and do not directly address impaired intestinal barrier function. In contrast, IMU-856 appears to have a unique targeted ability to strengthen and thereby normalize this function, potentially avoiding the bacterial triggers which can occur when the intestinal barrier is impaired. Moreover, because this approach appears to avoid any detrimental effects on the immune system, we believe that IMU-856 has the potential to change the treatment paradigm for gastrointestinal diseases."

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 an exclusive global option to obtain the exclusive right to license a group of compounds, designated by Immunic as IMU-856. Under this agreement, Immunic has the rights to commercialization of IMU-856 in all countries, including the United States, Europe and Japan. The option 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 Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company with 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. Immunic is developing three small molecule products: its lead development program, IMU-838, is 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; IMU-935 is an inverse agonist of RORγt; and IMU-856 targets the restoration of the intestinal barrier function. On August 2, 2020, Immunic announced positive top-line results from its phase 2 EMPhASIS trial of IMU-838 in patients with relapsing-remitting multiple sclerosis, reporting achievement of both primary and key secondary endpoints with high statistical significance, indicating activity for IMU-838 in this indication. IMU-838 is also in phase 2 clinical development for ulcerative colitis and COVID-19, with an additional phase 2 trial considered in Crohn's disease. 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.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-838, IMU-935 and IMU-856 to safely and effectively target diseases; preclinical data for IMU-856; the timing of 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, 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 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. 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, 2019, filed with the SEC on March 16, 2020, the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 3, 2020, 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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