IMU-856 has the potential to address one of the putative root causes of inflammatory bowel disease without impairing the immune system

NEW YORK, Dec. 4, 2019 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX),** a clinical-stage biopharmaceutical company focused on developing best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, announced that Hella Kohlhof, Ph.D., Chief Scientific Officer of Immunic, will present data on IMU-856, for the first time, at today's IBD Innovate: Product Development for Crohn's and Colitis conference in New York, hosted by the Crohn's and Colitis Foundation.

The presentation, entitled, "IMU-856: A Small Molecule Modulator Restoring the Gut Barrier Function," will be given as part of the "Small & Large Molecules" session, beginning at 11:40 am EST, which is intended to showcase innovative product development programs in inflammatory bowel disease (IBD). Dr. Kohlhof's presentation will highlight the potential of IMU-856 to revolutionize the treatment of multiple diseases related to intestinal barrier function.

IMU-856, which Immunic believes to be novel and highly innovative, is an orally available, small molecule modulator that targets a yet undisclosed protein which serves as a transcriptional regulator of the intestinal barrier function. Based on preclinical data, the compound appears to represent a new and potentially disruptive approach for the treatment of intestinal diseases by potentially restoring the intestinal barrier function while maintaining immunocompetency.

Highlights of Dr. Kohlhof's presentation will include:

- IMU-856 is an epigenetic regulator that appears to influence the tightly regulated network of genes and proteins associated with intestinal epithelial cell interaction and adhesion.
- IMU-856 has shown target modulation at very low concentrations in both cellular and non-cellular models.
- Preclinical data demonstrates that IMU-856 is able to restore intestinal barrier function in cytokine challenged Caco-2 cells and shows dose-depending activity in several dextran sulfate sodium (DSS) induced colitis mouse models.

"We are excited to present, for the first time, strong preclinical data of IMU-856 which shows potential significant advantages over current immunosuppressive treatments for intestinal barrier function associated diseases. IMU-856 appears to have a unique targeted ability to strengthen the intestinal barrier function, and we believe that a normalized intestinal barrier function may avoid bacterial triggers without impairing the immune system," stated Dr. Kohlhof. "This early data, therefore, further supports our belief that IMU-856 has the ability to change the treatment paradigm for patients suffering from a variety of gastrointestinal diseases. We look forward to learning more about the pharmacokinetics and safety of IMU-856 in our phase 1, single and multiple ascending dose studies, which we expect to initiate in the first half of 2020. We also plan to extend these studies to assess safety and mechanism-related biomarkers in patients suffering from diseases related to intestinal barrier function. We are hopeful that future clinical trials will validate IMU-856 as a safe, long-term treatment option for these patients."

IMU-856 was discovered and developed by Daiichi Sankyo Co., Ltd. (hereinafter, 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 U.S., Europe and Japan. Immunic plans to execute the option prior to entering phase 1 clinical development.

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 planned 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.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 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, 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 "Item 1A. Risk Factors," in the company's Current Report on Form 8-K filed on July 17, 2019, 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.immunic-therapeutics.com/sec-filings and on request from Immunic. 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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