Immunic, Inc.'s Interim Dosing Analysis of IMU-838 as Part of its Ongoing Phase 2 CALDOSE-1 Study in Patients with Moderate-to-Severe Ulcerative Colitis Establishes Broad, Potentially Safe and Effective Dose Range

– Unblinded Data Review Committee Recommended Continuation of the Lowest, 10 mg Dose as well as the Highest, 45 mg Dose –

– Company Now Plans to Continue Study with All Three Dosing Arms –

SAN DIEGO, September 5, 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 the results of a pre-planned interim dosing analysis in the phase 2 CALDOSE-1 study of IMU-838 in patients with moderate-to-severe ulcerative colitis (UC). Based on the available data, an unblinded and independent data review committee has concluded that the study's lowest, 10 mg dose was found not to be likely ineffective and that the highest, 45 mg dose was not intolerable. As a result, the company intends to continue the trial with all three dosing arms.

The phase 2 CALDOSE-1 trial is an international, multicenter, double-blind, placebo-controlled study being conducted in the United States and Europe and is designed to evaluate the company's lead compound, IMU-838, in patients with UC. The study's primary endpoint comprises a composite of a patient reported outcome and endoscopy-assessed outcome, both to be evaluated following ten weeks of induction treatment with IMU-838 or placebo.

Under an agreement between Immunic and the U.S. Food and Drug Administration (FDA), reached during the company's pre-IND meeting in 2017, the CALDOSE-1 trial was designed to begin enrollment with three active dosing arms of 10 mg, 30 mg and 45 mg, respectively, in addition to a placebo arm. Based on preclinical target engagement data, Immunic had hypothesized 30 mg to be the lowest effective dose. The 10 mg dose was added to the trial at the suggestion of the FDA to include a lower dose than the expected effective doses. The interim dosing analysis was to be conducted after approximately 60 patients were evaluable following their ten-week induction treatment. At the time, Immunic anticipated that the lowest, 10 mg dose might be found to be likely ineffective in this interim dosing analysis, and therefore discontinued.

The interim dosing analysis has now been performed by an unblinded and independent data review committee, which has concluded that the 10 mg dose appeared not to be likely ineffective, the 45 mg dose was not intolerable, and no safety signal was identified for any of the trial's three doses of IMU-838. The data review committee has not shared with the company any of the unblinded data underlying these conclusions, and the study remains blinded to the company, the investigators and the enrolled patients. The interim dosing analysis was not designed to be a futility analysis nor was the primary endpoint or any other endpoint of the study tested statistically.

As a result of these findings, the trial's steering committee has recommended continuation of all three dosing arms, which recommendation is intended to be implemented by Immunic. Expansion of IMU-838's potentially effective dose range will require inclusion of a third active dosing arm to the study's second enrollment period and will increase the overall number of patients expected to be included in the ongoing trial from a previously anticipated 195 patients, to a total of approximately 240 anticipated patients.

"While unexpected, we are very pleased to learn that even the lowest, 10 mg dose seems to show activity, suggesting that the potentially effective dose range for UC patients may be broader than previously thought," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Moreover, the knowledge that all three doses included in the CALDOSE-1 trial did not show unacceptable intolerance and are expected to be continued confirms the promising safety profile already established for IMU-838 in previous studies. These results speak to the strength of IMU-838 as a possible best-in-class oral therapy for this growing patient population. We look forward to continuing the study and reporting top-line data, when available."

Management noted that the positive findings of this interim dosing analysis will impact the timing of completion of patient enrollment, previously expected during the second half of 2020, as well as availability of top-line data, which was anticipated during the first quarter of 2021. Management will re-evaluate and report on its adjusted timeline with respect to the CALDOSE-1 study, as well as the expected dose selection and initiation of the CALDOSE-2 phase 2 trial of IMU-838 in Crohn's disease patients, after a thorough review has been completed.

Finally and as pre-defined in the study protocol, this interim dosing analysis was based on data from only a relatively small number of patients in the CALDOSE-1 trial, and no formal statistical analysis was performed. This interim dosing analysis and the conclusions made by the independent data review committee may not reflect results of a final analysis of the trial once the full data set is analyzed.

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 also intends to initiate an additional phase 2 trial in patients with Crohn's disease. 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 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 and clinical data for IMU-838; the timing of future clinical trials and expected results of such 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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