- Top-Line Data Expected in the Second Quarter of 2022 -

NEW YORK, Oct. 28, 2021 /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, today announced that the final patient has been enrolled and randomized in its phase 2 CALDOSE-1 trial of lead asset, IMU-838, the company's selective oral DHODH inhibitor, in patients with moderate-to-severe ulcerative colitis (UC). Top-line data for the induction phase is expected to be available in the second quarter of 2022.

"Enrollment of the last patient in our CALDOSE-1 trial brings us one step further in the clinical development of IMU-838 as a potential treatment for UC patients," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Backed by promising results from the phase 2a ENTRANCE trial performed in UC and Crohn's disease and the interim analysis of the CALDOSE-1 trial published in September 2019, along with IMU-838's already established, strong safety and tolerability profile, we believe that the drug could become a preferred oral treatment option for patients suffering from UC and looking for a convenient treatment option before being escalated to biologics. We look forward to obtaining the unblinded top-line data in the second quarter of next year."

The phase 2 CALDOSE-1 trial is a multicenter, randomized, double-blind, placebo-controlled, dose-finding study being conducted at more than 100 sites in 19 countries, including the United States and Western, Central and Eastern Europe. It is designed to evaluate the efficacy and safety of IMU-838 in patients with UC and includes a blinded induction and maintenance phase, with an option for open-label treatment extension. At the completion of patient recruitment, the trial has randomized a total of 263 patients into four arms: three active dosing arms of 10 mg, 30 mg and 45 mg, as well as placebo. The trial's primary endpoint comprises a composite of a patient-reported outcome and endoscopy-assessed outcome, both evaluated following ten weeks of induction treatment with IMU-838 or placebo. The assessment of endoscopy results is performed by an independent, central reader.

In September 2019, Immunic reported positive results from an interim dosing analysis in the CALDOSE-1 trial which showed that the lowest, 10 mg dose was not likely ineffective, that the highest, 45 mg dose was not intolerable and that no safety signal was identified for any of the trial's three doses. As a result, the trial continued with all three dosing arms.

For more information on this clinical trial, please visit: www.clinicaltrials.gov, NCT03341962.

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 host-based antiviral effect, which is independent with respect to specific virus proteins and their structure. Therefore, DHODH inhibition may be broadly applicable against multiple viruses. IMU-838 was successfully tested in two phase 1 clinical trials in 2017 and is currently being tested in a phase 2 trial in patients with ulcerative colitis. In the third quarter of 2020, the company reported positive results from its phase 2 EMPhASIS trial of IMU-838 in relapsing-remitting multiple sclerosis, achieving both primary and key secondary endpoints with high statistical significance. In the first quarter of 2021, Immunic announced that IMU-838 showed evidence of clinical activity in its phase 2 CALVID-1 trial in hospitalized patients with moderate COVID-19. Also, in the first quarter of 2021, the company reported positive top-line data from an investigator-sponsored phase 2 proof-of-concept clinical trial of IMU-838 in primary sclerosing cholangitis which was conducted in collaboration with Mayo Clinic. To date, IMU-838 has been tested in more than 800 individuals and has shown an attractive pharmacokinetic, safety and tolerability profile. IMU-838 is not yet licensed or approved in any country.

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, 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 RORγt, 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.

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 to safely and effectively target diseases, including ulcerative colitis; preclinical and clinical data for IMU-838; the timing of current and future clinical trials; the availability, safety or efficacy of potential treatment options for patients with ulcerative colitis or other conditions, if any; the potential availability and frequency of administration of IMU-838 as a potential treatment for patients with ulcerative colitis or for patients with other conditions; 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 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, 2020, filed with the SEC on February 26, 2021, 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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