- Top-Line Data Expected in Q1 2021 -

NEW YORK, Nov. 2, 2020 /PRNewswire/ -- **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 that the company has enrolled and randomized 200 patients, pre-specified in the protocol as sufficient to perform the main efficacy analysis of the phase 2 part of the CALVID-1 trial for its selective oral DHODH inhibitor, IMU-838, in hospitalized patients with moderate coronavirus disease 2019 (COVID-19). The aim of the CALVID-1 trial is to investigate IMU-838 as an oral treatment option for moderate COVID-19 and to support potential use of IMU-838 as a treatment for current and potential future viral pandemic threats. The trial is being conducted under an investigational new drug application granted by the U.S. Food and Drug Administration using a single global protocol with clinical sites in the United States, Germany and a range of other European countries.

The current part of CALVID-1 is defined as a phase 2 proof-of-activity trial. As per the protocol, approximately 200 patients were to be included in order to perform a main efficacy analysis which will be used, in consultation between Immunic and an Independent Data Monitoring Committee (IDMC), to assess clinical activity of IMU-838 in moderate COVID-19 based on pre-defined criteria. No formal statistical analysis was pre-specified for this main analysis and all endpoints will be analyzed descriptively. Enrollment continues while the analysis is being prepared. Apart from assessing the clinical activity of IMU-838, the main analysis of the phase 2 part of the CALVID-1 trial may also be used for sample size determination, endpoint selection and potential other trial adjustments in order to continue with a confirmatory phase 3 trial, if such continuation is warranted. The final design of the phase 3 portion will be submitted as a protocol amendment to regulatory authorities.

"Enrollment of 200 patients in the phase 2 part of our CALVID-1 trial is another notable achievement for our lead asset, IMU-838, and comes on the heels of the previously announced interim safety results that supported continuation of this trial without modifications," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Given the established broad antiviral activity of IMU-838 in multiple virus strains as well as different cell cultures infected with SARS-CoV-2, we look forward to the findings of the main efficacy analysis of the phase 2 part of our CALVID-1 trial, which is expected to be available in the first quarter of 2021, after which we will be able to evaluate whether the program may be expanded into a confirmatory phase 3 trial."

Andreas Muehler, M.D., Chief Medical Officer of Immunic, added, "We greatly appreciate the strong support we have received from both our clinical investigators and site study teams during such a challenging and unprecedented period. The Immunic team is extremely pleased with the speed at which the trial has enrolled, which is a direct result of the symbiotic partnership we have built with our investigators and local clinical Contract Research Organizations."

For more information on this clinical trial, please visit:www.clinicaltrials.gov, NCT04379271.

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 phase 2 trials in patients with ulcerative colitis and COVID-19. 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. Furthermore, Immunic's collaboration partner, the Mayo Clinic, has started an investigator-sponsored proof-of-concept clinical trial testing IMU-838 activity in patients with primary sclerosing cholangitis. To date, IMU-838 has already been tested in about 650 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 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. Immunic announced positive 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. 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 to safely and effectively target diseases; clinical data for IMU-838; the timing of current and future clinical trials; the potential for IMU-838 as a treatment for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections associated with coronavirus disease 2019 (COVID-19) and any clinical trials, collaborations and approvals relating to such potential treatment; 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.

Contact Information

Immunic, Inc.
Jessica Breu
Head of Investor Relations and Communications
+49 89 2080 477 09
jessica.breu@imux.com

US IR Contact
Rx Communications Group
Melody Carey
+1 917 322 2571
immunic@rxir.com

US Media Contact
KOGS Communication
Edna Kaplan
+1 781 639 1910
kaplan@kogspr.com

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