NEW YORK, Sept. 28, 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 the results of a pre-planned interim safety analysis and a recruitment update from the ongoing phase 2 CALVID-1 trial of its selective oral DHODH inhibitor, IMU-838, in patients with moderate coronavirus disease 2019 (COVID-19). Based on the available safety data, an Independent Data Monitoring Committee (IDMC) has concluded that the study should continue without changes. The IDMC will perform a second safety analysis when additional patient data is available. To date, 110 patients have been enrolled in the CALVID-1 trial and enrollment is progressing well.

During this interim safety analysis, all available study safety results were unblinded to the members of the IDMC, while the company, investigators and enrolled patients remained blinded and no unblinded data has been shared with Immunic. As pre-defined in the study protocol, the analysis was based on data from only a relatively small number of patients in the CALVID-1 trial, and no formal statistical analysis was performed. It was not designed to be a futility analysis nor was any assessment of efficacy done. This interim safety analysis and the conclusions made by the IDMC may not reflect results of a final analysis of the trial once the full data set is analyzed.

"The IDMC's recommendation to continue our CALVID-1 trial, without changes, is another important milestone in the development of IMU-838 as a potential treatment option for patients with COVID-19," stated Andreas Muehler, M.D., Chief Medical Officer of Immunic. "Interest in the study is strong, with a total of 110 patients already enrolled. We plan to report the results of a pre-planned unblinded interim analysis of all available efficacy, biomarker and virus titer data later this year, once approximately 200 patients have been treated, after which we will be able to evaluate whether an expansion of the program into a confirmatory phase 3 trial is warranted."

The aim of the CALVID-1 trial is to investigate IMU-838 as an oral treatment option for COVID-19 and to enable the use of IMU-838 as a treatment for current and potential future pandemic threats. The trial is expected to initially enroll approximately 230 patients at 10-35 centers across Europe and the United States. Patients will be randomized to receive either 22.5 mg of IMU-838 twice daily, or placebo twice daily, for 14 consecutive days. Patients in both arms are also eligible to receive investigator's choice of standard-of-care therapy throughout the duration of the study. Inclusion criteria call for hospitalized adult patients with a confirmed SARS-CoV-2 infection fulfilling clinical status category 3 or 4, as assessed with the nine-category ordinal scale proposed by the World Health Organization (WHO) COVID-19 Therapeutic Trial Synopsis, as well as certain additional clinical and laboratory conditions. The primary endpoint is the proportion of patients free of invasive ventilation throughout the entire study period. Secondary endpoints include duration of hospitalization, duration of intensive care unit (ICU) treatment, 28-day all-cause mortality, time to clinical improvement and time course of viral load. The study is designed to prevent clinically significant complications of hospitalized COVID-19 patients. Given the recently increased involvement of younger patients and the shifting dynamics in the global pandemic progression, Immunic will continue to adapt endpoints and clinical evaluations in anticipation of the potential transition into a clinical phase 3 trial. The genetic evolution to new variants of SARS-CoV-2 over the last few months is expected to have little influence on a therapy such as IMU-838 that targets human host cell metabolism required for virus replication as compared to therapies that rely on specific viral targets.

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 top-line 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 August 2020. 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. 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 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.

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https://ir.imux.com/2020-09-28-Immunic-Inc-Announces-Results-From-Interim-Safety-Analysis-and-Recruitment-Update-From-Its-Ongoing-Phase-2-CALVID-1-Trial-of-IMU-838-in-Patients-With-Moderate-COVID-19