NEW YORK, June 15, 2020 /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 dosing of the first patients in its phase 2, CALVID-1 clinical trial of IMU-838, the company's selective oral DHODH inhibitor, in coronavirus disease 2019 (COVID-19), at several sites in different European countries. Patients will be enrolled at 10 to 35 centers in Germany, the United States and a half dozen European countries.

CALVID-1 recently received regulatory allowance from the German health authority, BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte), from the U.S. Food and Drug Administration (FDA) and from regulatory authorities in other European countries involved in the study. It is a prospective, multicenter, randomized, placebo-controlled, double-blind clinical trial in patients with moderate COVID-19, designed to evaluate efficacy, safety and tolerability of IMU-838. Top-line data is expected to be available later this year.

"Dosing of the first patients in our CALVID-1 trial represents a key milestone in advancing our lead asset, IMU-838, as a potential, novel treatment option for COVID-19," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Moreover, the CALVID-1 trial is an important strategic expansion of our clinical development of IMU-838 and adds another near-term data readout to our pipeline."

Andreas Muehler, M.D., Chief Medical Officer of Immunic, noted, "Backed by strong preclinical data and a unique profile, IMU-838 has the potential to become an important therapy for treating COVID-19. We expect to include approximately 230 hospitalized COVID-19 patients to evaluate IMU-838's efficacy, safety and tolerability. An efficacy interim analysis is scheduled after approximately 200 patients have been enrolled. If activity is shown in this interim analysis, our goal is to expand into a confirmatory phase 3 trial using an adaptive trial design."

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 COVID-19, relapsing-remitting multiple sclerosis and ulcerative colitis. 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.

**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. The company is developing three small molecule products: 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. IMU-838 is in phase 2 clinical development for COVID-19, relapsing-remitting multiple sclerosis and ulcerative colitis, 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; preclinical and 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 March 31, 2020, filed with the SEC on May 8, 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.immunic-therapeutics.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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