Immunic, Inc. Receives First Regulatory Approval from German Health Authority BfArM to Initiate a Phase 2 Clinical Trial of its Selective Oral DHODH Inhibitor, IMU-838, in COVID-19 Patients

NEW YORK, May 13, 2020 – 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 it has received first regulatory approval from Germany's BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) to initiate a phase 2 clinical trial of its selective oral DHODH inhibitor, IMU-838, in coronavirus disease 2019 (COVID-19). The CALVID-1 study is a prospective, multicenter, randomized, placebo-controlled, double-blind phase 2 clinical trial in approximately 230 patients with moderate COVID-19, designed to evaluate efficacy, safety and tolerability of IMU-838. Dosing of the first patient is expected to occur later this month. Top-line data is expected to be available later this year.

"Approval to begin the CALVID-1 phase 2 clinical trial in Germany is a significant achievement that will allow for the near-term investigation of the oral DHODH inhibitor, IMU-838, in COVID-19 patients," commented Prof. Maria Vehreschild, M.D., Head of Infectious Diseases at University Hospital Frankfurt and Principal Investigator of one of the clinical sites participating in the study. "Given IMU-838's broad antiviral effect, recently confirmed preclinical activity against SARS-CoV-2 itself, as well as its selective effect against hyper-activated immune cell populations which may play a role in the potentially deadly complications of interstitial lung disease, IMU-838 represents a prospective, potential treatment option that merits urgent investigation."

Immunic recently announced that IMU-838 had successfully demonstrated preclinical activity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Specifically, IMU-838 was observed to inhibit replication of clinical isolates of SARS-CoV-2 associated with COVID-19. In cellular assays, IMU-838 demonstrated this antiviral activity at concentrations which are well below the blood concentrations associated with IMU-838 dosing regimens studied in ongoing and previous clinical trials. In addition, IMU-838 has an attractive pharmacokinetic, safety and tolerability profile and, to date, has already been tested in about 650 individuals.

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. All patients are also eligible to receive investigator's choice of standard-of-care therapy throughout the duration of the study. Inclusion criteria are 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 will be 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 viral titer reduction.

The CALVID-1 study will employ an adaptive trial strategy by including interim safety and efficacy assessments. If clinical activity of IMU-838 is confirmed by the Independent Data Monitoring Committee after the first interim analysis, which is scheduled to occur after approximately 200 patients have completed the blinded treatment period, an expansion of this trial into a confirmatory phase 3 trial could be recommended.

"The speed of preparation and approval for this important phase 2 clinical trial for IMU-838 speaks to the strength of our data package, while also reflecting the urgent global need to develop useful therapies against COVID-19," stated Andreas Muehler, M.D., Chief Medical Officer of Immunic. "IMU-838's profile, as an orally available DHODH inhibitor that employs a host-based mode of action, thereby providing broad-spectrum antiviral activity, makes it a unique, potential therapeutic option which may be applicable as either a standalone or combination therapy. All phase 2 preparatory activities have been completed and we anticipate beginning the trial in short order."

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 relapsing-remitting multiple sclerosis and ulcerative colitis. IMU-838 is also under investigation as a potential treatment option for SARS-CoV-2 infections associated with COVID-19. 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 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 considered in Crohn's disease. The company is also investigating IMU-838 as a potential treatment option for COVID-19. 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 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.

Contact Information

Immunic, Inc.
Jessica Breu
Manager 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
Knight Marketing Communications, Ltd.
Kevin Knight
+1-206-451-4823
kknightpr@gmail.com