Immunic, Inc. Reports that IMU-838, a Selective Oral DHODH Inhibitor, Has Demonstrated Preclinical Activity Against SARS-CoV-2 and Explores Plans for a Phase 2 Clinical Trial in COVID-19 Patients

– In Cellular Assays with SARS-CoV-2 Clinical Isolates, IMU-838 Shows Ability to Inhibit Viral Replication of SARS-CoV-2 –

– Live Webcast will be Held at 8:00am EST / 5:00am PST / 2:00pm CEST on Wednesday, April 22, 2020 –

NEW YORK, April 21, 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 reported that its lead asset, IMU-838, a selective oral DHODH inhibitor, has successfully demonstrated preclinical activity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). More specifically, IMU-838 was observed to inhibit replication of clinical isolates of SARS-CoV-2 associated with coronavirus disease 2019 (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. These positive results have encouraged Immunic to prepare a clinical development program for IMU-838 as a potential treatment option for patients with COVID-19 and potential other, future viral pandemics.

“The current COVID-19 pandemic poses a major challenge to the healthcare community, worldwide, and it is essential to find safe and efficacious therapies,” commented Prof. Maria Vehreschild, M.D., Head of Infectious Diseases at University Hospital Frankfurt. “While most such efforts are focused on drugs and vaccines aimed at viral targets, it is particularly important to explore treatment options targeting host cell factors that are able to act with less dependence on the genetic drift of viruses and synergistically to standard-of-care antiviral therapies. With that in mind, DHODH inhibitors, such as IMU-838, present a very promising approach.”

Prof. Vehreschild went on to note that, “DHODH inhibition selectively blocks the *de novo* production of pyrimidines, an essential RNA building block, in metabolically activated cells such as virus-infected cells. In addition, DHODH inhibitors may help reduce the severity or virulence of infection through several mechanisms. First, DHODH inhibition prevents the production of viral RNA and proteins and, therefore, prevents viral replication. Second, it induces innate immunity in an interferon independent setting as an early host-based antiviral response. Third, DHODH inhibition may ameliorate the overshooting immune response, as seen in severe COVID-19 cases, by selectively targeting highly activated immune cells, but without broader anti-proliferative or immunosuppressive effect.”

IMU-838 is already being investigated in ongoing phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis, ulcerative colitis and primary sclerosing cholangitis. Although the drug is being studied in these ongoing trials primarily for its anti-inflammatory effect, one of IMU-838's postulated benefits is a host-based antiviral effect, which may be important in these indications to potentially prevent virus reactivations known to occur with other immunomodulatory therapies. In support, IMU-838's antiviral

activity has previously been demonstrated *in vitro* against human immunodeficiency virus (HIV), hepatitis C virus (HCV), human cytomegalovirus (hCMV), Arenavirus and Influenza A virus. Given what is known about the natural course of the disease, IMU-838's combination of antiviral activity against the highly pathogenic SARS-CoV-2 and a selective immunomodulatory effect against highly activated immune cells may be a promising profile for the treatment of COVID-19. Importantly, IMU-838 has an attractive pharmacokinetic, safety and tolerability profile and, to date, has already been tested in about 650 individuals.

“The broad antiviral activity of IMU-838 has been well documented and preclinical testing affirms the antiviral activity of IMU-838 against SARS-CoV-2. As a result, we are exploring the initiation of a phase 2 clinical trial to determine if IMU-838 could be a meaningful therapeutic option for the current worldwide pandemic caused by COVID-19 and potential future pandemic threats,” stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. “In light of this recent data and the global health crisis caused by COVID-19, we view this strategic expansion of our core business focus as urgent and necessary. Implementation of this program requires a broad set of activities, and we are actively exploring additional sources to expand the current funding of this important new potential application for IMU-838. At the same time, we continue to progress our non-viral programs as previously planned.”

Management noted that Immunic is collaborating with several regulatory agencies and other institutions in the United States and in Europe to define and accelerate the development path for IMU-838 in COVID-19. The aim is to investigate IMU-838 as an oral treatment option for COVID-19 and to enable the use of IMU-838 in treating current and potential future pandemic threats. Immunic intends to initiate a prospective, multicenter, randomized, placebo-controlled, double-blind phase 2 clinical trial in patients with moderate COVID-19 disease and clinical symptoms, in order to evaluate efficacy, safety and tolerability. The plan is to test IMU-838 versus placebo on the background of investigator’s choice of standard-of-care therapy used in both treatment arms. Adequate drug supply exists to begin clinical testing in COVID-19 very soon.

“Our recent *in vitro* data confirms that IMU-838 may present a particularly promising approach for treating COVID-19, and even other, future viral pandemics,” said Andreas Muehler, M.D., Chief Medical Officer of Immunic. “Given that IMU-838 targets a step performed by the infected host cell and not the virus itself, we believe that IMU-838 may also provide an approach that is relatively protected from the development of drug resistance. In COVID-19, this would also potentially allow to combine the host cell-targeted treatment, IMU-838, with effective antiviral treatments. Based on our positive preclinical data, the fact that IMU-838 is a differentiated approach with potential for synergy with existing drugs, and its strong pharmacokinetic, safety and tolerability profile, we believe that IMU-838 is a particularly compelling candidate for development as a treatment option for COVID-19.”

In addition to IMU-838, Immunic also has several highly potent, antiviral drug candidates in early stages of development.

Live Webcast
Immunic will host a live webcast at 8:00am EST / 5:00am PST / 2:00pm CEST on Wednesday, April 22, 2020 to discuss the potential use of IMU-838 in COVID-19 and the envisaged clinical development program. Speakers will include Dr. Vitt, Dr. Muehler, Dr. Hella Kohlhof, Chief Scientific Officer, and Dr. Manfred Groeppel, Chief Operating Officer, as well as Prof. Vehreschild.

To participate in the live webcast, please follow this link:
https://www.webcaster4.com/Webcast/Page/2301/34001

The webcast will be held in English. Questions can be asked via the question and answer tool any time during the presentation. An archived replay of the webcast will be available on Immunic's website at: ir.imux.com.

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 causing 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.

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 potential treatment for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections causing coronavirus disease 2019 (COVID-19) and other viruses 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, 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, 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.

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