Immunic, Inc. Announces Enrollment of First Patient in its Phase 3 ENSURE Program of vidofludimus calcium (IMU-838) in Relapsing Multiple Sclerosis

NEW YORK, November 18, 2021 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases, today announced the first patient enrolled in its phase 3 ENSURE program of lead asset, vidofludimus calcium (IMU-838), the company's selective oral DHODH inhibitor, in patients with relapsing multiple sclerosis (RMS).

"Enrollment of the first patient in ENSURE, which comes on the heels of initiating our supportive phase 2 CALLIPER trial in patients with progressive multiple sclerosis, marks an important inflection point for Immunic as we advance our lead asset, vidofludimus calcium, into active clinical phase 3 development," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Based on the strong activity observed in our phase 2 EMPhASIS trial and the drug's well-established safety and tolerability profile to date, we believe that the design of the ENSURE program provides a straightforward path towards potential regulatory approval of vidofludimus calcium in RMS."

"The progression of this pivotal phase 3 program for vidofludimus calcium and approval of the trial design by many ethics committees and regulators reflects and validates our approach," added Andreas Muehler, M.D., Chief Medical Officer of Immunic. "The ENSURE program, along with the supportive phase 2 CALLIPER trial in progressive multiple sclerosis, designed to corroborate the neuroprotective potential of vidofludimus calcium and back its differentiated profile, gives us a strong foundation from which we hope to ultimately position the drug as a preferred oral therapeutic option that allows MS patients to continue their normal social lives without being reminded that they are on a chronic treatment."

The ENSURE program comprises twin multicenter, randomized, double-blind phase 3 trials designed to evaluate the efficacy, safety, and tolerability of vidofludimus calcium versus placebo in RMS patients. Each trial is expected to enroll approximately 1,050 adult patients with active RMS at more than 100 sites in more than 15 countries, including the United States, Latin America, Central and Eastern Europe, and India. Patients will receive either 30 mg daily doses of vidofludimus calcium or placebo and the primary endpoint for both trials is time to first relapse up to 72 weeks. Key secondary endpoints include volume of new T2-lesions, time to confirmed disability progression, time to sustained clinically relevant changes in cognition, and percentage of whole brain volume change, grey matter volume, and white matter volume. With regard to the disability progression endpoint, the ENSURE program applies a pooled analysis of disability worsening across both trials, which may be further supported by data from the CALLIPER trial.

An interim analysis to assess event rates is planned to occur after a certain number of relapses have occurred in the double-blind treatment periods. This analysis is intended to inform potential sample size adjustment and help ensure that the final study readout is not planned to occur before sufficient events have been achieved. This interim analysis will also allow for a non-binding futility analysis.

About Multiple Sclerosis
Multiple sclerosis (MS) is an autoimmune disease that affects the brain, spinal cord and optic nerve. In MS, myelin, the coating that protects the nerves, is attacked and damaged by the immune system. Thus, MS is considered an immune-mediated demyelinating disease of the central nervous system. MS affects approximately one million people in the United States, and more than 2.8 million people worldwide. The disease mainly affects young adults of prime working age, although MS can occur at any age. MS is at least two to three times more common in women than in men.

Relapsing MS (RMS) is the most common form of the disease. Approximately 85% of patients with MS are expected to develop RMS, with some of these patients later developing more progressive forms of the disease. RMS is characterized by clearly defined attacks of new or increasing neurologic symptoms. These relapses are followed by periods of remission, or partial or complete recovery. During remissions, all symptoms may disappear, or some symptoms may continue and become permanent. MS is a progressive disease which, without effective treatment, leads to severe disability.

About vidofludimus calcium (IMU-838)
vidofludimus calcium 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). vidofludimus calcium 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, vidofludimus calcium did not show an increased rate of infections compared to placebo. In addition, DHODH inhibitors, such as vidofludimus calcium, 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. vidofludimus calcium was successfully tested in two phase 1 clinical trials in 2017 and is currently being tested in a phase 2 trial in patients with ulcerative colitis. In the third quarter of 2020, the company reported positive results from its phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting multiple sclerosis, achieving both primary and key secondary endpoints with high statistical significance. In the first quarter of 2021, Immunic announced that vidofludimus calcium showed evidence of clinical activity in its phase 2 CALVID-1 trial in hospitalized patients with moderate COVID-19. Also, in the first quarter of 2021, the company reported positive top-line data from an investigator-sponsored phase 2 proof-of-concept clinical trial of vidofludimus calcium in primary sclerosing cholangitis which was conducted in collaboration with Mayo Clinic. To date, vidofludimus calcium has been tested in more than 800 individuals and has shown an attractive pharmacokinetic, safety and tolerability profile. vidofludimus calcium 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 focused on treating chronic inflammatory and autoimmune diseases. The company is developing three small molecule products: its lead development program, vidofludimus calcium (IMU-838), 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, is currently being developed as a treatment option for multiple sclerosis, ulcerative colitis, Crohn's disease, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγt, is targeted for development in psoriasis, castration-resistant prostate cancer and Guillain-Barré syndrome. IMU-856,

which targets the restoration of the intestinal barrier function, is targeted for development in diseases involving bowel barrier dysfunction. 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 vidofludimus calcium to safely and effectively target diseases, including relapsing or progressive multiple sclerosis; preclinical and clinical data for vidofludimus calcium; the timing of current and future clinical trials; the availability, safety or efficacy of potential treatment options for patients with relapsing or progressive multiple sclerosis or other conditions, if any; the potential availability and frequency of administration of vidofludimus calcium as a potential treatment for patients with relapsing or progressive multiple sclerosis or for patients with other conditions; preparations for a clinical phase 3 program for vidofludimus calcium in relapsing multiple sclerosis; the nature, strategy and focus of the company and further updates with respect thereto; 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, 2020, filed with the SEC on February 26, 2021, 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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