- Preplanned Interim Analysis of 12-Week MRI Data from 10 mg IMU-838 Dose and Placebo, in Combination with Existing 30 and 45 mg Dose Data, Establishes Clear Dose-Response Relationship for IMU-838 -

- Totality of Data Clearly Supports Decision that 30 mg Once Daily Dose of IMU-838 Will Now Be Targeted for Phase 3 Development in Relapsing-Remitting Multiple Sclerosis -

- As Previously Announced, Phase 3 Program Expected to Start in the Second Half of 2021 -

NEW YORK, April 15, 2021 /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 interim data from Cohort 2 of its phase 2 EMPhASIS trial of IMU-838 in relapsing-remitting multiple sclerosis (RRMS). Immunic has concluded from this data, along with previously published data from Cohort 1, that 30 mg once daily IMU-838 is the most appropriate dose for future phase 3 trials in patients with RRMS. In support, Immunic notes that both the 30 mg and 45 mg dosing groups of IMU-838 in Cohort 1 performed equivalently regarding efficacy-related endpoints and there was no safety signal for either dosing group, as compared to placebo.

The second cohort of the EMPhASIS trial was designed to confirm that a dose lower than the 30 mg and 45 mg daily dose groups studied in the first cohort was unlikely to match the efficacy seen in these higher doses, thus enabling a straightforward and simpler phase 3 design. As anticipated, the 10 mg dose of IMU-838 proportionally showed less magnetic resonance imaging (MRI) lesion suppression in RRMS than the previously published results of the 30 mg and 45 mg doses of IMU-838. In particular, the 10 mg dose of IMU-838 in Cohort 2 demonstrated a placebo-adjusted reduction of 32% and 40% in combined unique active and gadolinium-enhancing MRI lesions at week 12, respectively. This result is numerically lower than the analogous reduction in MRI lesions observed in the 30 mg and 45 mg IMU-838 dosing arms of Cohort 1 at week 12, which ranged between 62% and 75%. Collectively, Immunic believes that these data demonstrate a clear dose-response pattern for IMU-838 in RRMS. The Cohort 2 interim analysis was performed after 59 randomized patients, receiving either 10 mg of IMU-838 or placebo once daily, completed week 12 MRI assessments. All Cohort 2 patients continue to be treated and will proceed to complete their 24-week blinded treatment.

Immunic remains in discussions with regulatory authorities, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency, regarding the planned phase 3 program in RRMS. At the FDA's request, Immunic plans to proceed directly to submitting an Investigational New Drug (IND) application, instead of holding an end-of-phase 2 meeting. As previously announced, feasibility and other preparatory activities for the phase 3 program are already ongoing and initiation is expected in the second half of 2021.

"The positive outcome of the interim analysis of our Cohort 2 sub-trial of IMU-838 in RRMS further strengthens our understanding of the dose-response relationship of IMU-838. The 10 mg interim data and its comparison to the already available 30 mg and 45 mg data provides additional support to address potential regulatory requests in the context of the design and execution of our phase 3 program," commented Andreas Muehler, M.D., Chief Medical Officer of Immunic. "Based on all available data, we believe that the dose of 30 mg once daily IMU-838 should be considered the most appropriate dose for RRMS patients. While we continue our discussions with major regulatory authorities, we will move ahead with formal phase 3 feasibility activities."

"Reporting of this Cohort 2 sub-trial analysis, on time and with results fully matching our expectations, is a testament to the strength of our scientific and clinical teams," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "We look forward to announcing details for the design of our phase 3 program, which we intend to initiate in the second half of this year, as soon as the final regulatory feedback is available. Data thus far continues to convince us that IMU-838 may become an important, new, oral therapeutic option with an outstanding combination of safety, tolerability and robust efficacy for the treatment of patients suffering from RRMS, and we are eager to move ahead with its final clinical development steps."

About Relapsing-Remitting 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. Relapsing-remitting MS (RRMS) is the most common form of the disease. Approximately 85% of patients with MS are expected to develop RRMS, with some of these patients later developing more progressive forms of the disease. RRMS 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. MS affects more than 700,000 people in the United States, and more than 2.2 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.

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 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 IMU-838 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 IMU-838 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 IMU-838 in primary sclerosing cholangitis which was conducted in collaboration with Mayo Clinic. To date, IMU-838 has been tested in more than 800 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. The company is developing three small molecule products: its lead development program, 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, COVID-19, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγt, is targeted for development in psoriasis 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 relating to Immunic's three development programs and the targeted diseases; the potential for IMU-838 to safely and effectively target diseases, including relapsing-remitting multiple sclerosis; preclinical and clinical data for IMU-838; the timing of current and future clinical trials; the availability, safety or efficacy of potential treatment options for patients with relapsing-remitting multiple sclerosis or other conditions, if any, that may be supported by the company's phase 2 EMPhASIS trial data; future analysis of the EMPhASIS trial data and presentations related thereto; the potential availability and frequency of administration of IMU-838 as a potential treatment for patients with relapsing-remitting multiple sclerosis or for patients with other conditions; preparations for a clinical phase 3 program for IMU-838 in relapsing-remitting 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.

Contact Information

Immunic, Inc.
Jessica Breu
Head of Investor Relations and Communications
+49 89 2080 477 09
jessica.breu@imux.com

US IR Contact
Rx Communications Group
Paula Schwartz
+1-917-322-2216
immunic@rxir.com

US Media Contact
KOGS Communication
Edna Kaplan
+1 781 639 1910
kaplan@kogspr.com

SOURCE Immunic, Inc.
