Immunic, Inc. Publishes Full Unblinded Clinical Data From Phase 2 EMPhASIS Trial of IMU-838 in Patients With Relapsing-Remitting Multiple Sclerosis and Announces Poster Presentation at the MSVirtual2020

– Unblinded Subgroup Analyses Show Consistent Effect for MRI Lesion Suppression Across Different Populations –

– Time Course of MRI Lesion Suppression Shows Reduction of Lesions Already Present at First Post-Baseline Scan at Week 6, Validating Rapid Attainment of Stable Therapeutic Drug Levels of IMU-838 –

– A Robust Decrease in Serum Neurofilament Light Chain, A Biomarker for Axonal Damage, Was Observed in Both Treatment Arms of IMU-838 But Not in the Placebo Arm –

– Poster, Including Audio Track, With Summary of Full Data Set, to be Presented Online at the MSVirtual2020 / 8th Joint ACTRIMS-ECTRIMS Meeting by Robert J. Fox, M.D. –

– Conference Call and Webcast to Review the Full Unblinded EMPhASIS Data to be Held September 14, 2020 at 8:00 am ET –

NEW YORK, September 11, 2020 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, today announced that the full unblinded clinical data set from the company's phase 2 EMPhASIS trial of lead asset, IMU-838, a selective oral DHODH inhibitor, in patients with relapsing-remitting multiple sclerosis (RRMS) is now available and expands on and confirms the company's previously announced positive top-line results. A summary will be presented at the MSVirtual2020 / 8th Joint ACTRIMS-ECTRIMS Meeting, taking place September 11-13, 2020, online, by Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio.

Abstract Title: Top-line Results of EMPhASIS, a Phase 2 Clinical Trial of Vidofludimus Calcium (IMU-838) in Relapsing-Remitting Multiple Sclerosis
Abstract Number: 1409
Poster Number: P0241

The poster presentation, including Dr. Fox's audio track, will be published today at 8:00 am ET in the MSVirtual2020 E-Poster Hall. Dr. Fox's poster presentation as well as the full unblinded EMPhASIS data will be filed on Form 8-K today, before the opening of the U.S. financial markets, and will be accessible on the "Events and Presentations" section of Immunic's website at: ir.imux.com/events-and-presentations.

"The results from the phase 2 study of IMU-838 in patients with RRMS are encouraging, as the data show that the trial has met its primary and key secondary endpoints with high statistical significance," stated Dr. Fox. "Importantly, IMU-838 appears to be safe and well-tolerated with robust suppression of combined unique active MRI lesions, which compares favorably to other first-line and oral medications in RRMS." Dr. Fox receives compensation as a chair of the steering committee for the EMPhASIS trial.

As previously announced, the phase 2 EMPhASIS trial achieved all primary and key secondary endpoints. In particular, the study met its primary endpoint, demonstrating a statistically significant reduction in the cumulative number of combined unique active (CUA) magnetic resonance imaging (MRI) lesions up to week 24 in patients receiving 45mg of IMU-838 once-daily, by 62% (p=0.0002), as compared to placebo. The study also met its key secondary endpoint, showing a statistically significant reduction in the cumulative number of CUA MRI lesions for the 30mg once-daily dose, by 70% (p<0.0001), as compared to placebo.

Subgroup analyses of the full unblinded data set showed a consistent effect for MRI lesion suppression across different populations, including a treatment effect independent of the presence of pre-study treatment (being treatment-naïve or experienced), of number of relapses before study or of country of enrollment. Further, the time course of MRI lesion suppression indicated that the reduction of lesions was already present at the first time point of assessment in the trial (week 6), which is consistent with the rapid attainment of stable therapeutic drug levels which has previously been shown for IMU-838.

Other secondary endpoints beyond MRI effect, such as relapse activity or changes in Expanded Disability Status Scale (EDSS), a measurement of neurological status for patients, showed trends toward an advantage for IMU-838 treatment groups versus placebo regarding time-to-first relapse and annualized relapse rate, although the study's duration was too short to provide a formal assessment. This indicates that the MRI activity seen in the IMU-838 arms may translate into activity for clinical relapse-related endpoints in future studies with longer follow-up durations, as also supported by a third-party meta-analysis of other trials in RRMS.

Both treatment arms for IMU-838 provided a robust decrease of serum neurofilament at 24 weeks (-17.0% for 30mg and -20.5% for 45mg) as compared to baseline values, while patients on placebo experienced a small 6.5% increase in serum neurofilament over the same period. A decrease in serum neurofilament light chain, a biomarker for axonal damage, which has been shown consistently to correlate with neurodegenerative and neuroinflammatory processes, has become one of the most important serum biomarkers for MS over the past few years.

Consistent with the company's earlier announcement regarding top-line data, the full unblinded data set also confirms that IMU-838 was very well tolerated, in general, and that its safety profile was similar to the placebo group. The most common treatment-emergent adverse events were headache and nasopharyngitis, which occurred in more than 5% of both IMU-838 and placebo treated patients. Adverse events (AE) were generally mild, and only one AE of severe intensity (in the placebo group) occurred. In addition, only three patients experienced serious AEs in this study, one in the placebo arm (cervical carcinoma) and two in the IMU-838 treatment arms (open fracture, ureterolithiasis/hydronephrosis). The lack of any hepatotoxicity signal in the AE reports was confirmed by a detailed analysis which showed no generalized effect on liver enzymes or bilirubin. No generalized effect on hematological parameters and no cases of neutropenia, leukopenia or lymphopenia were observed during treatment with IMU-838. In addition, and confirming the findings from the company's phase 1 multiple ascending dose trial of IMU-838 with doses of up to 50mg/day with a 1-week dosing-in using half-dose of IMU-838, the EMPhASIS study did not show a generalized effect on serum uric acid levels or an increased incidence of hematuria at either dose of IMU-838. The rate of treatment withdrawals in the 24-week blinded treatment period was only 4.3% in the pooled IMU-838 treatment arms versus 7.2% in the placebo group.

"The complete study data significantly boosts our confidence about the potential for IMU-838 as a novel, oral treatment of choice for RRMS," noted Andreas Muehler, M.D., Chief Medical Officer of Immunic. "In particular, the results show that both doses of IMU-838 were equally effective when looking at all efficacy-related measurements and biomarkers, and that neither dose presented any safety concerns that would be an important differentiator. From the full analysis of this phase 2 trial, we believe that the 30mg/day dose of IMU-838 should be considered the most appropriate dose for the extended treatment of the RRMS patients still remaining in this trial."

"The strength of the full unblinded data set from the EMPhASIS trial corroborates our belief that IMU-838 could provide RRMS patients with a distinctive combination of robust efficacy combined with favorable safety and tolerability," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "The reduction of MRI lesions observed at the very first post-baseline scan in the trial is extremely exciting and suggests quick onset of effect for this drug. The discontinuation rate, which was substantially below that of patients on placebo, indicates an encouraging combination of tolerability and efficacy, and we were pleased to see favorable data regarding overall treatment satisfaction, as measured by the patient reported questionnaires. We believe that the absence of hepatotoxic signals and other adverse events distinguishes IMU-838 well from other oral RRMS treatments, and that the lowering of neurofilament levels provides evidence of neuroprotective activity. Given these impressive results, we are continuing to prepare a clinical phase 3 program for IMU-838 in RRMS and will give more guidance on next steps once our discussions with experts as well as regulatory authorities have been completed."

The phase 2 EMPhASIS trial was an international, multicenter, double-blind, placebo-controlled, randomized, parallel-group study, designed to assess the efficacy and safety of IMU-838 in patients with RRMS. Of the 210 patients randomized in 36 centers across four European countries, 209 patients received at least one dose of IMU-838 or placebo (placebo n=69, 30mg IMU-838 n=71, 45mg IMU-838 n=69), and 198 patients completed the blinded 24-week treatment period. All enrolled patients were required to have shown disease activity based on clinical evidence of relapse and additional MRI criteria. The primary and key secondary endpoints were the cumulative number of CUA MRI lesions, up to week 24, for 45mg and 30mg of IMU-838, respectively. MRI was performed at baseline and at weeks 6, 12, 18 and 24, and was evaluated centrally by an independent, blinded MRI reader. The study includes an optional, extended treatment period for up to 9.5 years to evaluate long-term safety and tolerability of IMU-838.

Conference Call and Webcast Information

Immunic's management team will host a public conference call and webcast on September 14, 2020 at 8:00 a.m. Eastern Time to discuss the detailed analysis of the full unblinded data from the phase 2 EMPhASIS trial of IMU-838 in relapsing-remitting multiple sclerosis.

To participate in the conference call, dial 1-877-870-4263 (USA) or 1-412-317-0790 (International) and ask to be joined into the Immunic, Inc. call. A live, listen-only webcast of the conference call can be accessed at https://www.webcaster4.com/Webcast/Page/2301/37321 or on the "Events and Presentations" section of Immunic's website at ir.imux.com/events-and-presentations.

An archived replay of conference call and webcast will be available approximately one hour after the completion for one year on Immunic's website at: ir.imux.com.

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 phase 2 trials in patients with ulcerative colitis and COVID-19. The company reported positive top-line 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 August 2020. 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. 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, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. Immunic is developing three small molecule products: its 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. On August 2, 2020, Immunic announced positive top-line results from its phase 2 EMPhASIS trial of IMU-838 in patients with relapsing-remitting multiple sclerosis, reporting achievement of both primary and key secondary endpoints with high statistical significance, indicating activity for IMU-838 in this indication. IMU-838 is also in phase 2 clinical development for ulcerative colitis and COVID-19, 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, 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; the potential for IMU-838 as a treatment for patients with relapsing-remitting multiple sclerosis or for patients with 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 treatments; preparations for a clinical phase 3 program for IMU-838 in relapsing-remitting multiple sclerosis; future readouts of clinical data from phase 2 trials of IMU-838 in COVID-19; 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, 2019, filed with the SEC on March 16, 2020, the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 3, 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.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
Melody Carey
+1-917-322-2571
immunic@rxir.com

US Media Contact
Speak Life Science, LLC
Amy Speak
+1-617-420-2461
amy@speaklifescience.com