

## **- Milestone Achieved Nine Months Ahead of Initial Schedule; Top-Line Data Expected in Q3 2020 -**

SAN DIEGO, Oct. 10, 2019 /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, announced that the final patient was enrolled and randomized today in the company's phase 2 EMPHASIS trial of IMU-838 for the treatment of relapsing-remitting multiple sclerosis (RRMS). Patient enrollment was completed well ahead of the original trial schedule. As previously announced, enrollment and randomization of the last patient had been expected during the first half of 2020.

"Achievement of this milestone for our lead program, IMU-838, in RRMS, substantially ahead of prior expectations, reflects not only our team's strength in executing on the company's drug development strategy, but also the urgent need from patients for a safer oral treatment option," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Backed by newly released preclinical data confirming the superior profile of IMU-838 versus the currently approved DHODH inhibitor, teriflunomide, we remain highly enthusiastic about the potential of IMU-838 to become an important new best-in-class oral therapeutic treatment alternative for patients with RRMS."

The phase 2 EMPHASIS trial is an international, multicenter, double-blind, placebo-controlled, randomized, parallel-group study that enrolled 210 patients in 36 centers across four European countries, compared with a targeted enrollment of 195 patients. All enrolled patients were required to have shown disease activity based on clinical evidence of relapse and magnetic resonance imaging (MRI) criteria. The study's primary objective is to evaluate the dose response of 30 mg/day and 45 mg/day of IMU-838, once daily, for the treatment of RRMS based on MRI assessments. The primary endpoint is the cumulative number of combined unique active (CUA) MRI lesions, up to week 24. The study also includes an optional extended treatment period to evaluate long-term safety and tolerability. The data will be unblinded after all patients have completed the main treatment portion and the study database has been locked. Management continues to anticipate top-line data becoming available during the third quarter of 2020.

For more information on this clinical trial, please visit: [www.clinicaltrials.gov](http://www.clinicaltrials.gov), NCT03846219.

### **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 direct antiviral effect. 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. Furthermore, Immunic's collaboration partner, Mayo Clinic, has started an investigator-sponsored proof-of-concept clinical trial testing IMU-838 activity in patients with primary sclerosing cholangitis. Immunic also intends to initiate an additional phase 2 trial in patients with Crohn's disease.

### **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 ROR $\gamma$ t; 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 planned 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.immunic-therapeutics.com](http://www.immunic-therapeutics.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 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 "Item 1A. Risk Factors," in the company's Current Report on Form 8-K filed on July 17, 2019, and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov) or [ir.immunic-therapeutics.com/sec-filings](http://ir.immunic-therapeutics.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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<https://ir.imux.com/2019-10-10-Immunic-Inc-Announces-Completion-of-Enrollment-for-its-Phase-2-EMPhASIS-Trial-of-IMU-838-in-Patients-with-Relapsing-Remitting-Multiple-Sclerosis>