

## **Preclinical Findings Confirm Favorable Profile of IMU-838 as Compared to Teriflunomide in the Potential Treatment of Relapsing-Remitting Multiple Sclerosis**

SAN DIEGO, Sept. 11, 2019 /[PRNewswire](#)/ -- **Immunic, Inc. (Nasdaq: IMUX)**, a clinical-stage biopharmaceutical company focused on developing potentially best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, announced that Andreas Muehler, M.D., Chief Medical Officer of Immunic, will present today selected available and previously unpublished preclinical data summarizing the profile of its lead oral compound, IMU-838, as compared to the dihydroorotate dehydrogenase (DHODH) inhibitor, teriflunomide, at the Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) 2019 in Stockholm, Sweden. The poster will be presented during Poster Session 1 being held today, from 5:15 pm to 7:15 pm CEST. IMU-838, in phase 2 development for relapsing-remitting multiple sclerosis (RRMS) and ulcerative colitis, is a novel, orally available, next-generation selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking DHODH.

The poster, entitled, *"The DHODH Inhibitor IMU-838/Vidofludimus Calcium Shows a Superior Compound Profile as Compared to the Approved DHODH Inhibitor, Teriflunomide,"* co-authored by Dr. Muehler, Hella Kohlof, Ph.D., Chief Scientific Officer of Immunic, Manfred Gröppel, Ph.D., Chief Operating Officer of Immunic and Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic, highlights the favorable profile of IMU-838 regarding safety, biological selectivity, pharmacokinetics and potency, as compared to teriflunomide. Highlights of Dr. Muehler's presentation will include these selected and previously unpublished findings:

- Selectivity for DHODH, and IMU-838's lack of off-target effects on kinases were confirmed;
- IMU-838 showed a strong cytokine inhibition on stimulated human peripheral blood lymphocytes;
- IMU-838's short blood half-life of approximately 30 hours should make it favorable for once-daily dosing, as well as rapid wash-out, if needed;
- Treatment with IMU-838 results in fast onset, reaching steady state concentrations within 5 to 7 days;
- Dosing in humans did not result in increased rates of diarrhea, alopecia or neutropenia, as compared to placebo;
- Due to biological selectivity, the molecule has no general antiproliferative effect on immune cells.

"These previously unpublished data, which we believe illustrate a superior profile compared to teriflunomide, serve to bolster our dossier on IMU-838, and offer further support for our belief in its potential to become an important new, best-in-class, oral therapeutic option for patients with RRMS and other immunologic diseases," stated Dr. Muehler. "We are honored to present this additional compelling data at the ECTRIMS 2019 Congress, giving us an important opportunity to talk directly to the scientific community about our lead, phase 2 pipeline program."

### **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. Immunic also intends to initiate an additional phase 2 trial in patients with Crohn's disease. 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.

### **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, IMU-935 and IMU-856 to safely and effectively target diseases; preclinical and clinical data for IMU-838; the timing of 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) 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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<https://ir.imux.com/2019-09-11-Immunic-Inc-to-Present-Selected-Available-and-Previously-Unpublished-Data-Regarding-Lead-Program-IMU-838-at-the-Congress-of-the-European-Committee-for-Treatment-and-Research-in-Multiple-Sclerosis-2019>