

NEW YORK, June 15, 2022 /PRNewswire/ -- **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 that data from its phase 2 EMPHASIS trial of lead asset, vidofludimus calcium (IMU-838), in patients with relapsing-remitting multiple sclerosis (RRMS), has been published in the peer reviewed journal, *Annals of Clinical and Translational Neurology*.

The paper, authored by coordinating investigator, Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio, is entitled, "*Safety and efficacy of vidofludimus calcium, a selective dihydroorotate dehydrogenase inhibitor, in relapsing-remitting multiple sclerosis (EMPHASIS): a double-blind, randomized, placebo-controlled phase 2 trial.*" It can be accessed through the following link: <https://onlinelibrary.wiley.com/doi/10.1002/acn3.51574>.

Vidofludimus calcium is a novel and second generation selective dihydroorotate dehydrogenase (DHODH) inhibitor without off-target effects on kinases seen with drugs of the same class, which may lead to a better safety and tolerability profile. The inhibition of DHODH has been shown to suppress magnetic resonance imaging (MRI) brain lesions and disease activity in multiple sclerosis. The paper assessed the safety and activity on MRI-based endpoints as well as clinical and biomarker assessments of vidofludimus calcium in patients with RRMS.

"The results from this phase 2 trial of vidofludimus calcium in patients with RRMS are encouraging, as the trial met its primary and key secondary endpoints for suppressing the number of combined unique active magnetic resonance imaging lesions," stated Dr. Fox. "Importantly, vidofludimus calcium was found to be safe and well-tolerated as compared to placebo, with no increase in the rate of infections, effects on liver or blood cell laboratory parameters and with a very low treatment discontinuation rate." Dr. Fox receives consulting fees for serving as an advisor to Immunic.

"The publication of the EMPHASIS trial results in a peer-reviewed journal is a testament to the importance of our phase 2 findings for vidofludimus calcium in patients with RRMS," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Based on these strong data, we have enrolled patients in our phase 2 CALLIPER trial in progressive multiple sclerosis patients to further explore vidofludimus calcium's neuroprotective potential, as exemplified by a slowing of brain atrophy and delay in disability worsening, which are often caused by axonal and neural damage. Equally exciting, we have also been enrolling patients in our phase 3 ENSURE program of vidofludimus calcium as a treatment for relapsing multiple sclerosis (RMS). We remain highly enthusiastic about the potential for this novel therapeutic to become a best-in-class DHODH inhibitor in RMS."

The full unblinded data from the double-blind, placebo-controlled, phase 2 EMPHASIS trial (Cohort 1 with 30 and 45 mg of vidofludimus calcium or placebo once-daily) were reported by Immunic in September of 2020 and are summarized in more detail in this peer-reviewed journal. The 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) MRI lesions up to week 24 in patients receiving 45 mg of vidofludimus calcium 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 30 mg once-daily dose, by 70% ( $p<0.0001$ ), as compared to placebo. The data set also confirms that vidofludimus calcium was very well tolerated, in general, and that its safety profile was similar to the placebo group.

Earlier in 2022, Immunic released data from a second, lower dose cohort of the EMPHASIS trial in RRMS (Cohort 2: 10 mg of vidofludimus calcium or placebo once-daily) which Immunic intends to summarize in a future publication. In the final Cohort 2 data set, the anti-inflammatory effects of vidofludimus calcium at the 10 mg dose were observed to be lower (13% reduction of gadolinium-enhancing magnetic resonance imaging lesions up to 24 weeks, as compared to placebo) than those found with the 30 mg vidofludimus calcium dose in the pooled Cohort 1 and 2 data (78% reduction), providing further support for the selection of 30 mg dosing in the ongoing ENSURE trials in RMS.

## **About Vidofludimus Calcium (IMU-838)**

*Vidofludimus* calcium is an investigational drug in development as an orally available, next-generation selective immune modulator that is designed to inhibit the intracellular metabolism of activated immune cells by blocking the enzyme dihydroorotate dehydrogenase (DHODH). Vidofludimus calcium has been observed to act 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. To date, vidofludimus calcium has been tested in more than 1,100 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, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor ROR $\gamma$ /ROR $\gamma$ t, 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](http://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, expected timing and results of clinical trials, 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; preclinical and clinical data for vidofludimus calcium; the timing of current and future clinical trials and anticipated clinical milestones; 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 substantial 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 financial and other resources to meet business objectives and operational requirements, the fact that the results of earlier preclinical studies and clinical 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, 2021, filed with the SEC on February 24, 2022, 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.imux.com/sec-filings](http://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](mailto:jessica.breu@imux.com)

### US IR Contact

Rx Communications Group  
Paula Schwartz  
+1 917 322 2216  
[immunic@rxir.com](mailto:immunic@rxir.com)

### US Media Contact

KOGS Communication  
Edna Kaplan  
+1 781 639 1910  
[kaplan@kogspr.com](mailto:kaplan@kogspr.com)

<https://ir.imux.com/2022-06-15-Immunic-Announces-Publication-of-Data-From-Its-Phase-2-EMPhASIS-Trial-of-Vidofludimus-Calcium-in-Relapsing-Remitting-Multiple-Sclerosis-in-Peer-Reviewed-Journal,-Annals-of-Clinical-and-Translational-Neurology>