

- *Long-Term Open-Label Treatment With Vidofludimus Calcium Was Associated With a Low Rate of Confirmed Disability Worsening (CDW) Over Time -*
- *CDW Data Compares Favorably to Historical Trial Data for Currently Available Multiple Sclerosis Treatments -*

NEW YORK, Feb. 22, 2023 /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 Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio, will present data from the blinded and open-label extension (OLE) parts of the company's phase 2 EMPhASIS trial of lead asset, vidofludimus calcium (IMU-838), a selective oral DHODH inhibitor, in relapsing-remitting multiple sclerosis (RRMS) at the eighth annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2023, taking place February 23-25 in San Diego, California. Dr. Fox has served as Coordinating Investigator in Immunic's multiple sclerosis (MS) programs and receives consulting fees for serving as an advisor to Immunic.

"The encouraging data from the 24-week double-blind main treatment period of the phase 2 EMPhASIS trial of vidofludimus calcium in RRMS patients showed that 12-week and 24-week Confirmed Disability Worsening (CDW) events occurred in 1.6% of subjects in the combined vidofludimus calcium treatment arms as compared to 3.7% in the placebo group," stated Dr. Fox. "Additionally, in the OLE phase, the proportion of patients free from 12-week CDW was 97.2% after 48 weeks and 94.2% after 96 weeks of vidofludimus calcium treatment, as measured from the start of the OLE phase. Similarly, 97.6% of patients were free from 24-week CDW after 48 weeks and 94.5% after 96 weeks."

"The opportunity to present data from our EMPhASIS trial at the ACTRIMS Forum 2023 is of high relevance for Immunic, allowing us to further highlight to the industry the potential of vidofludimus calcium in RRMS, especially as the CDW rates seen in this trial were on the lower end of those observed in historical trials with currently approved MS medications," added Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "We eagerly await reporting data from our ongoing phase 3 ENSURE program in relapsing MS as well as our ongoing phase 2 CALLIPER trial in progressive MS. In the second half of this year, we already expect to provide selected biomarker data from an interim analysis of the CALLIPER trial to guide study progress. Vidofludimus calcium's well established safety profile, combined with its anti-inflammatory, antiviral and neuroprotective effects shown, to date, are impressive and we remain enthusiastic about the potential for this novel therapeutic to become a new treatment option for MS patients."

Presentation Details:

- **Abstract Number:** 697
- **Poster Title:** *Assessment of effect of vidofludimus calcium on MS progression in the blinded treatment and open-label extension periods of the phase 2 study (EMPhASIS) in relapsing-remitting multiple sclerosis*
- **Poster Number:** P068
- **Authors:** Robert J. Fox, Christian Wolf, Andreas Muehler, Matej Ondrus, Valentina Sciacca
- **Poster Session:** Poster Session 1
- **Date:** Thursday, February 23, 2023
- **Time:** 6:30 – 7:30 pm PT
- **Location:** Pacific Ballroom

The poster presentation will be accessible on the "Events and Presentations" section of Immunic's website at: ir.imux.com/events-and-presentations.

EMPhASIS is an international, multicenter, double-blind, placebo-controlled, randomized, parallel-group trial, designed to assess the efficacy and safety of vidofludimus calcium in patients with RRMS. The trial included a 24-week blinded main treatment period testing 10, 30 and 45 mg of vidofludimus calcium and placebo. In the third quarter of 2020, Immunic reported that the trial achieved both primary and key secondary endpoints with high statistical significance, and a safety and tolerability profile similar to placebo.

The trial also includes an optional long-term OLE phase running up to 9.5 years. An interim analysis was performed with data extraction in October 2022, when 209 patients remained on treatment in the OLE phase, some of whom have already received more than 180 continuous weeks (approximately four years) of active treatment with vidofludimus calcium.

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 in preclinical studies 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. IMU-935, a selective inverse agonist of the transcription factor ROR γ /ROR γ t, is targeted for development in psoriasis, and castration-resistant prostate cancer. IMU-856, which targets the restoration of the intestinal barrier function and regeneration of bowel epithelium, 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, sufficiency of cash, 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, increasing inflation, impacts of the Ukraine - Russia conflict on clinical trials, 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 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.

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