

– Data Show Encouraging Signals for Vidofludimus Calcium for Preventing or Delaying Confirmed Disability Worsening –

– Virtual Multiple Sclerosis R&D Day to be Held Today, November 17, 2022 at 11:00 am ET –

NEW YORK, Nov. 17, 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 reported newly available data from its phase 2 EMPHASIS trial of lead asset, vidofludimus calcium (IMU-838), in relapsing-remitting multiple sclerosis (RRMS). Long-term open-label treatment with vidofludimus calcium was associated with a low rate of confirmed disability worsening over time, and compares favorably to historical trial data for currently available multiple sclerosis (MS) medications.

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, with a safety and tolerability profile similar to placebo.

The trial also includes an optional long-term open-label extension (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.

During the 24-week double-blind main treatment period, 12-week and 24-week Confirmed Disability Worsening (12w/24wCDW) events occurred in 1.6% of subjects in the combined vidofludimus calcium treatment arms as compared to 3.7% in the placebo group. In the OLE phase, the proportion of patients free from 12wCDW was 97.6% after 48 weeks and 94.5% after 96 weeks of vidofludimus calcium treatment as compared to the start of the OLE phase. Similar results were observed for 24wCDW and sustained CDW. The OLE phase also showed low relapse activity.

"The newly obtained data from our phase 2 EMPHASIS trial of vidofludimus calcium in RRMS patients demonstrate an encouraging signal in preventing 12-week and 24-week confirmed disability worsening events as compared to placebo during the double-blind treatment phase. In addition, only a few patients on continuous open-label treatment with vidofludimus calcium developed confirmed disability worsening events over a 2-year time frame, and those rates observed with vidofludimus calcium are on the lower end of those observed in historical trials with currently approved MS medications," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "We look forward to receiving further, confirmatory data from our phase 3 ENSURE program in relapsing MS as well as our phase 2 CALLIPER trial in progressive MS. Our next MS-related data inflection point is an interim analysis for CALLIPER at the end of 2023 which will provide selected biomarker and functional data to guide study progress. If approved, we believe that vidofludimus calcium has the potential to be a unique treatment option targeted to the biology of MS with combined anti-inflammatory, antiviral, and neuroprotective effects."

### **Multiple Sclerosis R&D Webcast**

Immunic will host a Multiple Sclerosis R&D Webcast today, November 17, 2022 at 11:00 am ET. During the event, Immunic will provide an update on the scientific, preclinical and clinical progress of vidofludimus calcium in MS. In addition to the above-mentioned new data from the EMPHASIS trial, the presentation will include an update the ongoing phase 3 ENSURE program in relapsing MS and the ongoing phase 2 CALLIPER trial in progressive MS, as well as the drug's potential strategic and commercial positioning in the MS landscape.

Moreover, three invited key opinion leaders will discuss recent scientific findings and their effect on the MS treatment landscape. The featured experts will be:

- Fred D. Lublin, M.D., Saunders Family Professor of Neurology, Director, The Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Icahn School of Medicine, Mount Sinai Hospital, New York, NY, USA
  - Dr. Lublin will discuss new data published in 2022 illustrating that relapse-independent worsening is responsible for approximately 50% of disability worsening in the relapsing phase of MS, and 100% in the progressive phase of MS (Lublin FD, et al. How patients with multiple sclerosis acquire disability. *Brain*. 2022 Sep 14;145(9):3147-3161).
- Lawrence Steinman, M.D., Professor of Neurology and Neurological Sciences, Pediatrics, and Genetics, Stanford University School of Medicine, Department of Neurology & Neurological Sciences, Stanford, CA, USA
  - Dr. Steinman will present new data published in 2022 confirming the presence of cross-reactive antibodies between the Epstein-Barr virus (EBV) antigen EBNA1 and the central nervous system (CNS) protein

GlialCAM found in the cerebrospinal fluid of MS patients (Robinson WH, Steinman L. Epstein-Barr virus and multiple sclerosis. *Science*. 2022 Jan 21;375(6578):264-265).

- Heinz Wiendl, M.D., Ph.D., Director Department of Neurology with Institute of Translational Neurology, University of Münster, Münster, Germany
  - Dr. Wiendl will elaborate on new data published in 2022 showing that T cells in MS patients continuously recognize known EBV antigens not seen in a control group, consistent with an ongoing anti-EBV immune reaction in MS patients (Schneider-Hohendorf T, et al. Broader Epstein-Barr virus-specific T cell receptor repertoire in patients with multiple sclerosis. *J Exp Med*. 2022 Nov 7;219(11):e20220650).

Speakers from Immunic will be:

- Daniel Vitt, Ph.D., Chief Executive Officer and President
- Andreas Muehler, M.D., M.B.A., Chief Medical Officer
- Hella Kohlhof, Ph.D., Chief Scientific Officer

"We look forward to discussing the preclinical and clinical development progress of vidofludimus calcium at our MS R&D Day and would like to extend our thanks to Dr. Fred Lublin, Dr. Larry Steinman and Dr. Heinz Wiendl for joining the event," said Andreas Muehler, M.D., Chief Medical Officer of Immunic. "We are very excited that these three experts, the main authors of three major publications changing our pathophysiological understanding of MS, are part of this R&D Day. Dr. Lublin's analysis showed that there is a major component of disability worsening, even in early MS disease, that is independent of relapse and supports the notion that a smoldering, slowly progressing disease is an essential part of this disease. The publications by Dr. Steinman and Dr. Wiendl provide strong new evidence that EBV and related immune reactions may play a role during the course of the disease and may be hypothesized to contribute to a smoldering chronic infection. We believe that vidofludimus calcium, with its signal in preventing or delaying confirmed disability worsening seen in our phase 2 EMPhASIS trial and its well documented antiviral activity, including on EBV, is well positioned to address the newly highlighted mechanisms of disease progression."

### **Webcast Information**

The MS R&D webcast will be held virtually via Zoom. To participate, please register in advance at: [https://imux.zoom.us/webinar/register/WN\\_vVlraQmQTpG2dmAb8c9Qng](https://imux.zoom.us/webinar/register/WN_vVlraQmQTpG2dmAb8c9Qng).

Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.

An archived replay of the webcast will be available approximately one hour after completion on the "Events and Presentations" section of Immunic's website at: [ir.imux.com/events-and-presentations](http://ir.imux.com/events-and-presentations).

### **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 $\gamma$ /ROR $\gamma$ t, is targeted for development in psoriasis, and castration-resistant prostate cancer. 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, 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](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.

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