NEW YORK, Feb. 29, 2024 /PRNewswire/ -- **Immunic, Inc.** (Nasdaq: IMUX), a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, today announced the presentation of data from the company's phase 2 CALLIPER and CALVID-1 clinical trials of lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), in two poster presentations at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2024, taking place from February 29 to March 2, in West Palm Beach, FL.

"Having two poster presentations on our lead asset, vidofludimus calcium, at the prestigious ACTRIMS Forum is a testament to the strength of the data we have generated," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "In the interim analysis of our phase 2 CALLIPER trial, we saw a clear separation of vidofludimus calcium from placebo in serum neurofilament light chain (NfL) levels across all progressive multiple sclerosis (PMS) patients as well as all subtypes. We believe that the data set provides biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, further reinforcing its neuroprotective potential. The next inflection point for this potentially first-in-class Nurr1 activator for the treatment of PMS is the CALLIPER top-line data, expected in April of next year."

Dr. Vitt continued, "Our second poster on the phase 2 CALVID-1 trial illustrates that, because of vidofludimus calcium's potential ability to prevent the reactivation of the Epstein-Barr virus (EBV), it may also contribute to the reduction of fatigue in MS patients. While fatigue is one of the most dominating symptoms for MS patients influencing their quality of life and ability to participate in social activities, it remains largely unsolved from the clinical perspective. Our clinical trial in COVID-19 patients showed an initial signal that patients treated with vidofludimus calcium showed the post COVID symptom of fatigue less frequent than patients in the placebo arm. Recent third-party data in post COVID patients identified EBV reactivation as a potential cause for fatigue in this patient group. We aim to confirm the ability of vidofludimus calcium to influence fatigue and EBV reactivation in our ongoing phase 3 ENSURE trials in relapsing MS patients and hope that this may create yet another differentiating feature for this medication candidate."

Presentation Details:

- **Poster Title**: *Impact of Vidofludimus Calcium on Serum Neurofilament in Progressive MS: Data from the CALLIPER Interim Analysis*
- **Presenting Author:** Robert J. Fox, MD, Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurological Institute, Cleveland Clinic, Cleveland, Ohio
- **Abstract Number:** 509
- **Poster Number:** P044
- **Poster Session:** 1
- **Date:** Thursday, February 29, 2024
- **Time:** 6:00 – 7:30 pm ET

CALLIPER is a multicenter, randomized, double-blind, placebo-controlled phase 2 trial assessing efficacy and safety of vidofludimus calcium in PMS. The trial enrolled 467 patients with primary PMS (35.2%), non-active secondary PMS (59.5%), and active secondary PMS (7.9%) who were randomized 1:1 to vidofludimus calcium or placebo. A pre-planned interim analysis was conducted after half of the study participants completed 24 weeks of study treatment and had biomarker data available at baseline and Week 24. In total, 203 patients were included in the interim analysis, of which 29% had primary PMS, 61% non-active secondary PMS, and 10% active secondary PMS. Compared to placebo, serum NfL was decreased in the treatment group by 22.4% (p=0.01, post hoc). Additionally, a reduction was seen across all subtypes: -18.8% in primary PMS, -20.1% in non-active secondary PMS and -43.3% in active secondary PMS.

- **Poster Title:** *May Vidofludimus Calcium Potentially be Used to Reduce Fatigue in Multiple Sclerosis by Blocking EBV Reactivation?*
- **Presenting Author:** Dr. Alexandra Herrmann, Manager Translational Pharmacology, Immunic
- **Abstract Number:** 6
- **Poster Number:** P271
- **Poster Session:** 2
- **Date:** Friday, March 1, 2024
- **Time:** 6:00 – 7:30 pm ET

In the phase 2 CALVID-1 trial, patients aged 18 years or older who tested positive for COVID-19 were randomized to receive placebo or 45 mg of vidofludimus calcium for 14 days, with both groups receiving standard-of-care treatment. An analysis of the antiviral activity of vidofludimus calcium revealed a dose-dependent reduction of lytic EBV reactivation in B cells as well as reduced lytic EBV production in Akata cells. Results from a post hoc analysis of post COVID syndrome (PCS) symptoms indicated a potential contribution of vidofludimus calcium to the prevention of long-term fatigue, which is one of the most common PCS symptoms and known to be related to EBV reactivation. 80% of patients who received placebo reported fatigue, compared to 50% who received 45 mg vidofludimus calcium. Fatigue decreased in both

treatment groups over the next 9-17 weeks to 33% for placebo and to 17% for vidofludimus calcium. Therefore, by preventing the reactivation of EBV, vidofludimus calcium may also contribute to the reduction of fatigue in multiple sclerosis patients.

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

About Immunic, Inc.
Immunic, Inc. (Nasdaq: IMUX) is a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases. The company's lead development program, vidofludimus calcium (IMU-838), is currently in phase 3 and phase 2 clinical trials for the treatment of relapsing and progressive multiple sclerosis, respectively, and has shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis, progressive multiple sclerosis and moderate-to-severe ulcerative colitis. Vidofludimus calcium combines neuroprotective effects, through its mechanism as a first-in-class nuclear receptor related 1 (Nurr1) activator, with additional anti-inflammatory and anti-viral effects, by selectively inhibiting the enzyme dihydroorotate dehydrogenase (DHODH). IMU-856, which targets the protein Sirtuin 6 (SIRT6), is intended to restore intestinal barrier function and regenerate bowel epithelium, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, for which it is currently in preparations for a phase 2 clinical trial. IMU-381, which currently is in preclinical testing, is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases. 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, development 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 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 and the conflict in the Middle East on planned and ongoing 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, 2023, filed with the SEC on February 22, 2024, 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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