– Based on a Review of Unblinded Data, an Independent Data Monitoring Committee (IDMC) Confirmed that Predetermined Futility Criteria Have Not Been Met –

– IDMC Also Recommended Continuing Trial without Changes, Including no Need for a Potential Upsizing –

– ENSURE Program Remains on Track to be Completed in 2026 –

– Webcast to be Held Today, October 22, at 8:00 am ET –

NEW YORK, Oct. 22, 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 a positive outcome of the non-binding, interim futility analysis of its phase 3 ENSURE program, investigating lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), for the treatment of relapsing multiple sclerosis (RMS). Based on the outcome of the interim futility analysis, an unblinded Independent Data Monitoring Committee (IDMC) has recommended that the trials are not futile and should continue as planned.

"While Immunic remains blinded to all data, the IDMC's favorable recommendations in this interim analysis corroborate our initial assumptions for the design, powering and relapse rate of the twin phase 3 trials of vidofludimus calcium in RMS, and suggest that they are in line with the data observed so far," stated Andreas Muehler, M.D., M.B.A., Chief Medical Officer of Immunic. "In particular, the planned sample size seems appropriate to address the primary endpoint of time to first relapse. As the IDMC recommends, we are continuing the ENSURE trials unchanged, with completion expected in 2026."

"I am particularly excited about the positive outcome of the interim analysis of our phase 3 ENSURE trials, marking the successful achievement of a critical milestone for the program," added Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "We are confident in vidofludimus calcium's potential to transform the oral MS market and continue to believe that the phase 3 program provides a clear and straightforward path towards seeking potential regulatory approval in RMS. Our next clinical milestone for vidofludimus calcium is the top-line readout of our phase 2 CALLIPER trial in patients with progressive multiple sclerosis (PMS), which we expect to release in April of next year. If this data set continues to show a neuroprotective effect for vidofludimus calcium, we believe our drug may be positioned as first-in-class oral treatment option for PMS, a form of MS with highest unmet medical needs."

The interim futility analysis of the phase 3 ENSURE program was performed by an unblinded IDMC and based on a pre-specified assessment after approximately half of the planned first relapse events occurred in the double-blind treatment periods of each of the twin ENSURE-1 and ENSURE-2 trials. The analysis was intended to inform potential sample size adjustment and help prevent the final study readout from occurring before sufficient events have been achieved. The unblinded IDMC was asked to make two decisions: The first question, as to whether the trials are futile, was answered by the IDMC with "futility criteria have not been met." The second question, as to whether the sample size in each trial should be increased, was answered by the IDMC with "continue as planned." Both decisions were based on the conditional power of the trials at the time of the interim analysis. Immunic has remained blinded during the interim analysis and has not seen any of the data available to the IDMC to make their recommendations.

The ongoing ENSURE program comprises two identical multicenter, randomized, double-blind phase 3 trials designed to evaluate the efficacy, safety and tolerability of vidofludimus calcium versus placebo in RMS patients. Each of the trials, titled ENSURE-1 and ENSURE-2, is expected to enroll approximately 1,050 adult patients with active RMS at more than 100 sites in more than 15 countries, including the United States, India and countries in Latin America, Central and Eastern Europe. Patients are being randomized in a double-blinded fashion to either 30 mg daily doses of vidofludimus calcium or placebo and the primary endpoint for both trials is time to first relapse up to 72 weeks. Key secondary endpoints include time to confirmed disability worsening based on Expanded Disability Status Scale (EDSS) disability progression, volume of new T2-lesions, time to sustained clinically relevant changes in cognition, and percentage of whole brain volume change, grey matter volume and white matter volume. As previously reported, completion of ENSURE-1 is anticipated in the second quarter of 2026, with completion of ENSURE-2 expected in the second half of 2026.

Webcast Information
Immunic will host a webcast today at8:00 am ET. To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_fSJNHWuxRMGRPaMl3hUlqg or on the "Events and Presentations" section of Immunic's website at: ir.imux.com/events-and-presentations. 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 Immunic's website at: ir.imux.com/events-and-presentations.

About Vidofludimus Calcium (IMU-838)
Vidofludimus calcium is a small molecule investigational drug in development as an oral next-generation treatment option for patients with multiple sclerosis and other chronic inflammatory and autoimmune diseases. The selective immune modulator activates the neuroprotective transcription factor nuclear receptor related 1 (Nurr1), which is associated with direct neuroprotective properties. Additionally, vidofludimus calcium is a highly selective inhibitor of the enzyme dihydroorotate dehydrogenase (DHODH), which is a key enzyme in the metabolism of overactive immune cells and virus-infected cells. This mechanism is associated with the anti-inflammatory and anti-viral effects of vidofludimus calcium. Vidofludimus calcium has been observed to selectively act on hyperactive T and B cells while leaving other immune cells largely unaffected and enabling normal immune system function, e.g., in fighting infections. To date, vidofludimus calcium has been tested in more than 1,800 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 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 and cash runway, 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; announcements regarding the positive outcomes of the interim analysis of the phase 3 ENSURE trials; 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, including the ability to satisfy the minimum average price and trading volume conditions required to receive funding in tranche 2 and 3 of the January 2024 private placement, 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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https://ir.imux.com/2024-10-22-Immunic-Announces-Positive-Outcome-of-Interim-Analysis-of-Phase-3-ENSURE-Program-of-Vidofludimus-Calcium-in-Relapsing-Multiple-Sclerosis