Immunic Reports New, Positive Long-Term Open-Label Extension Data From Phase 2 EMPhASIS Trial of Vidofludimus Calcium in Relapsing-Remitting Multiple Sclerosis

– At Week 144, 92.3% of Patients Remained Free of 12-Week Confirmed Disability Worsening (CDW) With 92.7% Remaining Free of 24-Week CDW –

– Vidofludimus Calcium Continues to Demonstrate Favorable Safety and Tolerability Profile; Long-Term Data Now Available up to 5.5 Years –

NEW YORK, June 24, 2025 – Immunic, Inc. (Nasdaq: IMUX), a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, today reported new long-term open-label extension (OLE) data from its phase 2 EMPhASIS trial of lead asset, orally available nuclear receptor-related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), in patients with relapsing-remitting multiple sclerosis (RRMS).

"It is meaningful to see that patients treated with vidofludimus calcium during the OLE period of our phase 2 EMPhASIS trial in RRMS experienced a low rate of confirmed disability worsening (CDW) events, as measured by the Expanded Disability Status Scale (EDSS). This data, representing approximately 952 treatment years, further underlines our belief that vidofludimus calcium holds great potential to effectively manage the disease, help preserve neurological function, allow patients to maintain independence and improve long-term quality of life," stated Andreas Muehler, M.D., M.B.A., Chief Medical Officer of Immunic.

The data at week 144 showed that 92.3% of patients remained free of 12-week CDW, and 92.7% free of 24-week CDW. A total of 29 CDW events were confirmed at 12 weeks following the trigger event through week 144. Of these, 44.8% were associated with relapse-associated worsening (RAW), while only 13.8% were associated with progression independent of relapse activity (PIRA). Additionally, the cumulative data available from the EMPhASIS OLE period, thus far, further reinforces the favorable safety and tolerability profile of vidofludimus calcium, showing low discontinuation rates and low rates of treatment-emergent and serious adverse events. Importantly, no new safety signals have emerged during treatment durations up to 5.5 years.

"This new data from the OLE period is very encouraging and continues to corroborate the prior strong results we observed in our phase 2 EMPhASIS trial in RRMS," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "The ability to maintain remarkably low rates of disability progression is among the most important unmet needs in relapsing MS despite the availability of multiple anti-inflammatory drugs approved for the treatment of MS relapses. By delaying disease progression, MS patients maintain greater independence, face a lower burden in managing their symptoms and experience more favorable long-term outcomes."

"Additionally, previously announced data across our multiple sclerosis (MS) program, including from the EMPhASIS trial as well as our recent top-line data from the phase 2 CALLIPER trial in progressive multiple sclerosis, has further highlighted vidofludimus calcium's potential to slow disease progression in MS and substantiated its neuroprotective capabilities through the activation of the Nurr1 target. As a reminder, despite 30-years of commercially available MS treatments, slowing and preventing disease progression

still remains a critical unmet need. Based on the data we have generated, to date, we continue to believe that vidofludimus calcium, with its combined neuroprotective, anti-inflammatory and anti-viral effects as well as its established, highly favorable safety and tolerability profile, could represent a unique new oral therapy targeted to the complex pathophysiology of MS."

The phase 2 EMPhASIS trial was an international, multicenter, double-blind, placebo-controlled, randomized, parallel-group study, designed to assess the efficacy and safety of vidofludimus calcium in patients with RRMS. The trial randomized 268 RRMS patients and included a 24-week blinded main treatment period testing 10, 30 and 45 mg of vidofludimus calcium and placebo. The trial achieved both primary and key secondary endpoints with high statistical significance and showed a favorable safety and tolerability profile similar to placebo. The trial includes an optional OLE period for up to 9.5 years to evaluate long-term safety and tolerability of vidofludimus calcium. Of the 268 patients that started the double-blind main treatment period, 254 patients continued in the OLE period. Patients were initially given either 30 mg or 45 mg of vidofludimus calcium once-daily, following which all patients received 30 mg of vidofludimus calcium once-daily. At the time of data cutoff on January 14, 2025, 182 patients (71.6% of patients starting OLE) were evaluated up to week 144, which translates into approximately 952 overall treatment years.

About Vidofludimus Calcium (IMU-838)
Vidofludimus calcium is an orally administered investigational small molecule drug being developed for chronic inflammatory and autoimmune diseases, currently in late-stage clinical trials for multiple sclerosis (MS). Uniquely, vidofludimus calcium's first-in-class, dual mode of action combines neuroprotective, anti-inflammatory and anti-viral effects to target the complex pathophysiology of MS. As a selective immune modulator, it activates the neuroprotective transcription factor, nuclear receptor-related 1 (Nurr1), which provides direct and indirect neuroprotective effects. Additionally, vidofludimus calcium achieves anti-inflammatory and anti-viral effects through highly selective inhibition of the enzyme dihydroorotate dehydrogenase (DHODH). Vidofludimus calcium is currently being evaluated in phase 3 clinical trials for the treatment of relapsing MS. In a phase 2 clinical trial, it has shown therapeutic activity in relapsing-remitting MS patients, significantly reducing brain lesions and demonstrating encouraging results in reducing confirmed disability worsening. Additionally, vidofludimus calcium has demonstrated clinical benefits in progressive MS patients by showing substantial reductions in confirmed disability worsening and thalamic brain volume in a phase 2 clinical trial. To date, vidofludimus calcium has been exposed to approximately 2,700 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 clinical trials for the treatment of relapsing multiple sclerosis, for which top-line data is expected to be available by the end of 2026. It has already shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis and progressive multiple sclerosis. 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 as well as inflammatory bowel

disease, Graft-versus-Host-Disease and weight management. 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; 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, increasing inflation, tariffs and macroeconomics trends, 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, any changes to the size of the target markets for the Company's products or product candidates, 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, 2024, filed with the SEC on March 31, 2025, and in the company's subsequent filings with the SEC. 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 of the contents of this press release.

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