– Enrollment Completed for Both Phase 3 ENSURE Trials of Vidofludimus Calcium in Relapsing Multiple Sclerosis; Top-Line Data Expected End of 2026 –

– Additional Data from Phase 2 CALLIPER Trial in Progressive Multiple Sclerosis Further Supports the Recently Released Positive Top-Line Results and Further Underlines Vidofludimus Calcium's Neuroprotective Potential –

– New CALLIPER Data Regarding Time to 24-Week Confirmed Disability Worsening Shows Substantial and Medically Relevant Reductions for Vidofludimus Calcium Over Placebo in the Overall Study Population and Major Disease Subtypes –

NEW YORK, June 5, 2025 /PRNewswire/ -- **Immunic, Inc.** (Nasdaq: IMUX), a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, announced the completion of enrollment for both phase 3 ENSURE trials of lead asset, nuclear receptor-related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), in patients with relapsing multiple sclerosis and additional phase 2 CALLIPER trial data in patients with progressive multiple sclerosis underlining the recently released positive top-line results.

Enrollment Completed for Both Phase 3 ENSURE Trials in Relapsing Multiple Sclerosis (RMS)

The 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, enrolled adult patients with active RMS at more than 100 sites in 15 countries, including the United States, India and countries in the Middle East and North Africa (MENA) region, Latin America, and Central and Eastern Europe. In total, 1,121 patients in ENSURE-1 and 1,100 patients in ENSURE-2 have been randomized in a double-blinded fashion to either 30 mg daily doses of vidofludimus calcium or placebo. The primary endpoint for both trials is time to first relapse up to 72 weeks. Secondary endpoints include time to confirmed disability worsening based on the Expanded Disability Status Scale (EDSS), volume of new T2-lesions, time to sustained clinically relevant changes in cognition, and magnetic resonance imaging (MRI)-based endpoints.

"The on-schedule enrollment of the final patients in our phase 3 ENSURE trials of vidofludimus calcium marks another significant milestone for our late-stage MS program, bringing us meaningfully closer to a potential new treatment option for people living with RMS," commented Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "We anticipate that the drug's unique neuroprotective effects observed to date will also play a crucial role in the ENSURE trials, where confirmed disability worsening serves as an important secondary outcome. If approved, we believe vidofludimus calcium, with its attractive safety and tolerability profile, compelling dual and novel mechanism of action and combination of neuroprotective, anti-inflammatory, and antiviral effects, could potentially transform the oral MS therapy market, offering a unique first-in-class treatment option by addressing the full spectrum of this disease. We eagerly anticipate the top-line data from both ENSURE trials by the end of 2026, which allows for a synchronized readout and a pooled assessment of the confirmed disability worsening secondary endpoint."

Werner Gladdines, Chief Development Officer of Immunic, added, "We are extremely proud to have reached this key milestone for our ENSURE program of vidofludimus calcium, right on schedule. Successfully completing enrollment of over 2,200 RMS patients across the twin phase 3 trials represents a major achievement and a true team effort. We extend our sincere thanks to all Immunic colleagues and vendor staff involved in the planning and execution of the ENSURE trials for their dedication to advancing our late-stage clinical program. We are also deeply grateful for the strong support from our clinical investigators, site study teams, and the study participants and their families. We look forward to analyzing the ENSURE top-line data, which we hope will ultimately pave the way for regulatory filings and the ultimate commercialization of vidofludimus calcium in RMS."

Additional Data Available from Phase 2 CALLIPER Trial in Progressive Multiple Sclerosis (PMS)

Building on the recently released data showing reductions in the relative risk of 24-week confirmed disability worsening (24wCDW) events based on the Expanded Disability Status Scale (EDSS) at the end of the main treatment period, newly available data for the secondary endpoint of time to 24wCDW based on the EDSS further reinforces the neuroprotective potential of vidofludimus calcium. In the overall PMS patient population (n=467), vidofludimus calcium demonstrated a clinically meaningful reduction of the hazard ratio (HR) for 24wCDW by 24% compared to placebo (HR 0.76). Further analyses by disease subtype showed that vidofludimus calcium was associated with a 33% reduction in 24wCDW in the primary progressive multiple sclerosis (PPMS) study population (n=152) compared to placebo (HR 0.67), a 19% reduction in the non-active secondary progressive multiple sclerosis (naSPMS) study population (n=268) compared to placebo (HR 0.81), and a 34% reduction in the active secondary progressive multiple sclerosis (aSPMS) study population (n=47) compared to placebo (HR 0.66).

Similarly, consistent with the recent top-line data, further analyses of subpopulations – both with and without inflammatory gadolinium-enhanced lesion activity at baseline, who are largely shown to not benefit from current anti-inflammatory

therapies – continued to demonstrate promising results. For the overall population, vidofludimus calcium reduced 24wCDW in patients without evidence of gadolinium-enhancing lesions at baseline by 34% compared to placebo (HR 0.66). Encouraging results were likewise observed for the PPMS (reduction in 24wCDW: 35%; HR 0.65) and naSPMS (reduction in 24wCDW: 30%; HR 0.70) study populations compared to placebo.

"Our recently released positive phase 2 CALLIPER trial data in PMS underlined vidofludimus calcium's neuroprotective potential and its ability to slow disease progression in MS patients with or without focal inflammation. We are very excited that additional analyses of time to 24-week confirmed disability worsening further support this potential, highlighting a significant opportunity ahead," stated Dr. Vitt. "The consistent results for 24wCDW between the general CALLIPER population and patients that show no evidence of focal inflammatory disease at baseline, as exemplified by gadolinium-enhancing lesions during MRI, both for the overall study population and for the PPMS and naSPMS subtypes, supports clinically measurable neuroprotective effects of vidofludimus calcium, consistent with its Nurr1 activation mechanism. We believe, because 24wCDW is an acceptable regulatory endpoint to determine clinical benefit in PMS, the suggestive evidence of clinical activity in 24wCDW clearly deserves further investigation in a phase 3 program."

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 feasibility of advancing vidofludimus calcium to a confirmatory phase 3 clinical trial in progressive multiple sclerosis; 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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