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

– Phase 2 CALLIPER Data Showed Vidofludimus Calcium Reduced 24-Week Confirmed Disability Worsening and Increased 24-Week Confirmed Disability Improvement Across Progressive Multiple Sclerosis and Its Subtypes, Reinforcing the Drug's Direct Neuroprotective Mechanism of Action –

– Long-Term Open-Label Data from Phase 2 EMPhASIS Trial of Vidofludimus Calcium in Relapsing-Remitting Multiple Sclerosis Showed Low Rates of Confirmed Disability Worsening Events and Favorable Long-Term Safety and Tolerability –

– U.S. Patent Allowed for Dose Strengths of Vidofludimus Calcium in Progressive Multiple Sclerosis, Strengthening Intellectual Property Protection Into 2041 –

NEW YORK, Jan. 7, 2026 /PRNewswire/ -- **Immunic, Inc.** (Nasdaq: IMUX), a late-stage biotechnology company pioneering the development of novel oral therapies for neurologic and gastrointestinal diseases, today highlighted its 2025 accomplishments and upcoming milestones.

"The past year has been transformational for our lead asset vidofludimus calcium (IMU-838)," statedDaniel Vitt, Ph.D., Chief Executive Officer of Immunic. "We are pleased to have completed enrollment in our twin phase 3 ENSURE-1 and ENSURE-2 trials of vidofludimus calcium in relapsing multiple sclerosis (RMS) and are deeply grateful to the Immunic team, our clinical investigators, site teams, and especially the participants for making this milestone possible. We now eagerly anticipate the synchronized top-line data readout by the end of 2026. The scale, quality, and geographic breadth of the ENSURE trials give us exceptional confidence that the results will provide a clear and comprehensive picture of vidofludimus calcium's potential to reshape the RMS treatment paradigm. Additionally, long-term open-label extension (OLE) data from the phase 2 EMPhASIS trial in relapsing-remitting multiple sclerosis (RRMS) showed that a substantial majority of patients remained free of confirmed disability worsening (CDW) over extended follow-ups, underscoring vidofludimus calcium's potential to meaningfully slow disease progression, giving patients greater independence and a lower burden in managing symptoms over the long term."

Jason Tardio, President and Chief Operating Officer of Immunic, added, "The ENSURE program represents more than a pivotal clinical milestone—it reflects an opportunity to advance how disease modification in RMS is approached. Today's oral RMS treatment landscape is largely defined by therapies with complex risk-benefit profiles that primarily target inflammation and relapses, while often falling short of adequately addressing the neurodegeneration that drives long-term disability. With a dual mechanism of action, vidofludimus calcium is designed to provide direct neuroprotection by enhancing neuronal survival and function through Nurr1 activation, as well as limiting new inflammatory injury through selective DHODH inhibition. Together with its favorable safety and tolerability profile to date, we believe vidofludimus calcium has the potential to offer the most compelling benefit-risk profile among oral disease-modifying therapies for RMS."

"Equally important are the strong signals we continue to see in progressive multiple sclerosis (PMS) from our phase 2 CALLIPER trial," continued Dr. Vitt. "In particular, the data has demonstrated clinically meaningful reductions in 24-week CDW (24wCDW) across the overall PMS population, supported by consistent trends across PMS subtypes and subpopulations. Notably, there was no dependency of the 24wCDW effect size on the presence of markers of inflammatory disease at baseline, such as gadolinium-enhancing lesions, supporting our hypothesis of clinical neuroprotective effects independent of anti-inflammatory effects. The positive 24-week confirmed disability improvement (24wCDI) results were statistically significant in the overall PMS population, with consistent trends across subtypes. The findings from our CALLIPER trial reinforce vidofludimus calcium's unique mechanism of action targeting neurodegeneration and help de-risk potential late-stage development in PMS."

Dr. Vitt concluded, "As we execute our MS strategy with vidofludimus calcium, we also remain committed to advancing IMU-856, our orally available and systemically acting small molecule modulator that targets Sirtuin 6 (SIRT6), as our next pipeline innovation. IMU-856's potential ability to restore intestinal barrier function and regenerate bowel epithelium has generated compelling early clinical signals in celiac disease patients, supporting potential development in various gastrointestinal disorders. Additionally, we have seen encouraging preclinical and early clinical effects that may indicate the potential for IMU-856 as an oral treatment option for weight management."

Vidofludimus Calcium 2025 Highlights and Upcoming Milestones

- Completed enrollment for both phase 3 ENSURE trials of vidofludimus calcium in patients with RMS. In total, 1,121 patients in ENSURE-1 and 1,100 patients in ENSURE-2 were randomized at more than 100 sites in 15 countries. Top-line data is expected by the end of 2026.

- Announced positive phase 2 CALLIPER data in PMS, highlighting vidofludimus calcium's neuroprotective potential across PMS as well as PMS subpopulations and subtypes. The data, showing consistent 24wCDW results across patient groups, including those without evidence of baseline inflammatory gadolinium-enhancing (Gd+) lesions, were seen in the overall population and in the key primary progressive multiple sclerosis (PPMS) and non-active secondary progressive multiple sclerosis (naSPMS) subgroups. 24wCDI data demonstrated more than a two-fold probability of clinical improvement versus placebo, achieving statistical significance in the overall PMS population with consistent trends across subtypes. Vidofludimus calcium also lowered thalamic atrophy and new or enlarging T2 lesion volume versus placebo. No new safety signals were observed and vidofludimus calcium continued to show a favorable safety and tolerability profile. Given that 24wCDW is an accepted regulatory endpoint in PMS, these results strengthen the evidence of clinical activity and should help to de-risk a potential phase 3 program.
- Reported new, positive long-term OLE data from the phase 2 EMPhASIS trial of vidofludimus calcium in patients with RRMS. At week 144, 92.3% of patients remained free of 12wCDW with 92.7% remaining free of 24wCDW. Vidofludimus calcium continued to demonstrate a favorable safety and tolerability profile with long-term data available up to 5.5 years.
- Received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent covering dose strengths of vidofludimus calcium for the treatment of PMS, including PPMS and SPMS. The company's multilayered intellectual property strategy now provides protection into 2041 in the United States, unless extended further.
- Presented key data highlighting vidofludimus calcium's therapeutic potential in MS at various scientific and medical conferences, including the 41st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), the 17th International Congress of the International Society of Neuroimmunology (ISNI), the 11th Congress of the European Academy of Neurology (EAN) – Helsinki 2025, the Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting 2025, the American Academy of Neurology (AAN) 2025 Annual Meeting and the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2025. The results from the phase 2 CALLIPER trial in PMS were also selected for the Best of ECTRIMS 2025 slide deck.

IMU-856 2025 Highlights and Upcoming Milestones

- Announced that IMU-856 demonstrated a dose-dependent increase of endogenous glucagon-like peptide-1 (GLP-1) levels in a post hoc analysis of patients from the phase 1b clinical trial in celiac disease. IMU-856 also showed a dose-dependent reduction of body weight gain and food consumption in preclinical *in vivo* testing. These effects may indicate the potential for IMU-856 as an oral treatment option for weight management.
- Presented further analyses from the phase 1/1b clinical trial of IMU-856 in healthy subjects and celiac disease patients at several key gastroenterology conferences, including at UEGW 2025 – United European Gastroenterology Week, Digestive Disease Week (DDW) and the 19th Congress of ECCO (European Crohn's and Colitis Organisation).
- The company continues preparing for further clinical testing of IMU-856, contingent on financing, licensing or partnering.

2025 Corporate Highlights

- Closed a $5.1 million registered direct offering led by Aberdeen Investments.
- Closed an oversubscribed $65 million underwritten public offering, co-led by BVF Partners and Coastlands Capital, and including participation from Aberdeen Investments, Adage Capital Partners LP, Janus Henderson Investors, and other institutional investors.

Immunic's management, business development and investor relations teams will be hosting one-on-one meetings in connection with the 44th Annual J.P. Morgan Healthcare Conference taking place January 12-15, 2026, in San Francisco. To schedule a meeting, please contact Jessica Breu at: jessica.breu@imux.com.

About Immunic, Inc.
Immunic, Inc. (Nasdaq: IMUX) is a late-stage biotechnology company pioneering the development of novel oral therapies for neurologic and gastrointestinal 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 Immunic's development programs to safely and effectively target diseases; preclinical and clinical data for Immunic's development programs; 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; the development and commercial potential of any product candidates of the company; expectations regarding the capitalization, resources and ownership structure of the company; the executive and board structure of the company; and the company's expected cash runway. 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 theMiddle 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, and the ability to raise sufficient capital to continue as a going concern, 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 onMarch 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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