Immunic Highlights 2024 Accomplishments and Upcoming Milestones

– Top-Line Data from Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis Expected in April –

– Reported Positive Outcome from Interim Analysis of Ongoing, Twin Phase 3 ENSURE Trials of Vidofludimus Calcium in Relapsing Multiple Sclerosis; Both Trials on Track to Be Completed in 2026 –

– Strengthened Management Team and Board of Directors with Key Hires –

– Announced a Three-Tranche Private Placement Totaling Up to $240 Million, Extending Cash Runway Into the Third Quarter of 2025, Based on Initial $80 Million Tranche –

NEW YORK, January 7, 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 highlighted its 2024 accomplishments and upcoming milestones.

"The past year was marked by substantial progress for our orally available lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), as we continued to advance both our phase 2 CALLIPER trial in patients with progressive multiple sclerosis (PMS) and our twin phase 3 ENSURE trials in relapsing multiple sclerosis (RMS)," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "Looking ahead, we eagerly anticipate reporting top-line data from the CALLIPER trial in April. The previously reported interim results showed a clear reduction versus placebo in neurofilament light chain (NfL) levels across the PMS patient population, hinting to potential neuroprotective effects of the drug."

"We also achieved a significant milestone for our phase 3 ENSURE program, having received a positive interim result from an unblinded Independent Data Monitoring Committee (IDMC), which concluded that the trials are not futile and recommended they should continue as planned, without any sample size increase. These favorable recommendations corroborated our initial assumptions about the design, powering and relapse rate of the trials and illustrate that they remain on track. The result makes us immensely confident and excited as we await the completion of the twin phase 3 trials: ENSURE-1 remains on track for completion in the second quarter of 2026, with ENSURE-2 expected to follow in the second half of 2026."

Jason Tardio, President and Chief Operating Officer of Immunic, added, "Since joining Immunic in July 2024, we have ramped up our efforts preparing for the potential commercial launch of vidofludimus calcium. There continues to be a large unmet medical need for new therapeutic advancements in the treatment of MS that address both the neuroinflammatory and neurodegenerative aspects of the disease to better slow disability worsening. Vidofludimus calcium is the only medicine in development that targets activation of Nurr1 for neuroprotection and combines that with selective inhibition of DHODH for anti-inflammatory and antiviral effects. We believe our drug has the potential to become the first oral disease-modifying therapy approved to treat both relapsing and progressive MS to address the full spectrum of the disease."

Dr. Vitt concluded, “In 2024, we were also honored to have had our previously reported results from the phase 1/1b clinical trial of IMU-856, our orally available and systemically acting small molecule modulator targeting Sirtuin 6 (SIRT6), a protein which serves as a transcriptional regulator of intestinal barrier function and physiological regeneration of bowel epithelium, published in the peer reviewed journal, *The Lancet Gastroenterology & Hepatology*. Data from this study showed that, in patients with celiac disease during periods of gluten-free diet and gluten challenge, IMU-856 demonstrated positive effects over placebo in four key dimensions of celiac disease, including protection of the gut architecture, improvement of patients’ symptoms, biomarker response, and enhancement of nutrient absorption. We continue to believe that IMU-856 could offer a new therapeutic approach for various gastrointestinal disorders, also beyond celiac disease.”

2024 Corporate Highlights

- Strengthened the Board of Directors in July, with the appointment of Simona Skerjanec, M.Pharm, MBA, a thought-leader in brain health with decades of experience.
- In July, appointed seasoned biopharmaceutical executive, Jason Tardio, as President and Chief Operating Officer, to lead internal efforts in positioning the company for the potential launch of vidofludimus calcium and to work closely with Patrick Walsh, Chief Business Officer, to prepare the company for a range of potential partnership outcomes. Additionally, reported that Werner Gladdines, former Vice President, Program Management & Clinical Development Operations, was promoted to Chief Development Officer.
- Announced a three-tranche private placement totaling up to $240 million, with participation from select new and existing investors, in January. The initial tranche successfully closed on January 8, 2024, with Immunic securing $80 million in gross proceeds.

Vidofludimus Calcium 2024 Highlights and Upcoming Milestones

- Completion of the ENSURE-1 trial of vidofludimus calcium in RMS is anticipated in the second quarter of 2026, with completion of ENSURE-2 expected in the second half of 2026.
- Top-line data for the phase 2 CALLIPER trial of vidofludimus calcium in PMS is expected in April of this year.
- Announced a positive outcome of the interim analysis of the phase 3 ENSURE program, investigating vidofludimus calcium for the treatment of RMS, in October. An unblinded IDMC confirmed that the trials are not futile and recommended they should continue without changes, including no need for a potential increase of the sample size.
- Presented key data on vidofludimus calcium in four presentations at the 40th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in September. The data included the NfL interim data from the phase 2 CALLIPER trial, antiviral data suggesting an effect on reducing fatigue, Nurr1 target data supporting a neuroprotective profile, and pathogenic T cell data further supporting the drug's anti-inflammatory effects.
- Announced enrollment of the first patient in the investigator-sponsored phase 2 RAPID_REVIVE trial of vidofludimus calcium in patients with post COVID syndrome in September.
- Hosted an MS R&D Day in New York City in September, focused on vidofludimus calcium’s potential to become the treatment of choice for both RMS and PMS patients. Presenting MS industry experts included Francesca Montarolo, Ph.D., Neuroscience Institute Cavalieri Ottolenghi

(NICO) and University of Turin, Italy and Amit Bar-Or, M.D., FRCPC, Department of Neurology, Perelman School of Medicine, University of Pennsylvania.

- Published extended data from the phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting MS in the peer reviewed journal, *Neurology® Neuroimmunology & Neuroinflammation*, an official journal of the American Academy of Neurology, in April.
- Hosted an MS R&D Day in San Francisco in April, during which management discussed the latest developments in the MS landscape, along with recent preclinical and clinical data supporting the neuroprotective potential of vidofludimus calcium.
- Received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) in March, for a patent covering the composition-of-matter of a specific polymorph of vidofludimus calcium and a related method of production of the material. The company's multilayered intellectual property strategy now provides protection into 2041 in the United States, unless extended further.
- Presented data from the company's phase 2 CALLIPER and CALVID-1 trials of vidofludimus calcium, in two poster presentations at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2024 in February.

IMU-856 2024 Highlights and Upcoming Milestones

- Announced the publication of data from the phase 1/1b clinical trial of IMU-856 in the peer reviewed journal, *The Lancet Gastroenterology & Hepatology* in November.
- Based on the positive data from the phase 1b clinical trial, the company continues preparing for clinical phase 2 testing of IMU-856, contingent on financing, licensing or partnering.

Immunic's management, business development and investor relations teams will be hosting one-on-one meetings in connection with the 43rd Annual J.P. Morgan Healthcare Conference taking place January 13-16, 2025, 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 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; 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, 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 of the contents of this press release.

Contact Information

Immunic, Inc.
Jessica Breu
Vice President Investor Relations and Communications
+49 89 2080 477 09
jessica.breu@imux.com

US IR Contact
Rx Communications Group
Paula Schwartz
+1 917 633 7790
immunic@rxir.com

US Media Contact
KCSA Strategic Communications
Caitlin Kasunich
+1 212 896 1241
ckasunich@kcsa.com