Immunic, Inc. InvestorRoom

– Evidence for Neuroprotective Activity of Vidofludimus Calcium from Phase 2 CALLIPER Interim Analysis, Consistent Across the Entire Progressive Multiple Sclerosis Population and All Subtypes –

– Phase 3 ENSURE Program in Relapsing Multiple Sclerosis Ongoing –

– Improvements in Gut Health Demonstrated in Phase 1b Clinical Trial of IMU-856 in Celiac Disease –

– Expanded Vidofludimus Calcium Patent Portfolio with Additional New Patents Granted; Exclusivity Protection Expected Into 2041 in the United States, Unless Extended Further –

– Significantly Strengthened Balance Sheet; Cash Runway Extended Into the Third Quarter of 2025 Based on First Tranch of January 2024 Financing –

NEW YORK, Jan. 5, 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 highlighted its 2023 accomplishments and upcoming milestones.

"The past year has been an extra-ordinarily productive and successful one for Immunic, with key clinical data releases highlighting the uniqueness and enormous value potential of each of our two latest-stage clinical assets," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "With vidofludimus calcium (IMU-838) and IMU-856, we have two development programs beyond clinical proof-of-concept which is an outstanding achievement of our entire team. Regarding our lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium, the interim biomarker analysis from the phase 2 CALLIPER trial demonstrated clear separation from placebo in serum neurofilament light chain (NfL) levels in patients with progressive multiple sclerosis (PMS). This effect was observed across all subpopulations, including non-active secondary progressive multiple sclerosis, which we believe represents the segment of greatest unmet need in multiple sclerosis (MS). We look forward to continuing development of this potentially groundbreaking asset. Enrollment in CALLIPER is complete, with top-line data expected in April 2025. Meanwhile, enrollment in our phase 3 ENSURE program remains active, with an interim futility analysis expected in late 2024 and the read-out of the first of the ENSURE trials anticipated in the second quarter of 2026."

Dr. Vitt continued, "Regarding IMU-856, our orally available and systemically acting small molecule modulator targeting Sirtuin 6 (SIRT6), results from our phase 1b trial demonstrated meaningful improvements over placebo in four key dimensions of celiac disease pathophysiology: histology, disease symptoms, biomarkers and nutrient absorption. We believe this data provides initial clinical proof-of-concept for a potentially new therapeutic approach to a multitude of gastrointestinal disorders through the regeneration of bowel architecture rather than the traditional immunomodulatory approaches in many gastrointestinal indications. We are currently preparing for phase 2 testing in ongoing active celiac disease (OACD), with further clinical applications in other gastrointestinal disorders also being considered."

"On a scientific level, we announced preclinical evidence showing that vidofludimus calcium acts as a potent Nurr1 activator, which may be associated with both its hypothesized neuroprotective effects and the reduced disability-worsening events observed in our phase 2 EMPhASIS trial in relapsing-remitting MS patients. We have also continued to strengthen our patent portfolio for vidofludimus and its salt and free acid forms, with additional new layers of patents granted, now providing protection into 2041 in the United States and into 2038 internationally. We expect to continue to expand the patent protection around vidofludimus calcium in the future," Dr. Vitt continued.

"Financially, we announced a three-tranche private placement of up to $240 million earlier today. We expect the first $80 million tranche to extend our cash runway into the third quarter of 2025, which well covers the top-line data readout of our CALLIPER trial in Aprill 2025. The second tranche, assuming it is excersied, would even finance us into the first quarter of 2027. Despite challenging capital markets, we are proud to see enormous support from new and existing investors, including lead investor BVF Partners, as well as Avidity Partners, Janus Henderson Investors, Soleus Capital, RTW Investments and Adage Capital Partners. Finally, I want to share my pride in our broader team, who were honored to win multiple, prestigious international awards in 2023 recognizing Immunic's excellence in a number of clinical, corporate and communications categories. I am very excited to see what our team can achieve in 2024 and beyond," concluded Dr. Vitt.

A more thorough review of recent events and upcoming milestones follows:

Corporate Highlights

- Announced a three-tranche private placement of up to $240 million with participation from select new and existing investors today.
- Strengthened Board of Directors in April 2023 with the addition of Richard Rudick, M.D., a thought-leader in MS with decades of experience in the clinic, academia and industry.

Vidofludimus Calcium 2023 Highlights and Upcoming Milestones

- Reported positive interim data from the phase 2 CALLIPER trial of vidofludimus calcium in PMS in October. Serum NfL improvements were consistently observed for vidofludimus calcium across PMS and all disease subtypes, as well as in patients who showed or did not show disease and/or magnetic resonance imaging (MRI) activity. Immunic believes that this data illustrates biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, further reinforcing its neuroprotective potential. Enrollment of the trial was completed in August. In total, 467 patients with primary PMS, or active or non-active secondary PMS, were randomized to either 45 mg of vidofludimus calcium or placebo.
- Published preclinical data in the peer-reviewed, high impact, Journal of Medicinal Chemistry in May, confirming that vidofludimus calcium acts as a potent Nurr1 activator, in addition to its known mode of action as a dihydroorotate dehydrogenase (DHODH) inhibitor. Data showed that activation of Nurr1 could be responsible for the drug's postulated neuroprotective effects and may contribute to the previously reported reduction of confirmed disability worsening events seen in the phase 2 EMPhASIS trial in relapsing-remitting MS patients.
- Reported positive data from the maintenance phase of the phase 2b CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe ulcerative colitis in April.
- Significantly strengthened the multiple layers of patent protection around vidofludimus calcium, and other salt and free acid forms, with the receipt of two Notices of Allowance from the USPTO, covering the dosing regimens in MS and the dose strength for the treatment of RMS. The current patent portfolio provides protection into 2041 in the United States and into 2038 internationally, unless extended further.
- Top-line data from the phase 2 CALLIPER trial of vidofludimus calcium in PMS is expected in April 2025.
- An interim futility analysis of the ENSURE program is expected in late 2024. The read-out of the first of the ENSURE trials is currently anticipated in the second quarter of 2026; and the second ENSURE trial in the second half of 2026.

IMU-856 2023 Highlights and Upcoming Milestones

- Announced, for the first time, IMU-856's molecular mode of action as a highly selective and potent small molecule modulator of SIRT6, a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium, in May.
- Announced positive results from the part C portion of the phase 1 clinical trial of IMU-856 in patients with celiac disease in May. The data demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well-tolerated in this trial. Immunic believes this data provides initial clinical proof-of-concept for an entirely new therapeutic approach to gastrointestinal disorders by promoting regeneration of bowel architecture.
- The company is preparing for clinical phase 2 testing of IMU-856 in OACD patients.

Award Recognition

- **MS R&D webcast** held in November 2022:
  - Gold German Stevie Awards for 'Best Medical Event' and 'Best B2B Event'
  - American Business Gold Awards in the 'Conferences & Meetings – Medical Congress' and 'Conferences & Meetings – Scientific Congress' categories and Bronze Award in the 'Corporate & Community – B2B Event' category
  - International Business Gold Award in the 'Conferences & Meetings - Medical Congress' category
- **Newly designed, accessibility-friendly website:**
  - Gold German Stevie Award for 'Best Overall Design' and Bronze Stevie Award for 'Special Achievement in Diversity & Inclusion'
  - American Business Silver Award in the 'Achievement in Diversity & Inclusion' category
- **BioTech Breakthrough Award winner for the 'Developmental Immunology Solution of the Year'** for the IMU-856 development program, including the positive phase 1b clinical trial results in

celiac disease
- **Hella Kohlhof, Ph.D.**, Chief Scientific Officer of Immunic, was awarded a **Silver Stevie Award for Women in Business in the 'Women in Healthcare'** category

Immunic's management, business development and investor relations teams will be hosting one-on-one meetings in connection with the 42nd Annual J.P. Morgan Health Care Conference taking place January 8-11, 2024 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 expected future events, including the private placement and expected proceeds, 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 ability to raise additional capital, if needed; 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; 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, 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, 2022, filed with the SEC on February 23, 2023, 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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