– Unblinded Interim Biomarker Analysis Expected in the Fall of 2023 –

– Full Data Readout Expected in April 2025 –

NEW YORK, Aug. 17, 2023 /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 announced the completion of enrollment of its phase 2 CALLIPER trial of lead asset, vidofludimus calcium (IMU-838), in patients with progressive multiple sclerosis (PMS). In total, 467 patients with primary PMS, or active or non-active secondary PMS have been randomized to either 45mg of vidofludimus calcium or placebo. The trial, running concurrently and as a complement to the company's twin phase 3 ENSURE trials in relapsing multiple sclerosis (RMS), is focused on progressive forms of multiple sclerosis (MS) and is designed to corroborate vidofludimus calcium's neuroprotective potential in this patient population.

Anticipated Milestones for the CALLIPER Trial:

- An interim analysis comprising unblinded biomarker data, including serum neurofilament light chain (NfL), is expected to be available in the fall of 2023 and will include data for approximately half of the enrolled patients (225) who have completed a follow-up period of at least 24 weeks of study treatment.
- A top-line data readout of the full 467 patients is now expected in April of 2025.

"Our phase 2 CALLIPER trial is designed to corroborate the neuroprotective potential of vidofludimus calcium in a progressive patient population. Enrollment of the final PMS patient, according to plan, is another important milestone in the clinical development of our lead asset in MS," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "We believe that the data from the CALLIPER trial, along with that from our ENSURE program, in conjunction with vidofludimus calcium's postulated neuroprotective effects as a first-in-class nuclear receptor related 1 (Nurr1) activator as well as its strong safety and tolerability profile shown, to date, may further strengthen the uniqueness of this treatment approach compared to other oral MS medications and result in a highly attractive commercial positioning."

"As reported in May of this year, in preclinical testing, we have discovered strong Nurr1 agonism by vidofludimus calcium. The known characteristics of Nurr1 activation suggest broad therapeutic potential in neurodegenerative pathologies including MS," added Andreas Muehler, M.D., Chief Medical Officer of Immunic. "The neuroprotective properties of vidofludimus calcium were already identified in our phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting MS, by showing an initial signal for prevention of confirmed disability worsening, as reported in November of last year. We look forward to reporting the interim analysis of our CALLIPER trial, expected in the fall of this year, to assess biomarkers that have been shown in third-party research to consistently correlate with disease activity in neurodegenerative disorders."

CALLIPER is an international, multicenter, randomized, double-blind, placebo-controlled phase 2 trial which enrolled 467 patients at more than 70 sites throughout North America as well as Western, Central and Eastern Europe, with patients randomized to either 45 mg daily doses of vidofludimus calcium or placebo. The trial's primary endpoint is the annualized rate of percent brain volume change up to 120 weeks. Key secondary endpoints include the annualized rate of change in whole brain atrophy and time to 24-week confirmed disability progression based on the expanded disability status scale (EDSS).

For more information on this clinical trial, please visit: www.clinicaltrials.gov, NCT05054140.

About Progressive Multiple Sclerosis
Multiple sclerosis (MS) is an autoimmune disease that affects the brain, spinal cord and optic nerve. In MS, myelin, the coating that protects the nerves, is attacked and damaged by the immune system. Thus, MS is considered an immune-mediated demyelinating disease of the central nervous system. Progressive multiple sclerosis (PMS) includes both primary progressive MS (PPMS) and secondary progressive MS (SPMS). PPMS is characterized by steadily worsening neurologic function from the onset of symptoms without initial relapse or remissions. SPMS is identified following an initial relapsing remitting course, after which the disease becomes more steadily progressive, with or without other disease activity present.

About Vidofludimus Calcium (IMU-838)
Vidofludimus calcium is a small molecule investigational drug in development as an oral next-generation treatment option for patients with multiple sclerosis and other chronic inflammatory and autoimmune diseases. The selective immune modulator activates the neuroprotective transcription factor nuclear receptor related 1 (Nurr1), which is associated with direct neuroprotective properties. Additionally,

vidofludimus calcium is a known inhibitor of the enzyme dihydroorotate dehydrogenase (DHODH), which is a key enzyme in the metabolism of overactive immune cells and virus-infected cells. This mechanism is associated with the anti-inflammatory and anti-viral effects of vidofludimus calcium. Vidofludimus calcium has been observed to selectively act on hyperactive T and B cells while leaving other immune cells largely unaffected and enabling normal immune system function, e.g., in fighting infections. To date, vidofludimus calcium has been tested in more than 1,400 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 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 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, where 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, 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, the COVID-19 pandemic, increasing inflation, impacts of the Ukraine – Russia conflict 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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