– Improvement in Serum Neurofilament Light Chain (NfL) Observed in Both Treatment Arms of Vidofludimus Calcium Over Placebo –

– NfL Effect Consistent With Recently Released Data from Separate, Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis –

NEW YORK, Oct. 11, 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, announced that Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurological Institute, Cleveland Clinic, Cleveland, Ohio, today presented data from the company's phase 2 EMPhASIS trial of nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), in relapsing-remitting multiple sclerosis (RRMS) at MSMilan2023: The 9th Joint ECTRIMS-ACTRIMS Meeting, taking place October 11-13 in Milan, Italy.

"The neurologic biomarker NfL has been consistently found to correlate with both clinical relapses as well as magnetic resonance imaging (MRI) disease activity in MS patients," stated Dr. Fox. "In the EMPhASIS trial, treatment with vidofludimus calcium was associated with a decrease in serum NfL compared to placebo in the overall study population, and even among subjects with no MS activity during the study." Dr. Fox has served as Coordinating Investigator in Immunic's multiple sclerosis (MS) programs and receives consulting fees for serving as an advisor to Immunic.

Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic, added, "The observation in our EMPhASIS trial that vidofludimus calcium shows a meaningful improvement in serum NfL even in a non-active MS patient population is very encouraging, as it suggests that the drug may even be active in the absence of inflammation, further supporting a potential role in neuroprotection. We believe that these effects may be related to vidofludimus calcium's potent Nurr1 activation."

Poster Details:

- **Title:** *Reduction in Neurofilament Light Chain by Vidofludimus Calcium: The EMPhASIS Study*
- **Abstract Number:** 1290
- **ePoster Number:** P1390
- **Poster Session:** Imaging and non-imaging biomarkers - Fluid Biomarkers
- The poster presentation is accessible on the "Events and Presentations" section of Immunic's website at: https://ir.imux.com/events-and-presentations.

EMPhASIS was an international, multicenter, double-blind, placebo-controlled, randomized, parallel-group trial, designed to assess the efficacy and safety of vidofludimus calcium in patients with RRMS. The trial randomized 268 RRMS patients and included a 24-week blinded main treatment period testing 10, 30 and 45 mg of vidofludimus calcium and placebo. The trial achieved both primary and key secondary endpoints with high statistical significance, and a safety and tolerability profile similar to placebo. The trial is currently continuing in the open-label extension phase running up to 9.5 years.

On October 9, 2023, Immunic announced positive interim data from its phase 2 CALLIPER trial of vidofludimus calcium in patients with progressive multiple sclerosis (PMS). The 24-week data from the first half of patients showed improvements in NfL, consistent throughout the overall PMS population as well as all sub-analyses.

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.

Contact Information

Immunic, Inc.
Jessica Breu
Head of 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
KOGS Communication
Edna Kaplan
+1 617 974 8659
kaplan@kogspr.com

SOURCE Immunic, Inc.

---

https://ir.imux.com/2023-10-11-Immunic-Presents-Data-From-Phase-2-EMPhASIS-Trial-of-Vidofludimus-Calcium-in-Relapsing-Remitting-Multiple-Sclerosis-at-MSMilan2023-The-9th-Joint-ECTRIMS-ACTRIMS-Meeting