

– Fifth U.S. Patent Directed to Use of Vidofludimus Calcium in Multiple Sclerosis –

– Comprehensive Intellectual Property Strategy Secures Protection Into 2041 in the U.S., Unless Extended Further –

NEW YORK, Sept. 9, 2025 /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 that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application 18/529,946, entitled, "Treatment of multiple sclerosis comprising DHODH inhibitors."

Specifically, the resulting patent covers dose strengths associated with lead asset, vidofludimus calcium (IMU-838), and other salt forms as well as free acid forms, at a daily dose of about 10 mg to 45 mg, for the treatment of progressive multiple sclerosis (PMS), including the sub-groups primary progressive multiple sclerosis (PPMS) and secondary progressive multiple sclerosis (SPMS). The patent is expected to provide protection into 2041, and potential Patent Term Extension may offer additional market exclusivity in the United States.

"Allowance of this new key patent represents a significant advancement for our vidofludimus calcium program in PMS and further strengthens its robust, multi-layered intellectual property portfolio," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "The patent comes at a pivotal time, closely on the heels of our positive phase 2 CALLIPER trial data in PMS. Vidofludimus calcium continued to demonstrate neuroprotective potential by delaying time to 24-week confirmed disability worsening (24wCDW), supporting its ability to slow disease progression in multiple sclerosis patients, with or without focal inflammation. These findings also reinforce the reductions in the annualized rate of thalamic brain volume loss and volume of new/enlarging T2 lesions seen in the CALLIPER trial. Given that 24wCDW would be an acceptable regulatory endpoint of a pivotal phase 3 trial, we look forward to continuing to discuss the opportunity with healthcare authorities to determine next steps toward our goal of bringing this novel and exciting approach to patients with progressive forms of multiple sclerosis, where there continues to be a significant unmet medical need."

Vidofludimus calcium is covered by several layers of granted patents in the United States, Europe and other jurisdictions around the world. These patents are directed towards composition-of-matter for salt forms of vidofludimus, including the specific calcium salt form used in Immunic's clinical trials; the treatment of relapsing multiple sclerosis and progressive multiple sclerosis with a specific dose strength used in the clinical trials; the dosing regimens, including those used in clinical trials for the treatment of multiple sclerosis, as well as composition-of-matter of a specific polymorph of vidofludimus calcium and a related method of production of the material. In the United States, these patents provide protection into 2041, or even beyond. In addition, a pending application is directed towards the use of vidofludimus calcium and other salt forms as well as free acid forms for treating neurodegenerative diseases. If granted, this application could provide protection up to 2044, unless extended further. Finally, further undisclosed patent applications dedicated to strengthening the exclusivity period are currently in process. On top of the patent exclusivity, vidofludimus calcium, as a new chemical entity, should also benefit from regulatory data protection.

About Vidofludimus Calcium (IMU-838)

Vidofludimus calcium is an orally administered investigational small molecule drug being developed for chronic inflammatory and autoimmune diseases, currently in late-stage clinical trials for multiple sclerosis (MS). Uniquely, vidofludimus calcium's first-in-class, dual mode of action combines neuroprotective, anti-inflammatory and anti-viral effects to target the complex pathophysiology of MS. As a selective immune modulator, it activates the neuroprotective transcription factor, nuclear receptor-related 1 (Nurr1), which provides direct and indirect neuroprotective effects. Additionally, vidofludimus calcium achieves anti-inflammatory and anti-viral effects through highly selective inhibition of the enzyme dihydroorotate dehydrogenase (DHODH). Vidofludimus calcium is currently being evaluated in phase 3 clinical trials for the treatment of relapsing MS. In a phase 2 clinical trial, it has shown therapeutic activity in relapsing-remitting MS patients, significantly reducing brain lesions and demonstrating encouraging results in reducing confirmed disability worsening. Additionally, vidofludimus calcium has demonstrated clinical benefits in progressive MS patients by showing substantial reductions in confirmed disability worsening and thalamic brain volume in a phase 2 clinical trial. To date, vidofludimus calcium has been exposed to approximately 2,700 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 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 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, increasing inflation, tariffs and macroeconomics trends, 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, 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 on March 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.

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

SOURCE Immunic, Inc.

<https://ir.imux.com/2025-09-09-Immunic-Receives-Notice-of-Allowance-for-United-States-Patent-Protecting-Vidofludimus-Calciums-Dose-Strengths-in-Progressive-Multiple-Sclerosis>