

Immunic Presents Key Vidofludimus Calcium Data at the ACTRIMS Forum 2025, Highlighting Its Potential in Multiple Sclerosis

- *Vidofludimus Calcium’s Activation of Nurr1 Reduces Neuronal Loss and Injury Directly and Indirectly By Decreasing Microglial Activations in Preclinical Models* –
- *Top-Line Data from Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis Expected in April* –

NEW YORK, February 26, 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 announced the presentation of data on its lead asset, nuclear receptor-related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), in two poster presentations at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2025, taking place from February 27 to March 1, in West Palm Beach, Florida.

“Having two poster presentations on vidofludimus calcium at the prestigious ACTRIMS Forum highlights the unique importance of our drug candidate and its promise as a potential new treatment option for multiple sclerosis (MS),” stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. “For the first time, we analyzed the baseline characteristics of patients in subpopulations from our phase 2 CALLIPER trial in progressive multiple sclerosis (PMS), and compared to those from four major PMS trials. The goal of this analysis was to identify how the differences may impact comparability of trial outcomes, including our top-line data readout of the phase 2 CALLIPER trial, expected in April. The CALLIPER data is expected to provide valuable insights into the effects of vidofludimus calcium in a non-active PMS population. We believe any impact of vidofludimus calcium on 24-week confirmed disability worsening in this group would likely primarily reflect its influence on compartmentalized pathology within the central nervous system, expressed clinically as progression independent of relapse activity (PIRA).”

Presentation Details:

- **Poster Title:** *Baseline Characteristics Across Major Clinical Trials in Progressive Multiple Sclerosis: Insights from ORATORIO, EXPAND, MS-STAT2, HERCULES, and CALLIPER*
- **Presenting Author:** Robert J. Fox, M.D., Staff Neurologist, Mellon Center for Multiple Sclerosis, Vice-Chair for Research, Neurological Institute, Cleveland Clinic, Cleveland, Ohio
- **Abstract Number:** 452
- **Poster Number:** P102
- **Poster Session:** 1
- **Session Date:** Thursday, February 27, 2025
- **Session Time:** 6:00 pm – 7:30 pm ET (even-numbered posters present from 6:00-6:45 pm)

Hella Kohlhof, Ph.D., Chief Scientific Officer of Immunic, continued, “Our second poster highlights, via a series of both *in vitro* and *in vivo* experiments, evidence of the neuroprotective potential of vidofludimus calcium through its activation of the transcription factor Nurr1. Overall, the data from these preclinical studies underlines that vidofludimus calcium reduces neuronal loss and injury directly and indirectly by decreasing microglial activation and that its potential neuroprotective effects are most likely mediated by Nurr1.”

Presentation Details:

- **Poster Title:** *Vidofludimus Calcium Shows a Potential Neuroprotective Function in Multiple Sclerosis through its Activity on Nurr1 in Preclinical Models*
- **Presenting Author:** Evelyn Peelen, Ph.D., Head of Research, Immunic
- **Abstract Number:** 427
- **Poster Number:** P317
- **Poster Session:** 2
- **Session Date:** Friday, February 28, 2025
- **Session Time:** 6:00 pm – 7:30 pm ET (odd-numbered posters present from 6:45-7:30 pm)

Both poster presentations will be accessible on the "Events and Presentations" section of Immunic's website at: <https://ir.imux.com/events-and-presentations>.

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 effects. Additionally, vidofludimus calcium is a highly selective 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 1,800 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, 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 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, 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, 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, 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.

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