

- *Preclinical Data Published in the Peer-Reviewed Journal of Medicinal Chemistry Identifies Vidofludimus Calcium as a Potent Nurr1 Activator* -
- *Nurr1 Activation Suggested to Prevent Neurodegeneration Which is Relevant in Multiple Sclerosis, Parkinson's Disease and Beyond* -

NEW YORK, May 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 publication of preclinical data confirming that vidofludimus calcium (IMU-838) acts as a potent nuclear receptor related 1 (Nurr1) activator, in addition to its known mode of action as a dihydroorotate dehydrogenase (DHODH) inhibitor. 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 in multiple sclerosis patients. Specifically, preclinical data shows potent Nurr1 activation by vidofludimus calcium at low concentrations in several test systems. The data was published in the peer-reviewed, high impact Journal of Medicinal Chemistry, in a paper entitled, "[*Development of a potent Nurr1 agonist tool for in vivo applications.*](#)"

Nurr1 is a neuroprotective transcription factor and an emerging target in neurodegenerative diseases. Immunic, together with its collaboration partner at Ludwig-Maximilians-University Munich, has discovered in preclinical testing strong, meaningful Nurr1 activation by vidofludimus calcium and a range of derivative compounds in Immunic's portfolio. In addition, vidofludimus calcium has shown preference over the highly related receptors Nur77 and NOR-1.

Prof. Dr. Daniel Merk, Chair of Pharmaceutical and Medicinal Chemistry, Department of Pharmacy, Ludwig-Maximilians-University Munich, commented, "Nurr1 has been identified as a promising target for neuroprotection in diseases such as multiple sclerosis or Parkinson's disease. However, there has been a lack of potent and selective Nurr1 agonists for sufficient target validation. From what we have now seen in our preclinical models, vidofludimus calcium and structurally related molecules are among the most potent Nurr1 agonists in literature."

"The neuroprotective characteristics of Nurr1 suggest broad therapeutic potential for pharmacological activation of this transcription factor in neurodegenerative pathologies. In preclinical testing, we have discovered strong Nurr1 agonism by vidofludimus calcium," stated Hella Kohlhof, Ph.D., Chief Scientific Officer of Immunic. "The neuroprotective properties of vidofludimus calcium were already identified in our phase 2 EMPHASIS trial in patients with relapsing-remitting multiple sclerosis, where the trial data showed encouraging clinical signals regarding prevention of confirmed disability worsening as well as a remarkable reduction of the biomarker neurofilament light chain (NfL)."

"The preclinical data confirming vidofludimus calcium as a potent Nurr1 activator is another exciting milestone for our lead development program as it suggests that Nurr1 may be responsible for the drug's postulated neuroprotective effects," added Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "With this data, we have also taken steps to strengthen our intellectual property position with the submission of a new patent application in the United States and European Union. Importantly, our ongoing phase 2 CALLIPER trial in progressive multiple sclerosis is designed to further corroborate the neuroprotective potential of vidofludimus calcium in a progressive patient population, for which we expect to report an interim analysis providing selected biomarker data, including serum NfL and glial fibrillary acidic protein (GFAP), in the second half of this year."

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 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. Additionally, vidofludimus calcium activates the neuroprotective transcription factor nuclear receptor related 1 (Nurr1), which is associated with direct neuroprotective properties. 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), currently in phase 3 clinical trials for the treatment of multiple sclerosis and which has shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis and moderate-to-severe ulcerative colitis, selectively inhibits activated immune cells and shows combined anti-inflammatory, anti-viral and neuroprotective effects. IMU-856 is targeted to restore intestinal barrier function and regenerate bowel epithelium, which would be applicable in numerous gastrointestinal diseases, such as celiac disease, where it is currently in preparations for a phase 2 clinical trial. 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 development, timing 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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<https://ir.imux.com/2023-05-17-Immunic-Announces-That-Vidofludimus-Calcium-Acts-as-Potent-Nurr1-Activator,-Reinforcing-Neuroprotective-Potential-in-Multiple-Sclerosis>