

*– Patent Will Also Cover a Related Method of Production of the Material –*

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

*– Multilayered Intellectual Property Strategy Provides Protection Into 2041 in the United States and Into 2039 Internationally, Unless Extended Further –*

NEW YORK, March 20, 2024 /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 16/981,122, entitled, "Calcium salt polymorphs as anti-inflammatory, immunomodulatory and anti-proliferative agents," covering the composition-of-matter of a specific polymorph of vidofludimus calcium (IMU-838) and a related method of production of the material. The claims are expected to provide protection into 2039, unless extended further. The patent was previously granted to the company in Australia, Canada, Indonesia, Japan and Mexico.

"Allowance of this key composition-of-matter patent, covering the specific polymorph of vidofludimus calcium, provides another important layer of proprietary intellectual property protection around our lead, late-stage asset," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "A significant part of this patent will also cover the related method of producing material of vidofludimus calcium used in our studies. Importantly, we meanwhile have eight patent families active for vidofludimus. Our commitment to protecting the technology behind this phase 3 asset remains paramount and is made that much stronger by the addition of this fourth U.S. patent directed to the use of vidofludimus calcium in multiple sclerosis."

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 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, as reported in this announcement. In the United States, these patents provide protection into 2041, unless extended further. 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 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 1,800 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, for which 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](http://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 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, 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](http://www.sec.gov) or [ir.imux.com/sec-filings](http://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/2024-03-20-Immunic-Receives-Notice-of-Allowance-for-Composition-of-Matter-Patent-of-a-Specific-Polymorph-of-Vidofludimus-Calcium-in-the-United-States>