

NEW YORK, Feb. 2, 2022 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX)**, a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases, today announced that the company received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for patent application 16/644581, entitled, "IL-17 and IFN-gamma inhibition for the treatment of autoimmune diseases and chronic inflammation". The company also received notice of allowance of patent application EP18762111.5 in Europe, and notice of grant of patent application 2018330633 in Australia. All three patents cover composition-of-matter of IMU-935 and related formulations, and are expected to provide protection into at least 2038, without accounting for potential Patent Term Extension (PTE) in the United States or Supplementary Protection Certificates (SPC) in Europe, respectively.

"We believe IMU-935 is a highly potent and selective oral inhibitor of IL-17, which so far, has shown a remarkably differentiated safety and tolerability profile. Allowance of composition-of-matter patents for this molecule in the United States, Europe and Australia, each with significant lifespan, is incredibly important as we continue to advance IMU-935 through the clinic," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "This is especially true on the heels of our recently announced positive results from the single and multiple ascending dose parts of the phase 1 clinical trial of IMU-935, and the ongoing part C in moderate-to-severe psoriasis patients. Additionally, our ongoing phase 1 clinical trial of IMU-935 in patients with metastatic castration-resistant prostate cancer continues to enroll patients and we look forward to receiving initial clinical data from this indication as well."

#### **About IMU-935**

IMU-935 is a highly potent and selective inverse agonist of ROR $\gamma$ /ROR $\gamma$ t (retinoic acid receptor-related orphan nuclear receptor gamma / truncated). The nuclear receptor ROR $\gamma$ t is believed to be the main driver for the differentiation of Th17 cells and the release of cytokines involved in various inflammatory and autoimmune diseases. This target is believed to be an attractive alternative to approved antibodies for targets, such as IL-23, the IL-17 receptor and IL-17 itself. IMU-935 showed strong cytokine inhibition targeting both Th1 and Th17 responses in preclinical testing, as well as indications of activity in animal models for psoriasis, graft versus host disease, multiple sclerosis and inflammatory bowel disease. Preclinical experiments indicated that, while leading to a potent inhibition of Th17 differentiation and cytokine secretion, IMU-935 did not affect thymocyte maturation. IMU-935 is an investigational drug product that has not been approved in any jurisdiction.

#### **About Immunic, Inc.**

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company with a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases. The company is developing three small molecule products: its lead development program, vidofludimus calcium (IMU-838), a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH and exhibits a host-based antiviral effect, is currently being developed as a treatment option for multiple sclerosis, ulcerative colitis, Crohn's disease, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor ROR $\gamma$ /ROR $\gamma$ t, is targeted for development in psoriasis, castration-resistant prostate cancer and Guillain-Barré syndrome. IMU-856, which targets the restoration of the intestinal barrier function, is targeted for development in diseases involving bowel barrier dysfunction. 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, 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 three development programs and the targeted diseases; the potential for IMU-935 to safely and effectively target diseases; preclinical and clinical data for IMU-935; the timing of current and future clinical trials; 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 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, 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 resources to meet business objectives and operational requirements, the fact that the results of

earlier studies and 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, 2020, filed with the SEC on February 26, 2021, 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/2022-02-02-Immunic-Receives-Notice-of-Allowance-for-Composition-of-Matter-Patents-in-the-United-States-and-in-Europe-for-IMU-935,-a-Potentially-Best-in-Class-Oral-IL-17-Inhibitor>