- Represents the First Time Patients Will Be Treated With the Company's Potentially Best-In-Class RORγt Inverse Agonist -

NEW YORK, Oct. 27, 2021 /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 enrollment of the first psoriasis patient in Part C of its ongoing phase 1 clinical trial of IMU-935, a highly potent and selective inverse agonist of the transcription factor RORγt.

Part C is structured as a 28-day, double-blind, placebo-controlled trial designed to enroll approximately 52 patients, randomized 3:1 versus placebo with two treatment cohorts. The primary objective is to evaluate the safety and tolerability of IMU-935 in moderate-to-severe psoriasis patients. Secondary objectives include evaluation of trough plasma concentration levels and effects on skin symptoms utilizing the Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), psoriasis affected body surface area (BSA), Physicians Global Assessment (PGA), and Itch Numeric Rating Scale (NRS). The trial also assesses pharmacodynamic marker changes, including serum cytokines, *ex vivo* peripheral blood mononuclear cell gene expression profiles and histological biomarker analysis in skin biopsies. More than 10 sites in Australia and New Zealand are expected to participate in Part C.

"The initiation of treatment of patients with active disease with IMU-935 marks a significant milestone in the continued advancement of our development pipeline," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "We chose to target psoriasis as we strongly believe that it provides an ideal pathophysiology to assess safety as well as biomarkers related to IMU-935's mechanism of action. In addition, we believe that there is an urgent medical need to translate the significant therapeutic advances in IL17-targeted therapies in psoriasis into a more convenient oral treatment option for patients. We also eagerly await completion of the single and multiple ascending dose parts of this phase 1 trial in healthy volunteers later in 2021, which, if successful in showing a favorable safety and pharmacokinetic profile for IMU-935, should bolster our thesis behind this program and allow us to further progress with our development plan."

"RORγt is a target that has generated a great deal of interest in the scientific and medical community, given its potential to restore the balance between pro-inflammatory and regulatory lymphocytes, and to modulate a range of cytokines involved in various immune-mediated diseases," added Hella Kohlhof, Ph.D., Chief Scientific Officer of Immunic. "Based on preclinical and clinical data generated thus far, we continue to believe that IMU-935 has the potential to be a best-in-class, orally available, and potent IL-17 inhibitor for the safe and efficacious treatment of the millions of patients affected by autoimmune diseases, worldwide."

About IMU-935
IMU-935 is a highly potent and selective inverse agonist of RORγt (retinoic acid receptor-related orphan nuclear receptor gamma truncated) with additional activity on DHODH (dihydroorotate dehydrogenase). The nuclear receptor RORγt is believed to be the main driver for the differentiation of Th17 cells and the expression 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, IL-17 receptor and IL-17, itself. IMU-935 shows strong cytokine inhibition targeting both Th17 and Th1 responses in preclinical testing, as well as indications of activity in animal models for psoriasis and inflammatory bowel disease. Preclinical experiments indicate 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, 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 RORγt, 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.

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 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.

Contact Information

Immunic, Inc.
Jessica Breu
Head of Investor Relations and Communications
+49 89 2080 477 09
jessica.breu@imux.com

US IR Contact
Rx Communications Group
Paula Schwartz
+1 917 322 2216
immunic@rxir.com

US Media Contact
KOGS Communication
Edna Kaplan
+1 781 639 1910
kaplan@kogspr.com

SOURCE Immunic, Inc.
