SAN DIEGO, Sept. 18, 2019 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX),** a clinical-stage biopharmaceutical company focused on developing potentially best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced dosing of the first healthy volunteer in the company's phase 1 clinical program of IMU-935, a highly potent and selective inverse agonist of the transcription factor RORγt, believed to be the main driver for the differentiation of Th17 cells and the expression of cytokines involved in various inflammatory and autoimmune diseases. Immunic's Australian subsidiary, Immunic Australia Pty Ltd., received clearance from the Bellberry Human Research Ethics Committee in Australia to begin phase 1 trials of IMU-935 under the Clinical Trial Notification (CTN) scheme of the Australian Therapeutic Goods Administration (TGA). The phase 1 program includes single and multiple ascending dose trials in healthy volunteers. Immunic also plans to extend these studies to assess safety and mechanism-related biomarkers in patients with psoriasis.

The first phase 1 trial is a single ascending dose, double-blind, placebo-controlled study of IMU-935 in healthy volunteers. The trial is designed to evaluate the drug's safety and pharmacokinetic profile and will also include the evaluation of food effects.

"The dosing of the first healthy volunteer in our phase 1 program of IMU-935 represents an important inflection point for Immunic, as we progress, on plan, with the development of this important pipeline candidate," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "RORγt is a target that has generated a high degree of interest within the pharmaceutical and biotechnology communities, given its potential to restore the balance between pro-inflammatory and regulatory lymphocytes and modulate a range of cytokines involved in various immune-mediated diseases. The strength of our own preclinical data leads us to believe that IMU-935 has best-in-class potential as an oral therapy for a number of inflammatory and autoimmune diseases."

Following the phase 1 single ascending dose trial, Immunic plans to initiate a second phase 1 trial which will be a multiple ascending dose, double-blind, placebo-controlled study in healthy volunteers with IMU-935 given daily for 14 consecutive days. This study will assess the safety, pharmacodynamic and pharmacokinetic properties of IMU-935. The company expects to extend these multiple ascending dose studies in the first half of 2020 by including mild-to-moderate psoriasis patients given IMU-935 daily over 28 consecutive days, in order to assess safety and mechanism-related biomarkers in patients with psoriasis.

Andreas Muehler, M.D., Chief Medical Officer of Immunic, noted, "We look forward to expanding the study to psoriasis patients next year, as we believe that psoriasis provides a prototype disease where the safety and biomarkers related to the mechanism of action of IMU-935 can be evaluated within the dosing limitations of an early clinical trial. Importantly, this may help to guide the planning of a phase 2 program and we expect that it will provide us with preliminary insights regarding the optimal dosing range which may be safe and active."

About IMU-935
IMU-935 is a highly potent and selective inverse agonist of RORγt (retinoic acid receptor-related orphan nuclear receptor gamma) 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.

About Immunic, Inc.
Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. The company is developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of RORγt; and IMU-856 targets the restoration of the intestinal barrier function. Immunic's lead development program, IMU-838, is in phase 2 clinical development for relapsing-remitting multiple sclerosis and ulcerative colitis, with an additional phase 2 trial planned in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. For further information, please visit: www.immunic-therapeutics.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-838, IMU-935 and IMU-856 to safely and effectively target diseases; preclinical data for IMU-935; the timing and implementation of future clinical trials; the nature, strategy and focus of the company; 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, 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 "Item 1A. Risk Factors," in the company's Current Report on Form 8-K filed on July 17, 2019, 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.immunic-therapeutics.com/sec-filings and on request from Immunic. 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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