NEW YORK, Dec. 9, 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 patient in its open-label phase 1 trial of IMU-935, a highly potent and selective inverse agonist of the transcription factor RORγt, in metastatic castration-resistant prostate cancer (mCRPC).

The trial's Principal Investigator is Johann Sebastian de Bono, M.D., Ph.D., Regius Professor of Cancer Research and Professor in Experimental Cancer Medicine, The Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust, London. The trial has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA), the Research Ethics Committee (REC) and the Health Research Authority (HRA) in the United Kingdom.

"After receiving available established treatments, many of which are being given soon after diagnosis, few effective treatments remain for men suffering from mCRPC with this disease being invariably fatal. There is therefore an urgent need to find alternative therapeutic options," stated Professor de Bono. "Preclinical data indicate that IMU-935 may suppress the expression of the mutated AR-V7 receptor, which is a hallmark and progression driver of CRPC. In addition, by repressing pro-tumorigenic Th17 cells and IL-17 cytokines, IMU-935 may further impact tumor growth. I look forward to exploring the anticancer activity of this agent against mCRPC."

"As one of world's leading experts on the subject of castration-resistant prostate cancer, Professor de Bono's expertise and deep understanding of the unique mechanism of action of IMU-935 provides important corroboration of this key pipeline program within the scientific and clinical communities," noted Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Based on the compelling preclinical data highlighting the therapeutic potential of IMU-935 to affect mCRPC, which is the second leading cause of cancer-related death among men, we recognize the potential importance of this program. We are pleased to have enrolled the first patient on plan and look forward to continuing to progress the trial."

The phase 1 trial is structured in two portions: a dose-escalation part and an optional expansion part. A total of between 18 and 24 patients are planned to be enrolled in the dose-escalation part at three dose levels of IMU-935 to be given for three cycles of 28 days each. At each of the three dose levels, a safety analysis after 28 days and an interim analysis after three months of treatment will be performed. The main analysis for this trial is planned after the last patient has received six months of study treatment. The primary objective is to evaluate the safety and tolerability of increasing doses of IMU-935 to establish the maximum tolerated dose and the recommended phase 2 dose. The trial will also evaluate the anti-tumor activity of IMU-935 by means of prostate-specific antigen (PSA) levels, circulating tumor cell (CTC) numbers, and radiographic response assessments of tumor progression. Patients who receive a benefit from IMU-935 will have the option to continue treatment until progression. Following completion of all dose-escalation cohorts, an expansion cohort at one or two therapeutically active dose levels with up to 18 additional patients may be performed to support selection of a recommended phase 2 dose. Initial clinical data is expected to be available in the third quarter of 2022.

The company also re-iterates its prior guidance that data from the multiple ascending dose part of the ongoing phase 1 trial of IMU-935 is expected in the fourth quarter of 2021, with initial clinical data in psoriasis expected in the second quarter of 2022, and that regarding vidofludimus calcium (IMU-838), phase 2 top-line data in ulcerative colitis is expected to be available in the second quarter of 2022.

For more information on the phase 1 clinical trial of IMU-935 in mCRPC, please visit: www.clinicaltrials.gov, NCT05124795.

About Castration-Resistant Prostate Cancer
Castration-resistant prostate cancer (CRPC) is a form of advanced prostate cancer. Approximately 200,000 new cases of prostate cancer are diagnosed each year in the United States, with roughly 40,000 cases progressing to CRPC. Because early stages of prostate cancer rely on testosterone to grow, approaches to lower testosterone can be employed therapeutically. With CRPC, the cancer no longer completely responds to treatments that lower testosterone, significantly limiting available treatment options in these patients. Common sites of metastasis are lymph nodes, bones, bladder, rectum, lung, or liver. Although metastatic CRPC may be asymptomatic, typical signs/symptoms include problems urinating, pain while passing urine or blood in the urine, tiredness, weakness, weight loss, shortness of breath, or bone pain. The main goal in treating metastatic CRPC is to control symptoms and slow progression.

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, 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 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 Immunic's development programs to safely and effectively target diseases; preclinical and clinical data for Immunic's development programs; 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 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.

---

https://ir.imux.com/2021-12-09-Immunic,-Inc-Announces-Enrollment-of-the-First-Patient-in-its-Phase-1-Trial-of-IMU-935-in-Metastatic-Castration-Resistant-Prostate-Cancer