- IMU-935 Has Been Observed In Vitro to Inhibit the Generation of Th17 Cells and Production of IL-17 Cytokines Without Impairing RORγt Function Required for Normal Thymocyte Development; May Avoid Risk of Lymphoma Formation Seen in Third-Party RORγt Programs -

- Full Pharmacokinetic and Blinded Safety Data Set From the Completed Single-Ascending Dose Part of the Ongoing Phase 1 Clinical Trial of IMU-935 in Healthy Volunteers Now Available -

- Presentation Will Also Include New Preclinical Data Supporting IMU-935 as a Potential Treatment for Castration-Resistant Prostate Cancer; Company Preparing for a Phase 1 Clinical Trial -

- Conference Call and Webcast to be Held Today, July 12, 2021 , at 4:00 pm ET -

NEW YORK, July 12, 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, announced that it will host a virtual R&D Day today at 4:00 pm ET. Immunic's management and Zuoming Sun, Ph.D., a key opinion leader specializing in RORγt biology, will discuss new preclinical data for IMU-935, a highly potent and selective inverse agonist of the transcription factor RORγt, and provide an update on its clinical development strategy as a potential treatment for psoriasis and metastatic castration-resistant prostate cancer (mCRPC). The full data sets will be publicly disclosed in a Current Report on Form 8-K and will be available on Immunic's website at ir.imux.com.

Topics to be discussed during the event include the following:

IMU-935 Inhibits Cytokine Production While Maintaining Physiological Functions of Maturing T Lymphocytes

In *ex vivo* mouse cell differentiation and maturation assays, IMU-935 was recently observed to selectively inhibit RORγt-dependent gene expression during Th17 differentiation without affecting either RORγt-dependent gene regulation relevant to thymocyte development, or the viability of these cells. In third-party research[1], impairment of thymocyte development has been shown to be associated with serious safety issues, including, among others, T cell malfunction and potential lymphoma formation. Immunic believes that IMU-935's observed selectivity may enable it to inhibit both the generation of Th17 cells and the production of IL-17 cytokines that are responsible for the development of autoimmune diseases, without impairing thymocyte development, which is associated with the potential risk of lymphoma seen with other, third-party RORγt programs.[2]

Full Pharmacokinetic and Blinded Safety Data From the Single-Ascending Dose Part of the Ongoing Phase 1 Trial of IMU-935 Now Available

Analysis of the full pharmacokinetic data set from the completed single-ascending dose part of the ongoing phase 1 clinical trial of IMU-935, which is being conducted in Australia, in healthy volunteers revealed dose-linear pharmacokinetics and a blood half-life that Immunic believes may be appropriate for once or twice daily dosing. Although the trial is still blinded, no significant safety findings have been detected to date in the single-ascending dose cohort (up to 400 mg IMU-935 daily).

The multiple ascending dose part of the phase 1 trial with 14-day daily dosing in healthy volunteers is ongoing and progressing. Immunic expects to extend the trial in the third quarter of 2021 by including moderate-to-severe psoriasis patients given IMU-935 daily over 28 consecutive days, in order to assess safety and exploratory disease endpoints in psoriasis patients.

New Preclinical Data Highlights IMU-935's Therapeutic Potential in Castration-Resistant Prostate Cancer

Recently published third-party studies[3] have shown that RORγ plays an important pro-tumor role by driving expression of the androgen receptor (AR), leading to tumor growth. During tumor progression, AR tends to mutate into AR-V7, leading to resistance of AR-axis-targeted therapies.

In preclinical studies, IMU-935 was observed to inhibit the expression of mutated AR-V7, and the tumor growth of prostate cancer cell lines *in vitro*. Finally, Immunic believes IMU-935's potency in inhibiting tumorigenesis-promoting IL-17 and Th17 cells *in vitro* may result in further antitumoral activity in humans.

Preparation for a Phase 1 Clinical Trial of IMU-935 in Metastatic Castration-Resistant Prostate Cancer

Based on these strong preclinical results, Immunic is currently preparing an open-label phase 1 dose escalation trial designed to establish a recommended phase 2 dose and to assess safety, tolerability, anti-tumor activity, biomarkers and pharmacokinetics of IMU-935 in patients with progressive mCRPC. The Principal Investigator of the trial 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 and The Royal Marsden NHS Foundation Trust, London, United Kingdom.

"There are currently few effective treatments for patients with metastatic CRPC, leading to an extremely poor prognosis for this patient population," stated Dr. de Bono. "IMU-935 possesses a unique mechanism of action which may prove transformative in its ability to effectively treat a range of underserved diseases. Preclinical studies have shown that IMU-935 potently suppresses the expression of IL-17, indicating that it may also inhibit tumorigenesis, and suppresses the expression of AR-V7 in prostate cancer cell lines, thus potentially inhibiting tumor growth in CRPC patients. I am looking forward to collaborating with Immunic on this important phase 1 clinical trial in metastatic CRPC."

Conference Call and Webcast Information

Immunic's management team will host a virtual R&D Day today,July 12, 2021, at 4:00 p.m. Eastern Time to discuss the updates on the preclinical and clinical development of the company's IMU-935 program.

Speakers from Immunic:

- Daniel Vitt, Ph.D., Chief Executive Officer and President
- Hella Kohlhof, Ph.D., Chief Scientific Officer
- Andreas Muehler, M.D., Chief Medical Officer

Featured key opinion leader:

- Zuoming Sun, Ph.D., Professor, Department of Molecular Imaging & Therapy, City of Hope,Duarte, CA, USA

To participate in the conference call, dial 1-877-870-4263 (USA) or 1-412-317-0790 (International) and ask to be joined into the Immunic, Inc. call. A live, listen-only webcast of the conference call can be accessed at https://www.webcaster4.com/Webcast/Page/2301/41824 or on the "Events and Presentations" section of Immunic's website at ir.imux.com/events-and-presentations.

An archived replay of the conference call and webcast will be available approximately one hour after the completion for one year on Immunic's website at ir.imux.com.

[1] Guntermann, C. et al. Retinoic-acid-orphan-receptor-C inhibition suppresses Th17 cells and induces thymic aberrations, JCI Insight. 2017;2(5):e91127. https://doi.org/10.1172/jci.insight.91127.
[2] Gege, C. (2021). Retinoic acid-related orphan receptor gamma t (RORγt) inverse agonists/antagonists for the treatment of inflammatory diseases – where are we presently?, Expert Opinion on Drug Discovery. https://doi.org/10.1080/17460441.2021.1948833.
[3] Wang, J., Zou, J., Xue, X. et al. ROR-γ drives androgen receptor expression and represents a therapeutic target in castration-resistant prostate cancer. Nat Med 22, 488–496 (2016). https://doi.org/10.1038/nm.4070.

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 onFebruary 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

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