

## **- Presentation Will Include Preclinical Data of IMU-838 Against SARS-CoV-2 as Well as First Pharmacokinetic Data From the Ongoing Phase 1 Clinical Trial of IMU-935 -**

### **- Live Webcast to be Held From 9:00 am to 1:00 pm ET -**

NEW YORK, May 19, 2020 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX)**, a clinical-stage biopharmaceutical company focused on developing best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, announced that it will host a virtual R&D Day today, May 19, 2020, from 9:00 am to 1:00 pm ET. Immunic's management and invited key opinion leaders, specializing in multiple sclerosis and inflammatory bowel disease, will discuss today's treatment options for, and the unmet medical needs of, chronic inflammatory and autoimmune diseases, as well as clinical progress of Immunic's selective oral immunology programs and their potential advantages over the current treatment landscape. Management will also discuss the company's coronavirus disease 2019 (COVID-19) program.

During the event, Immunic will provide recently obtained preclinical data testing the company's lead asset, IMU-838, a selective oral DHODH inhibitor, against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), showing that, in *in vitro* models, IMU-838 is able to inhibit replication of clinical isolates of SARS-CoV-2, obtained from patients with COVID-19, at drug concentrations consistent with previously employed IMU-838 dosing regimens. Highlights will include:

- Validation of previously published antiviral data against SARS-CoV-2 in monkey Vero cells showing antiviral activity with EC<sub>90</sub> of 7 µM
- Determination of strong antiviral activity in human lung epithelial cells infected with SARS-CoV-2 clinical isolates, achieving a virus reduction of 3-log units with 10 µM of IMU-838; EC<sub>50</sub> concentrations are ranging between 1 and 6 µM in various assay systems
- Review of previously published IMU-838 pharmacokinetic data, showing that in earlier trials, steady state concentrations of 10-30 µM were reached, and that these dosing regimens have been associated with favorable safety and tolerability profiles in prior clinical data sets
- Insights into the anticipated multifold antiviral mode of action of IMU-838 by inhibiting viral replication, inducing innate immunity and dampening the excessive immune response thought to be associated with cytokine storm
- Data showing IMU-838's broad-spectrum antiviral activity *in vitro* for HIV, HCV, hCMV and the Arenavirus causing Lassa fever

Immunic will also present preclinical mode of action and first pharmacokinetic data from the current, single ascending dose part in healthy volunteers of the ongoing phase 1 trial of IMU-935, a potentially best-in-class RORγt inverse agonist. Highlights will include:

- How IMU-935 improves the balance between regulatory T cells and Th17 cells, and how it shows selectivity towards IL-17 cytokines and Th17 cells over other cellular effects
- Data from the first four cohorts of the ongoing and still blinded clinical phase 1 single ascending dose part of the study, demonstrating dose linear pharmacokinetics and a benign safety profile

The full data sets will be publicly disclosed in a Current Report on Form 8-K.

### **Webcast Details**

Speakers from Immunic will be:

- Dr. Daniel Vitt, Chief Executive Officer and President
- Dr. Andreas Muehler, Chief Medical Officer
- Dr. Hella Kohlhof, Chief Scientific Officer
- Dr. Manfred Groeppel, Chief Operating Officer

Featured key opinion leaders will be:

- For multiple sclerosis: Robert Fox, MD, Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio
- For inflammatory bowel disease: Jean-Frederic Colombel, MD, Professor of Medicine, Director of The Susan and Leonard Feinstein Inflammatory Bowel Disease Center, Director of The Leona M. and Harry B. Helmsley Inflammatory Bowel Disease Center, Icahn School of Medicine, Mount Sinai Hospital, New York

Agenda (Eastern time, times are estimates):

- 09:00 – 09:10 Welcome and Company Introduction

- 09:10 – 09:30 Introduction to Lead Asset IMU-838
- 09:30 – 10:00 IMU-838 as a Potential Treatment Option for COVID-19
- 10:00 – 10:40 Multiple sclerosis: Robert Fox, MD
- 10:40 – 11:15 Clinical Development Program for IMU-838
- 11:15 – 11:25 Introduction to IMU-935
- 11:25 – 11:40 Positioning of IMU-935 and Ongoing Phase 1 Program
- 11:40 – 11:50 Introduction to IMU-856
- 11:50 – 12:30 Inflammatory Bowel Disease: Jean-Frederic Colombel, MD
- 12:30 – 12:45 Positioning of IMU-856 and Clinical Planning
- 12:45 – 01:00 Summary and Closing Remarks

To participate in the live webcast, please follow this link:

<https://www.webcaster4.com/Webcast/Page/2301/33871>

The webcast will be held in English. Questions can be asked via the question and answer tool any time during the presentation. An archived replay of the webcast will be available on Immunic's website at: [ir.imux.com](http://ir.imux.com).

#### **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 ROR $\gamma$ t; 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 considered in Crohn's disease. The company is also investigating IMU-838 as a potential treatment option for COVID-19. 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.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 management's participation in conferences; Immunic's three development programs and the targeted diseases; the potential for IMU-838 to safely and effectively target diseases; preclinical and clinical data for IMU-838; the timing of current and future clinical trials; the potential for IMU-838 as a treatment for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections associated with coronavirus disease 2019 (COVID-19) and any clinical trials, collaborations and approvals relating to such potential treatment; 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, 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, 2019, filed with the SEC on March 16, 2020, the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 8, 2020, 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.immunic-therapeutics.com/sec-filings](http://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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