



**Immunic**  
THERAPEUTICS



# Immunic Therapeutics

Developing Selective Oral DHODH Inhibitor IMU-838 as  
COVID-19 Therapy

April 22, 2020



# Cautionary Note Regarding Forward-Looking Statements

- Certain statements contained in this presentation regarding matters that are not historical facts are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. These include statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Immunic undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA.
- Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management. Risks and uncertainties that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: Immunic’s plans to develop and commercialize its product candidates, including IMU-838, IMU-935 and IMU-856; the timing of initiation of Immunic’s planned clinical trials; expectations regarding potential market size; the timing of the availability of data from Immunic’s clinical trials; the timing of any planned investigational new drug application or new drug application; Immunic’s plans to research, develop and commercialize its current and future product candidates; Immunic’s ability to successfully collaborate with existing collaborators or enter into new collaboration agreements, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Immunic’s product candidates; Immunic’s commercialization, marketing and manufacturing capabilities and strategy; Immunic’s ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Immunic’s competitors and industry; the impact of government laws and regulations; Immunic’s ability to protect its intellectual property position; Immunic’s listing on The Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of the company; the executive and board structure of the company; Immunic’s estimates regarding future revenue, expenses, capital requirements and need for additional financing; the nature, strategy and focus of the company; and the other risks set forth in the company’s filings with the Securities and Exchange Commission (“SEC”).
- Forward-looking statements included in this presentation are based on information available to Immunic as of the date of this presentation. Immunic does not undertake any obligation to update such forward- looking statements to reflect events or circumstances after the date of this presentation.

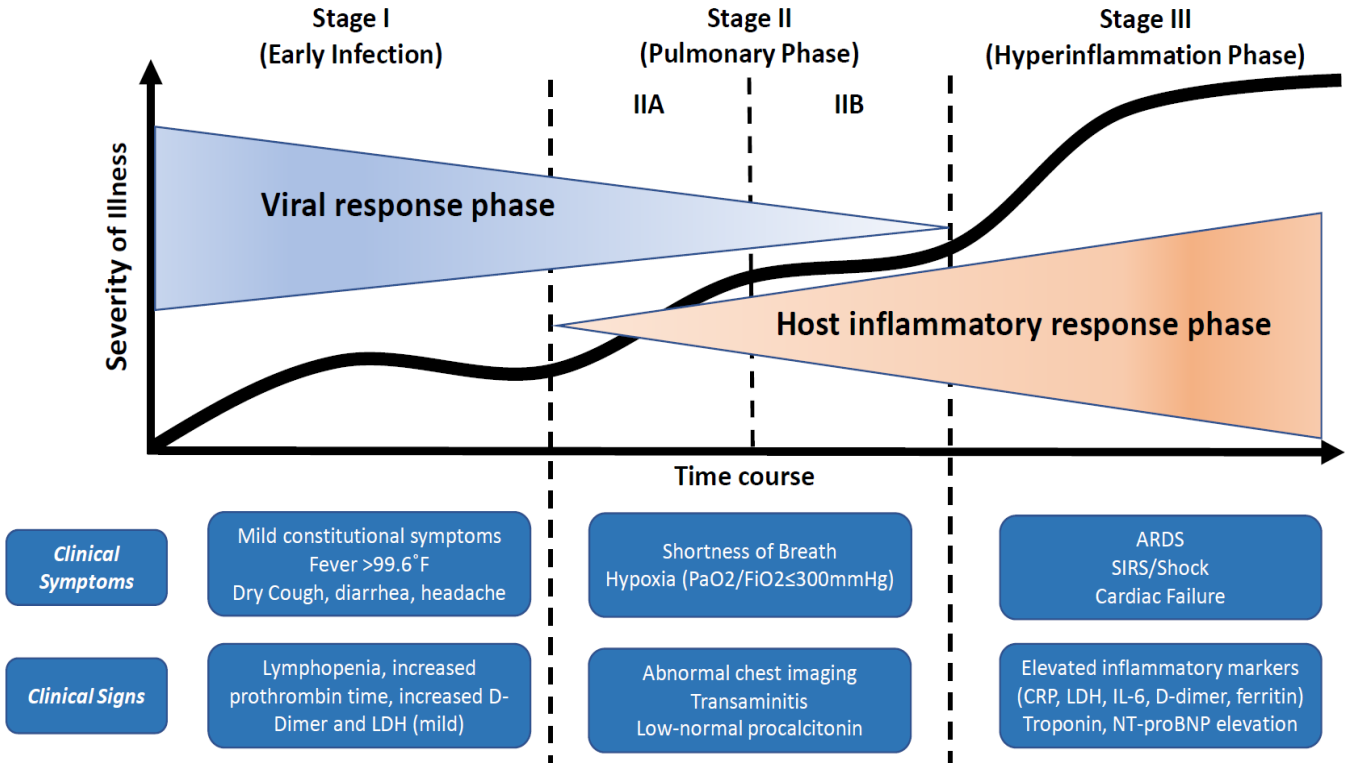


## Our Vision

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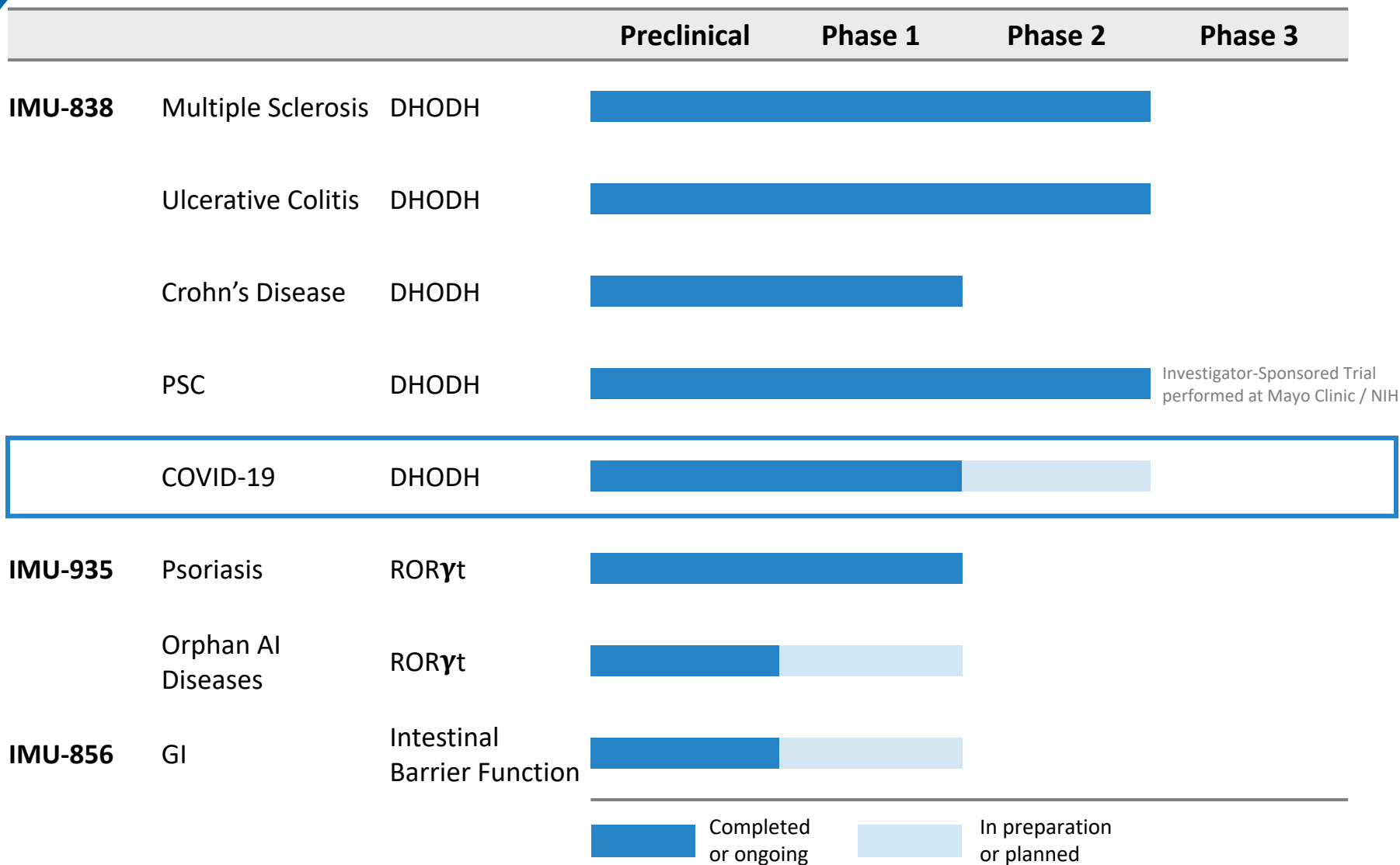
We are developing new therapies with best-in-class potential for the treatment of chronic inflammatory and autoimmune diseases.

# COVID-19: The Therapeutic Challenge



COVID-19 Illness in Native and Immunosuppressed States: A Clinical-Therapeutic Staging Proposal Siddiqi H. and Mehra M. (2020)

# Development Pipeline





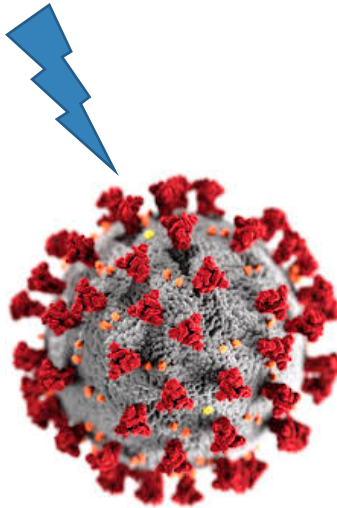
# IMU-838: Potential Treatment Option for COVID-19

- IMU-838 is an orally available DHODH inhibitor with both, **antiviral and anti-inflammatory** effects
- **Advanced clinical drug candidate** with attractive pharmacokinetic, **safety and tolerability** profile with **more than 650 individuals exposed** to date
- Host-based mechanism avoids dependence on specific viral proteins and, therefore, offers **broad-spectrum antiviral activity**

# IMU-838: Activity Against SARS-CoV-2 and Other Viruses

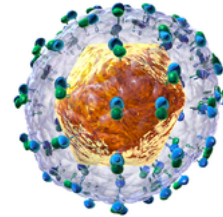
- IMU-838 is active against SARS-CoV-2
- IMU-838 has shown broad-spectrum antiviral activity against different pathogenic viruses with  $EC_{50}$  values in single digit  $\mu$ M range

IMU-838

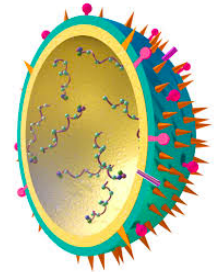


SARS-CoV-2

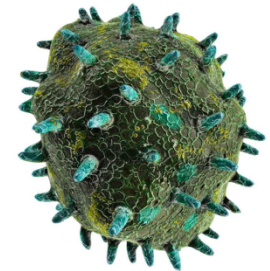
HCV



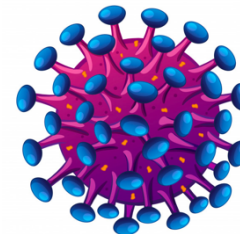
Influenza viruses



Arenavirus

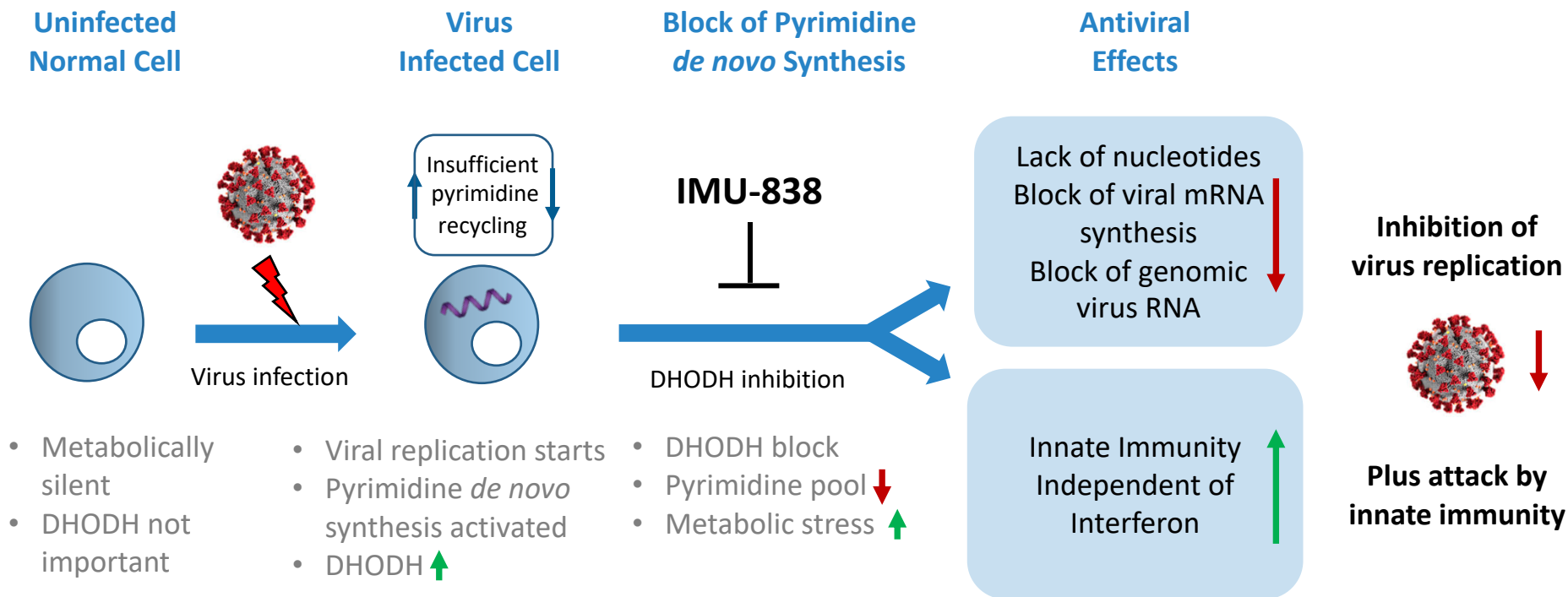


HIV



# IMU-838: Small Molecule DHODH Inhibitor

## DHODH Inhibitors: Active Against SARS-CoV-2<sup>1</sup>



**IMU-838 antiviral double attack: direct antiviral + activation of innate immunity**

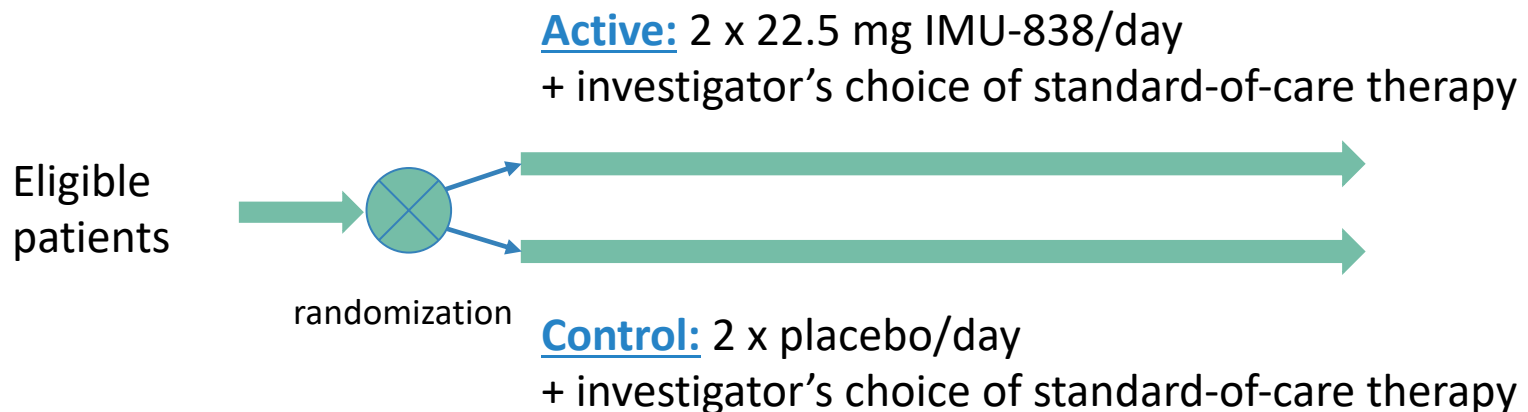


# IMU-838: Advanced Clinical Drug Candidate

- Three phase 2 trials ongoing
  - Multiple sclerosis – phase 2 with 210 patients – fully recruited
  - Ulcerative colitis – phase 2 with 240 patients – ongoing
  - Primary sclerosing cholangitis – 30 patients, IST – ongoing
- Well tested safety: 650 individuals exposed to date with IMU-838
  - Doses up to 50 mg IMU-838 per day shown to be safe
  - Safety profile similar to placebo in already unblinded trials
  - No increased rates of neutropenia
  - Selective immunomodulation without general effects on bone marrow
- Very good pharmacokinetic properties for once and twice daily dosing
  - Active exposure levels reached within hours
  - Trough level at steady state for 40-50 mg dose:  $\approx 15 \mu\text{M}$ , C-max  $\approx 30 \mu\text{M}$

# IMU-838: Potential Phase 2 Clinical Trial Design in COVID-19

- Immunic intends to initiate a prospective, multicenter, randomized, placebo-controlled, double-blind phase 2 clinical trial in patients with moderate COVID-19 disease and clinical symptoms
  - Adequate drug supply exists to begin clinical testing in COVID-19 very soon





## Questions?

Thank you for listening!

We are happy to answer your questions  
through the question and answer tool

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