



ViralClear™

Merimepodib a host-  
directed antiviral for  
the treatment of  
COVID-19

July 2020

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# Vision

ViralClear aspires to make the world a safer place by developing a therapeutic platform to address existing and emerging pathogenic threats so that people can engage in everyday life normally and safely



# Who are we?

- Formed March 2020 in response to COVID-19 pandemic
- BioSig (NASDAQ BSGM) Subsidiary March 24<sup>th</sup>
- Raised \$12M May 2020
- Lead molecule merimepodib (MMPD; VX-497)
- IND submitted April 23<sup>rd</sup>; study allowed to proceed May 15<sup>th</sup>
- First Phase 2 trial initiated June 2020 in combination with remdesivir
- Virtual company with 20 employees and consultants supported by BioSig





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COVID-19 pandemic



COVID-19

The Biggest Global Health and  
Economic Crisis of Our Lifetimes



Confirmed Cases

>29.1M\*

Deaths

>925K\*



Confirmed Cases

>6.5M\*

Deaths

>194K\*

- There is no approved medical treatment yet that cures or prevents COVID-19
- So the disease progresses on with devastating health, human and economic consequences

\*Johns Hopkins COVID-19 Dashboard September 14, 2020

# Seeking to establish MMPD as the platform antiviral in the treatment of COVID-19



We believe MMPD has the potential to be used by a broad prescriber base across multiple settings



Hospitals



Clinics



Primary Care Physicians



Therefore, upon regulatory approval, MMPD would need a breadth of commercial support

There may not be a single silver bullet solution for COVID-19  
We believe that we must focus on a multi-faceted approach...not just vaccines

Approaches include, but are not limited to:

Direct  
Treatments

**Antivirals** for inhibition of viral replication

**Immune Modulators** to control inflammatory response and cytokine storm

Prevention

**Vaccines**

Durability of vaccines may be questionable



Dr. Anthony Fauci: “When you look at the history of coronaviruses, the common coronaviruses that cause the common cold, the reports in the literature are that the durability of immunity that’s protective ranges from 3 to 6 months to almost always less than a year. That’s not a lot of durability and protection.”



**Urgent Need for Effective Direct Treatments**

# Goals for treating pathogenic viral threats including COVID-19

- ✓ Stop disease progression
- ✓ Hasten healing
- ✓ Accelerate viral clearance
- ✓ Stop viral shedding
- ✓ Prevention of infection
  - ✓ Vaccines
  - ✓ Prophylaxis



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## **Oral IMPDH inhibitor initially developed by Vertex Pharmaceuticals Inc.**

- Deprives replicating virus guanosine, essential for nucleic acid synthesis
- In vitro antiviral activity for RNA and DNA viruses
- A lead development asset for chronic hepatitis C before shelving

## **Drug licensed to**

- Trek Therapeutics, PBC, 2016
- ViralClear Pharmaceuticals Inc., 2020

## **Chemistry, Manufacturing and Controls (CMC)**

- Drug substance [active pharmaceutical ingredient (API)] process developed to be commercially ready for different indications
- MMPD Oral Solution formulation to conduct Phase 2 trials and pivotal trial

## **Clinical**

- 7 Phase 1 studies for different indications – 122 health volunteers/patients exposed to MMPD
- 5 Phase 2 studies for different indications – 339 patients exposed to MMPD
  - 4 chronic hepatitis C studies and 1 psoriasis study
  - 248 chronic hepatitis C patients treated for 6 months or more

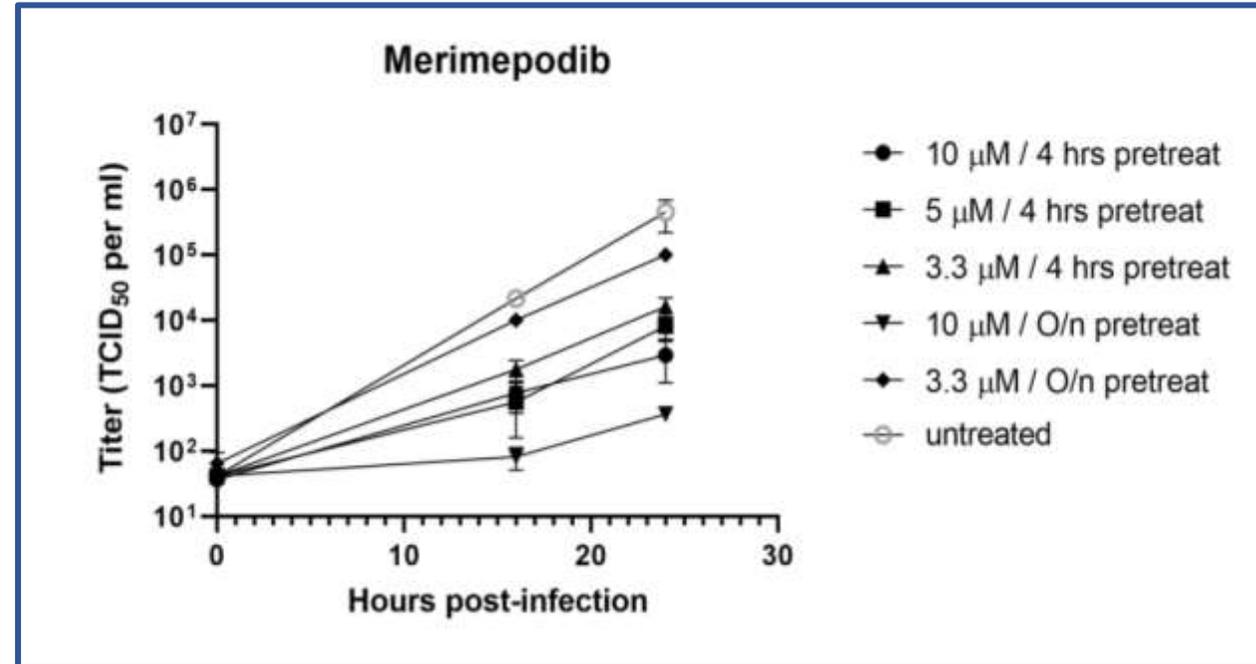


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# Preclinical data in SARS-CoV-2

# MMPD reduced SARS-CoV-2 viral titers in a Vero Cell culture model

MMPD pre-treated Vero Cells (either 4 hours or overnight [O/n]) were infected with SARS-CoV-2.

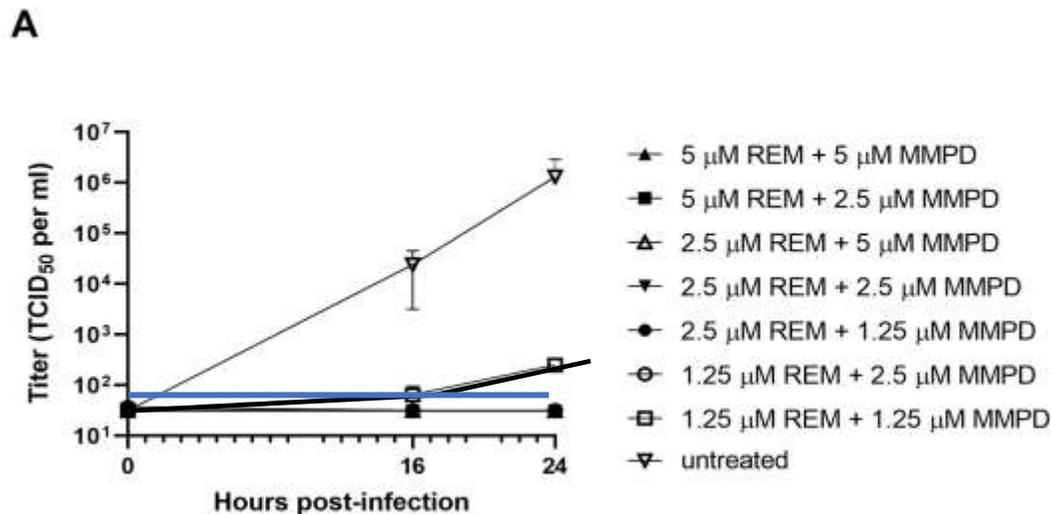


Bukreyeva N, Mantlo EK, Sattler RA, Huang C, Paessler S, Zeldis J. The IMPDH inhibitor merimepodib suppresses SARS-CoV-2 replication in vitro. bioRxiv doi:

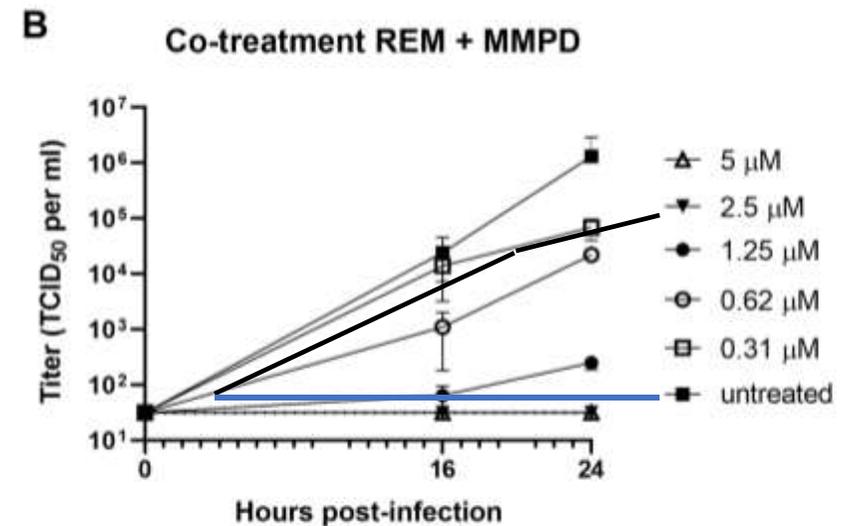
<https://doi.org/10.1101/2020.04.07.028589>

# In vitro, merimepodib and remdesivir in combination reduce production of infectious SARS-CoV-2 to undetectable levels

Co-treatment with MMPD + REM at concentrations as low as 2.5 $\mu$ M + 1.25 $\mu$ M reduces new production of infectious SARS-CoV-2 to undetectable levels



Co-treatment with equimolar concentrations of MMPD + REM at either 2.5 $\mu$ M or 5 $\mu$ M reduces new production of infectious SARS-CoV-2 to undetectable levels





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# Merimepodib Development Strategy

# Planned Development Strategy (Next 6 Months)

- ✓ Current COVID-19 Phase 2 trials
  - Hospitalized patients as combination with remdesivir
    - 1:1 randomization to merimepodib or placebo
    - 40 subjects -Enrolling
  - Hospitalized patients as monotherapy
    - 1:1 randomization to merimepodib or placebo
    - 40 subjects -Initiating
- ✓ All current clinical research with MMPD Oral Solution; other formulations being developed
  - Create path for
    - Emergency Use Authorization/NDA filing
  - Initiate pivotal trial
  - Initiate outpatient COVID-19 trials



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# Planned Longer Term Development (> 6 months)

- Study merimepodib's role in all stages of COVID-19
- Explore Viral Diseases of Interest and Emerging Infections
  - Dengue
  - Hemorrhagic Fever
  - Other coronavirus diseases (MERS, SARS)



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# CMC Objectives

- ✓ Onboard multiple API suppliers for NDA registration batches and commercial launch
- ✓ Identify drug product manufacturer for NDA registration batches and commercial launch
- ✓ Start the NDA filing planning process, including requesting an End Of Phase 2 CMC meeting with FDA





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# Summary Focus and Speed

- Quickly repositioned merimepodib for COVID-19 and raised supporting capital
- Established an accomplished Development and Management team
- Top-line data on Phase 2 trials anticipated in 3Q20
- Initiate pivotal trial planned for 4Q20
- File NDA 2Q2021