
COVID19
Keeping Up with a Moving Target

CME Information

Jointly provided by Postgraduate Institute for Medicine, DKBmed, and the Institute for Johns Hopkins Nursing.

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The faculty reported the following financial relationships or relationships they or their spouse/life partner have with commercial interests related to the content of this continuing education activity:

Name of Faculty or Presenter	Reported Financial Relationship
Paul G. Auwaerter, MD, MBA, FIDSA	JNJ: Ownership equity Scientific Consulting: Verily, EMD Serono DMSB: Humanigen

Dr. Auwaerter has indicated that he will be referencing the unlabeled or unapproved use of agents currently being investigated in on-going studies and trials, including monoclonal antibodies, baricitinib, and several vaccine platforms.

All activity, content, and materials have been developed solely by the activity directors, planning committee members, and faculty presenters, and are free of influence from a commercial entity.

CME Information

To attest for CME/CE/AAPA credit, please visit

COVID19.dkbmed.com

Learning Objectives

- Discuss the role of monoclonal antibodies for prevention of COVID-19

Thank You

This activity is supported by an educational grant from Gilead Sciences, Inc.

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Please see **COVID19.DKBmed.com** for additional resources and educational activities

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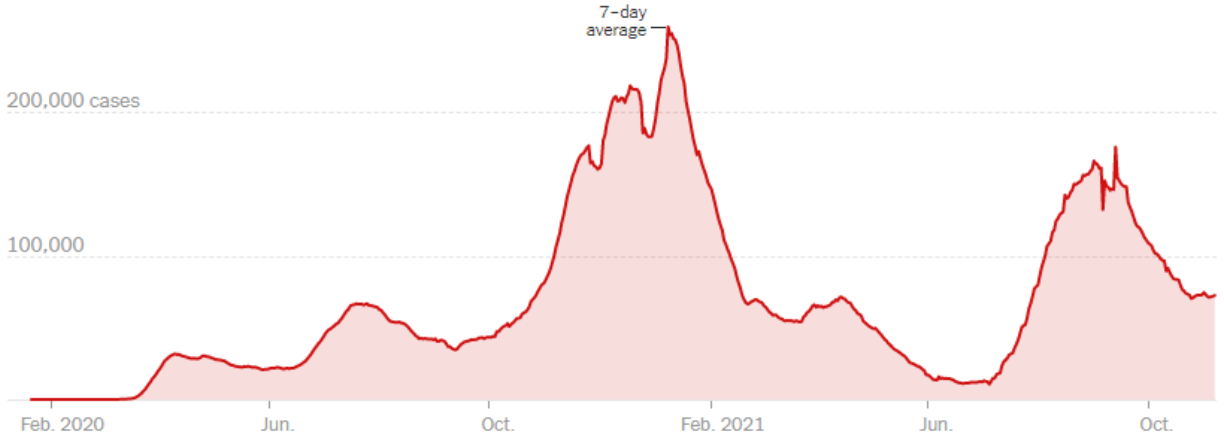
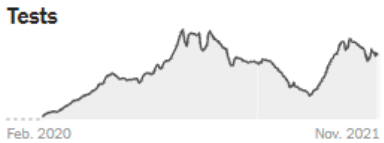
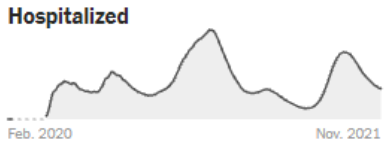
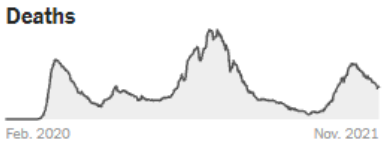
Johns Hopkins University School of Medicine

US COVID-19 Cases/Hospitalizations/Deaths









	DAILY AVG. ON NOV. 7	14-DAY CHANGE	TOTAL REPORTED
Cases	72,436	Flat	46,449,331
Tests	1,391,203	+9%	—
Hospitalized	46,934	−13%	—
Deaths	1,217	−19%	754,051

About this data:

Sources: State and local health agencies (cases, deaths); U.S. Department of Health and Human Services (tests, hospitalizations). Tests, hospitalizations and deaths show seven-day averages. Hospitalization data may not yet be available for yesterday. The number of average tests is for the most recent day for which all states have reported data. 14-day change is hidden if not enough data is available to make a comparison. Figures shown are the most recent data available.

Outpatient therapies for COVID-19

What's available now and the near future

Monoclonal Antibodies

Directed against the Spike protein of SARS-CoV-2

3 available under FDA EUA for treatment, and 2 for post-exposure prophylaxis (PEP) for high-risk pts

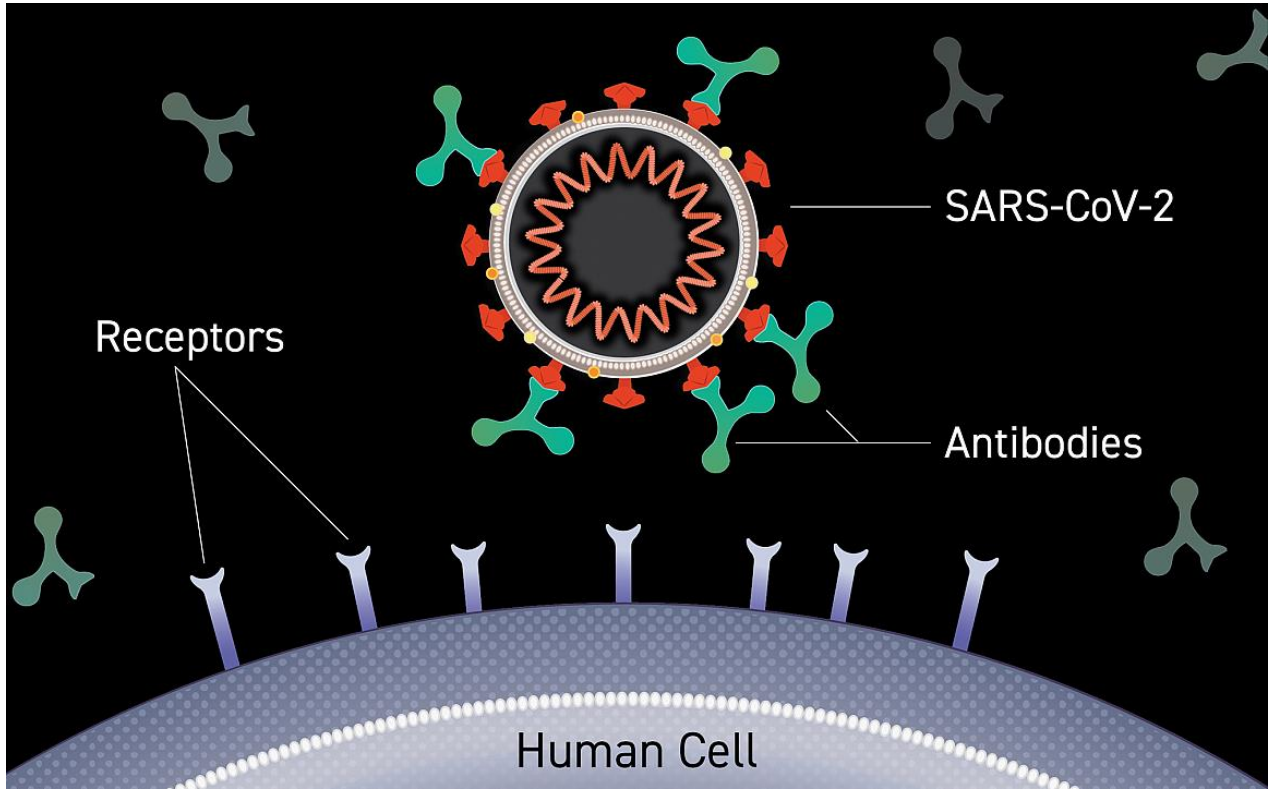
- Bamlanivimab/etesevimab IV
- Casirivimab/imdevimab IV or SC
- Sotrovimab IV

Treatment:

- 70-85% relative reduction in hospitalization or death

PEP

- 40-80% reduction symptomatic infections, ED visits, hospitalization or death.



NIH

Fluvoxamine: an Old-Time SSRI

152 pt RCT, double-blind

- Primary endpoint: clinical deterioration
  - 0/80 vs 6/72 in placebo group [absolute difference 8.7%, 95% CI, 1.8%-16.4%]

TOGETHER trial RR ER/hospitalization, 29% reduction

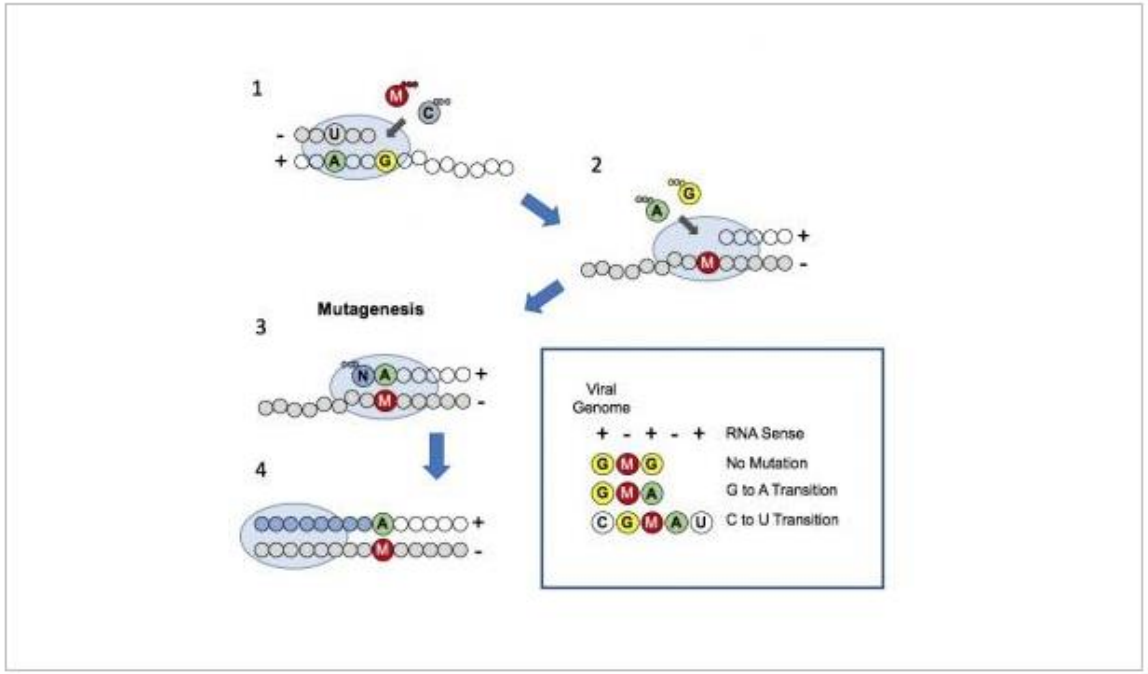
- Brazil RCT outpt COVID: 100 mg BID x 10d v. placebo
- Primary endpoint: 6h in ED or hospitalization

Arm	Patient #	Number of events	Relative Risk [95% CI]
Fluvoxamine	741	79	0.68 [0.52-0.88]
Placebo	756	111	reference

Lenze, *JAMA*. 2020;324(22):2292-2300
Reis, Lancet Global Health, Oct 28, 2021

Molnupiravir: Nucleoside Analogue

Mutagenesis Model



Credit Matthias Gotte, University of Alberta School of Medicine

Oral Therapy for COVID-19

Preliminary Phase 3 results

N = 775, placebo RCT, outpt COVID

Primary endpoint: hosp. or death 29d

- 7.3% molnupiravir v. 14.1% placebo (p=0.0012)
  - ~50% reduction

Deaths:

- 0 molnupiravir v. 8 placebo

Adverse events similar in groups

https://www.merck.com/news/merck-and-ridgebacks-investigational-oral-antiviral-molnupiravir-reduced-the-risk-of-hospitalization-or-death-by-approximately-50-percent-compared-to-placebo-for-patients-with-mild-or-moderat/

Molnupiravir

Approved for use in the UK

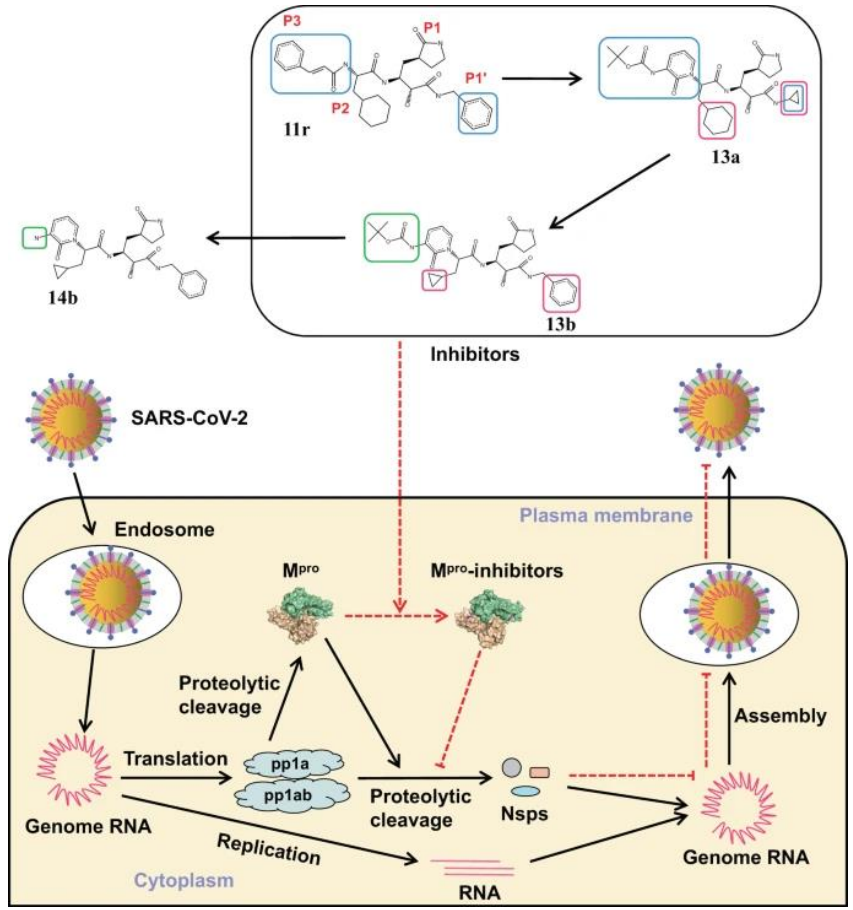
Data to be discussed by FDA, Nov. 30, 2021

Although treatment course short, concerns raised regarding mutagenesis

- May promulgate viral mutants that lead to immune escape?
  - Suboptimal dosing, as t ½ < 3.5 hours
- Potential for human DNA mutations (tumors, pregnancy)?

PF-07321332 (AKA‘332), Oral Protease Inhibitor

Protease Inhibitors for SARS-CoV-2



Mengist, Nature 2020
Pfizer press release, 11/5/21

Phase 3 Outpatient COVID-19 Trial

Preliminary Results

RCT: twice daily w/ boosted with ritonavir x 5 vs. placebo

774 patients

If given within 3d of symptoms

- 89% decrease hospitalizations/death
- 0 deaths (vs. 7 in placebo)

If given within 5d of symptoms

- 85% reduction hospitalizations/death

Phase 2/3 safety data, less adverse events in active arm

Do you think the current COVID-19 vaccines will require periodic “boosters” or additional doses for people at low/average risk?

Will PCR confirmation of SARS-CoV-2 be required for oral antiviral use? Would that limit use?

Thank You!

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To ask your own question, email:

- QA@dkbmed.com