FACT SHEET: New Pfizer and Merck Antivirals – Risk Concerns, Unknowns and Alternatives

In Brief:

- Pfizer and Merck have developed new antivirals (Paxlovid and Molnupiravir) for treatment of COVID.
- Both were approved under Emergency Use Authorization as of February 15, 2022
- The available documentation raises significant safety and effectiveness concerns.
- Proven antivirals – ivermectin and hydroxychloroquine – remain the safe and effective prevention and treatment.

1. Paxlovid (Pfizer) information from EUA filing:[1]

- Consists of two tablets of nirmatrelvir co-packaged with one tablet of ritonavir.
- Both are protease inhibitors that interfere with viral protein synthesis, but *only* the nirmatrelvir inhibits the COVID-19 virus. The ritonavir slows the breakdown of nirmatrelvir and allows it to remain in the body longer
- Two tablets of nirmatrelvir and one tablet of ritonavir are taken twice a day for 5 days for a total of 30 tablets.
- Authorized for adults and pediatric patients 12 and older weighing at least 88 pounds who have a positive COVID-19 test and are at "high risk" for progression of disease.
- Should be started as early as possible and within 5 days of diagnosis.
- Is not authorized for pre- or post-exposure prophylaxis.
- Clinical trial was *only* based on adults 18 years or older. No patients between 12 and 18 were included in the reported and referenced trial.
- "The safety and effectiveness of Paxlovid for the treatment of COVID-19 continue to be evaluated."

2. Molnupiravir (Merck) information from EUA filing[2]:

- 4 capsules are taken twice a day for 5 days for a total of 40 capsules.
- This drug inhibits viral replication **by causing significant mutations in the virus, which hopefully will be fatal to the virus**. Technically, this medicine is a nucleoside analogue.
- Molnupiravir was based on the "MOVe-OUT clinical trial" which showed "it is reasonable to believe that Molnupiravir *may be* effective for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19".
- Not authorized for patients younger than 18.
- EUA filing warns that Molnupiravir may cause harm to a developing baby (teratogenesis). It is *not* recommended for use during pregnancy.
- Reliable means of birth control are recommended for women during the course of treatment and for 4 days after the final dose.
- Men who are sexually active with women of childbearing potential are advised to use birth control during Molnupiravir therapy **and for at least 3 months afterwards**. Merck does not explain the different warning for men vs. women, but states that patients should discuss the adverse effect on sperm cells with their healthcare professional.
- Not authorized for pre-or post-exposure prophylaxis.
- Evaluation was limited to only 29 days of clinical observation (including 5 days of treatment).
- **"Molnupiravir is not FDA-approved for any uses, including use as treatment for COVID-19."**

3. Additional Sources of Risk and Concern

- Molnupiravir was not successful in animal trials: "human lung mice" required 4x the equivalent recommended human dose for observable symptomatic improvement.[3]
- There is the risk of Molnupiravir "supercharging" viral mutations, which poses risk to humans.[4]
- One study showed Molnupiravir may also cause mutation in mammalian cells.[5]
- Some researchers have questioned possibility of Molnupiravir to cause cancer in the host[6]
- Paxlovid may interact with many common heart medications.[7]
- Paxlovid in patients with undiagnosed HIV-1 infection may lead to HIV-1 drug resistance.

4. Safe and Effective Alternatives[8,9,10]

- 35 Early Treatment studies have shown 64% effectiveness of hydroxychloroquine.
- 32 Randomized Clinical Trials have shown 63% improvement in early use of ivermectin.
- Doctors report 80-90% effectiveness using hydroxychloroquine and ivermectin as part of sequenced multi-drug regimens for early home-based treatment of COVID-19 illness, reducing hospitalizations and deaths.

www.truthforhealth.org/fact-sheets

Summary: Truth for Health Foundation Expert Consensus Position

The Medical Advisory Council Consensus is that for these three reasons:

1) there is limited evidence of significant benefits on the COVID-19 illness progression
2) there is evidence of potential serious risks for teratogenesis and mutagenesis with the new anti-virals
3) there is potential for serious drug interactions with other commonly prescribed medications patients may be taking for other conditions

We cannot ethically recommend use of these *emergency use authorization (EUA) products* at this time. It is our position that longer term safety studies are needed to fully assess these risks. It is our position that there are safer, more effective antiviral medications already in widespread use globally that do not have a track record of the above risks and concerns.

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1 Paxlovid EUA press release: https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-fda-authorizes-first-oral-antiviral-treatment-COVID-19

2 Molnuparivir EUA press release: https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-fda-authorizes-additional-oral-antiviral-treatment-COVID-19-certain

3 Sheehan, T. P. et al. An orally bioavailable broad-spectrum antiviral inhibits SARS-CoV-2 in human airway epithelial cell cultures and multiple coronaviruses in mice. Science Translational Medicine 12, eabb5883 (2020) https://pubmed.ncbi.nlm.nih.gov/32253226/

4 Haseltine, W.A., "Supercharging New Viral Variants: The Dangers Of Molnupiravir (Part 1)" https://www.forbes.com/sites/williamhaseltine/2021/11/01/supercharging-new-viral-variants-the-dangers-of-molnupiravir-part-1/?sh=131136216b15

5 Zhou, S., et.al., "β-D-N4-hydroxycytidine Inhibits SARS-CoV-2 Through Lethal Mutagenesis But Is Also Mutagenic To Mammalian Cells" https://academic.oup.com/jid/article/224/3/415/6272009

6 Haseltine, W.A., "Harming Those Who Receive It: The Dangers Of Molnupiravir (Part 2)" https://www.forbes.com/sites/williamhaseltine/2021/11/02/harming-those-who-receive-it-the-dangers-of-molnupiravir-part-2/?sh=6960e7dc1490

7 Pearson, A., "Caution: Paxlovid Interacts With Many Heart Meds" https://www.medpagetoday.com/opinion/skeptical-cardiologist/96692?xid=nl_mpt_DHE_2022-01-18&eun=g875816d0r&utm_source=Sailthru&utm_medium=email&utm_campaign=Daily%20Headlines%20Top%20Cat%20HeC%20%202022-01-18&utm_term=NL_Daily_DHE_dual-gmail-definition

8 "COVID-19 early treatment: real-time analysis of 1,484 studies" https://c19early.com/

9 McCullough, P, et.al., "Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19)" https://www.imrpress.com/journal/RCM/21/4/10.31083/j.rcm.2020.04.264/htm

10 FLCCC "Prevention and Treatment Protocols for COVID-19" https://COVID19criticalcare.com/COVID-19-protocols/