Pfizer Announces Paxlovid is Not Effective at Preventing Covid-19 Infection Through a Household Contact — AFTER Biden Purchases 20 Million Doses

Description

Pfizer announced Friday that a recent trial study revealed its antiviral pill Paxlovid was not effective at preventing Covid-19 infection in adults who had been exposed to the virus through household contact.

Pfizer's Paxlovid became the first US authorized home COVID-19 treatment. The U.S. Food and Drug Administration issued an emergency use authorization for Pfizer's antiviral pill to treat mild-to-moderate COVID-19 infections in December.

According to the press release, Paxlovid significantly reduced the proportion of people with COVID-19-related hospitalization or death from any cause by 88%.

Biden administration announced this week to double the number of locations that carry Paxlovid. They secured funding to purchase 20 million treatment courses of the antiviral pill, per CNN.

White House Covid-19 Response Coordinator Dr. Ashish Jha tweeted about Biden's plan to make the pill available.

"Paxlovid is extraordinarily effective at preventing bad outcomes. We're getting it out to the American people," Jha tweeted.

As the Gateway Pundit previously reported, more and more reports of patients taking Pfizer's antiviral pill experienced a second round of Covid-19 shortly after recovering. Experts are still investigating the causes and they are baffled.

Scientific documentation about post-Paxlovid relapse has been available since last fall. Pfizer's application to the FDA for emergency use authorization of Paxlovid stated that in the placebo-controlled clinical trial — which included 2,246 participants — "several subjects appeared to have a rebound in SARS-CoV-2 RNA levels around Day 10 or Day 14" after beginning treatment, NBC reported.

Following this report, Pfizer released a statement admitting that it failed to reduce the risk of confirmed and symptomatic COVID-19 infection in adults living with someone who had been exposed to the virus.

“We designed the clinical development program for PAXLOVID to be comprehensive and ambitious with the aim of being able to help combat COVID-19 in a very broad population of patients,” said Albert Bourla, Chairman and Chief Executive Officer, Pfizer.

“While we are disappointed in the outcome of this particular study, these results do not impact the strong efficacy and safety data we’ve observed in our earlier trial for the treatment of COVID-19 patients at high risk of developing severe illness, and we are pleased to see the growing global use of PAXLOVID in that population,” Bourla added.

More from Pfizer’s news release:

> Pfizer Inc. (NYSE: PFE) today shared top-line results from the Phase 2/3 EPIC-PEP (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **P**ost-**E**xposure **P**rophylaxis) study evaluating PAXLOVID™ (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) for post-exposure prophylactic use. In this trial, compared to placebo, Pfizer observed risk reductions of 32% and 37% in adults who received PAXLOVID for five and ten days, respectively, to prevent infection. These results, however, were not statistically significant and, as such, the primary endpoint of reducing the risk of confirmed and symptomatic COVID-19 infection in adults who had been exposed to the virus through a household contact was not met.
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> Available safety data for PAXLOVID has been generally consistent in more than 3,500 PAXLOVID-treated participants across the EPIC-HR, EPIC-SR and EPIC-PEP studies, as well as in reported post-market safety experience. In EPIC-PEP, this safety profile remained generally consistent when PAXLOVID was used for either five or ten days. Analyses of all secondary endpoints and sub-groups are ongoing, and results will be included in the publication or presentation of the final study results.
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> **About the Phase 2/3 EPIC-PEP Study**
> The top-line analysis evaluated data from 2,957 adults. Enrolled adults had a negative SARS-CoV-2 rapid antigen test result and were asymptomatic household contacts with exposure within 96 hours to an individual who was symptomatic and recently tested positive for SARS-CoV-2. Each patient was randomized (1:1:1) to receive orally twice daily one of the following: (i) PAXLOVID for five days followed by placebo for 5 days, (ii) PAXLOVID for ten days or (iii) placebo for ten days.
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> Recruitment began in September 2021 and was completed during the peak of the COVID-19 Omicron wave.
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> **Risk of Serious Adverse Reactions Due to Drug Interactions:** Initiation of PAXLOVID, a CYP3A inhibitor, in patients receiving medications metabolized by CYP3A or initiation of medications metabolized by CYP3A in patients already receiving PAXLOVID, may increase

plasma concentrations of medications metabolized by CYP3A. Initiation of medications that inhibit or induce CYP3A may increase or decrease concentrations of PAXLOVID, respectively. These interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications
- Clinically significant adverse reactions from greater exposures of PAXLOVID
- Loss of therapeutic effect of PAXLOVID and possible development of viral resistance

Consult Table 1 of the Fact Sheet for Healthcare Providers for clinically significant drug interactions, including contraindicated drugs. Consider the potential for drug interactions prior to and during PAXLOVID therapy; review concomitant medications during PAXLOVID therapy and monitor for the adverse reactions associated with the concomitant medications.

Hypersensitivity reactions have been reported with PAXLOVID including urticaria, angioedema, dyspnea, mild skin eruptions, and pruritus. Cases of anaphylaxis, TEN, and Stevens-Johnson syndrome have also been reported with components of PAXLOVID (refer to NORVIR labeling). If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue PAXLOVID and initiate appropriate medications and/or supportive care.

Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir. Therefore, caution should be exercised when administering PAXLOVID to patients with **pre-existing liver diseases, liver enzyme abnormalities, or hepatitis**.

Because nirmatrelvir is co-administered with ritonavir, there may be a **risk of HIV-1 developing resistance to HIV protease inhibitors** in individuals with uncontrolled or undiagnosed HIV-1 infection.

Adverse events in the PAXLOVID group (?1%) that occurred at a greater frequency (?5 subject difference) than in the placebo group were dysgeusia (6% and <1%, respectively), diarrhea (3% and 2%), hypertension (1% and <1%), and myalgia (1% and <1%). The proportions of subjects who discontinued treatment due to an adverse event were 2% in the PAXLOVID group and 4% in the placebo group.

The following adverse reactions have been identified during post-authorization use of PAXLOVID. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Read more here.

By Jim Hoft

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