FDA advisers back full approval of Paxlovid

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Paxlovid, a medication that has helped millions of high-risk COVID-19 patients avoid hospitalization and death since late 2021, moved one step closer to getting full approval from the U.S. Food and Drug

Administration on Thursday.

An FDA advisory panel voted 16-1 that the Pfizer drug remains a safe and effective treatment and should be given full approval. It has only received emergency use authorization until now, but the FDA is expected to make a final decision on full approval by May, the Associated Press reported. The vote was not a surprise, given that Paxlovid continues to be a well-used treatment while other drugs no longer work against a mutated virus.

While data for healthy adults show the drug makes no meaningful difference, it shows significant benefits for high-risk adults. Paxlovid reduces the chance of hospitalization and death by about 60 to 85 percent for seniors and adults who have health issues that include obesity, diabetes, lung disease, and immune system disorders, the AP reported.

Paxlovid could prevent 1,500 deaths and 13,000 hospitalizations each week, according to the FDA. The United States still sees about 4,000 COVID-19 deaths and 35,000 hospitalizations weekly, according to the AP.

One issue the panel addressed is whether Paxlovid increases the chances of COVID rebound. The panel agreed there was not a clear link, the AP reported. About 10 to 16 percent of patients in multiple Pfizer studies had symptoms return, but that was true even if they received a placebo. These cases "likely reflect natural COVID-19 progression," the FDA concluded. About 95 percent of Americans have protection against COVID-19 from at least one vaccine dose and/or prior infection.

The panelists said prescribing Paxlovid will remain a case-by-case decision, the AP reported.

More information: *Associated Press* Article

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