Monoclonal Antibody Combo Authorized for COVID-19 PrEP

FDA authorizes Evusheld for immunocompromised people who may not respond well to COVID-19 vaccines.

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On December 8, the Food and Drug Administration granted emergency use authorization (EUA) of AstraZeneca's monoclonal antibody combination Evusheld (tixagevimab plus cilgavimab) for COVID-19 pre-exposure prophylaxis (PrEP) for immunocompromised people, who make up around 3% of the U.S. population.

"Vaccines have proven to be the best defense available against COVID-19. However, there are certain immune-compromised individuals who may not mount an adequate immune response to COVID-19 vaccination, or those who have a history of severe adverse reactions to a COVID-19 vaccine, and therefore cannot receive one and need an alternative prevention option," Patrizia Cavazzoni, MD, director of the FDA's Center for Drug Evaluation and Research, said in a statement.

Monoclonal antibodies are manufactured proteins that mimic the immune system's ability to fight SARS-CoV-2, the coronavirus that causes COVID-19. Tixagevimab and cilgavimab are long-acting antibodies that target two different sites on the SARS-CoV-2 spike protein, which the virus uses to enter human cells.

The concept of PrEP is best known in the HIV field, where it has transformed the prevention landscape. But PrEP for COVID-19 has a substantially narrower scope.

Evusheld (formerly known as AZD7442) is indicated for adults and adolescents with moderately to severely compromised immune systems due to medical conditions or immune-suppressing medications who may not respond adequately to COVID-19 vaccines, as well as for those with prior severe adverse reactions to the vaccines or their components.

People who may not respond to vaccination—even after a booster—include organ transplant recipients who take immunosuppressive drugs to prevent rejection, people with advanced or untreated HIV and people taking certain types of cancer treatment.

This EUA does not cover people currently infected with SARS-CoV-2 or those who have recently been exposed to someone with the virus. Other monoclonal antibody combinations are already

authorized for the early treatment of people with mild to moderate COVID-19 who are at risk for disease progression. The FDA has also authorized Eli Lilly's bamlanivimab plus etesevimab and Regeneron's REGEN-COV (casirivimab plus imdevimab) for post-exposure prophylaxis (PEP) to prevent COVID-19 in high-risk people who have been in close contact with someone known to have SARS-CoV-2.

The Phase III PROVENT trial, which enrolled more than 5,000 seniors and people with other risk factors for severe COVID-19, showed that a single dose of Evusheld, administered as two intramuscular injections, reduced the risk of symptomatic COVID-19 by 83% compared with a placebo. The antibody combination may be effective as COVID-19 PrEP for six months. However, it is not yet clear how well the antibodies will work against the new SARS-CoV-2 Omicron variant.

Evusheld is generally safe and well tolerated. Adverse effects may include hypersensitivity reactions, bleeding at the injection site, headache, fatigue and cough. Serious cardiac adverse events were infrequent in the PROVENT trial, but occurred more often in the Evusheld group compared with the placebo group. Everyone who experienced such events had risk factors for or a prior history of cardiac disease, and it is not clear whether Evusheld caused them.

Oral antivirals in the pipeline could make COVID-19 pre-exposure and post-exposure prevention simpler and less expensive. Merck's molnupiravir was recently shown to cut the risk of hospitalization by 30% when taken within five days after developing symptoms, while Pfizer's Paxlovid reduced the risk of hospitalization or death by 89% when taken within three days of symptom onset. Antivirals are now being studied for PEP and PrEP.

While oral COVID-19 medications would be easier to use than monoclonal antibodies, experts do not expect that they will be used the same way as HIV PrEP pills, which are indicated for most people at substantial risk for acquiring HIV. Despite decades of research, there is still no vaccine for HIV prevention.

For COVID-19, in contrast, vaccines are the best way to cut the risk of serious illness and death and reduce the likelihood of infection and transmission. But for immunocompromised people who are not adequately protected by the vaccines, PrEP could be a game-changer.

Click here for more news about COVID-19 vaccines and treatment.
Click here for the FDA's Evusheld EUA fact sheet.

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