

Positive results for Lilly and Regeneron COVID antibodies

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SARS-CoV-2 (shown here in an electron microscopy image). Credit: National Institute of Allergy and Infectious Diseases, NIH

US pharmaceutical company Eli Lilly's combination of two synthetic antibodies against COVID-19 reduced hospitalizations and deaths by 70

percent in high-risk patients with recent positive tests, the company said Tuesday.

The results were called "very encouraging" by Stephen Evans, a professor of pharmacoepidemiology at the London School of Hygiene & Tropical Medicine.

"They are the first anti-viral drugs that demonstrably work in the first phase of the disease just after the virus has infected someone but before it has had time to cause a lot of damage," he said.

The phase 3 trial involving 1,035 people achieved its main goal, and the study also met its secondary goals of reducing patients' viral load and their time to recover from the disease.

Patients were assigned either a placebo or the combination of bamlanivimab and etesevimab, the two antibodies, at 2.8 grams each.

There were 11 hospitalizations in the patients who received the therapy, or 2.1 percent of that group.

In the placebo arm, there were 36 deaths or hospitalizations, or 7.0 percent of the group.

The therapy thus represented a risk reduction of 70 percent, and the result was statistically significant, meaning it was unlikely to have occurred by chance.

There were 10 deaths total, all of which occurred in patients taking placebo, and none in the therapy group.

"Bamlanivimab and etesevimab together have the potential to be an important treatment that significantly reduces hospitalizations and death

in high-risk COVID-19 patients," Lilly's chief scientific officer Daniel Skovronsky said.

The company said it would continue to study the drug in another trial to examine whether lower doses would yield the same impact.

A peer-reviewed scientific paper is still awaited.

'Passive vaccination'

In another development, US biotech firm Regeneron announced positive interim results from its phase 3 study of REGEN-COV, a combination of two antibodies, for use as a passive vaccine.

An exploratory analysis looked at data from approximately 400 patients, roughly half given the 1.2 grams of the drug by a subcutaneous injection, the other half given a placebo.

Out of 223 given the placebo, eight went on to get symptomatic COVID-19, while none of the 186 given REGEN-COV did—in other words a 100 percent reduction in symptomatic infections.

It also reduced the overall rate of infection, whether with symptoms or without, by 50 percent.

Finally, the drug markedly decreased the levels of the virus among people who received the drug and became asymptotically infected versus those in the placebo group.

"These data using REGEN-COV as a passive vaccine suggest that it may both reduce transmission of the virus as well as reduce viral and disease burden in those who still get infected," said George Yancopoulos, Regeneron's president and chief scientific officer.

The final results of the study are expected in the second quarter.

Slow uptake

Monoclonal antibodies are lab-made versions of the body's natural infection-fighting defenses.

Our bodies develop these proteins in response to pathogens, and vaccines train the immune systems to be prepared without encountering the live microbe itself.

Giving people ready-made antibodies can help those who are at high risk of severe disease because of weak immunity or underlying conditions.

Many scientists have welcomed their COVID fighting potential, and both Lilly and Regeneron have received US emergency use authorizations for their therapies.

But their uptake has been limited by several factors, from a lack of patient interest to not enough staffing and specific places inside hospitals to administer them.

It can also be challenging to identify suitable candidates who are at high risk but haven't yet progressed to severe COVID, because by that stage targeting the virus has less impact than using drugs to reduce the body's overactive immune response.

In its press release, Lilly acknowledged some of these difficulties.

"Lilly has received feedback from front-line nurses and doctors administering these infusions regarding the complexity and time requirements for preparation and administration," the statement said.

As a result, the company is working with the Food and Drug Administration to potentially reduce the infusion time from the current 60 minutes to as little as 16 minutes.

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