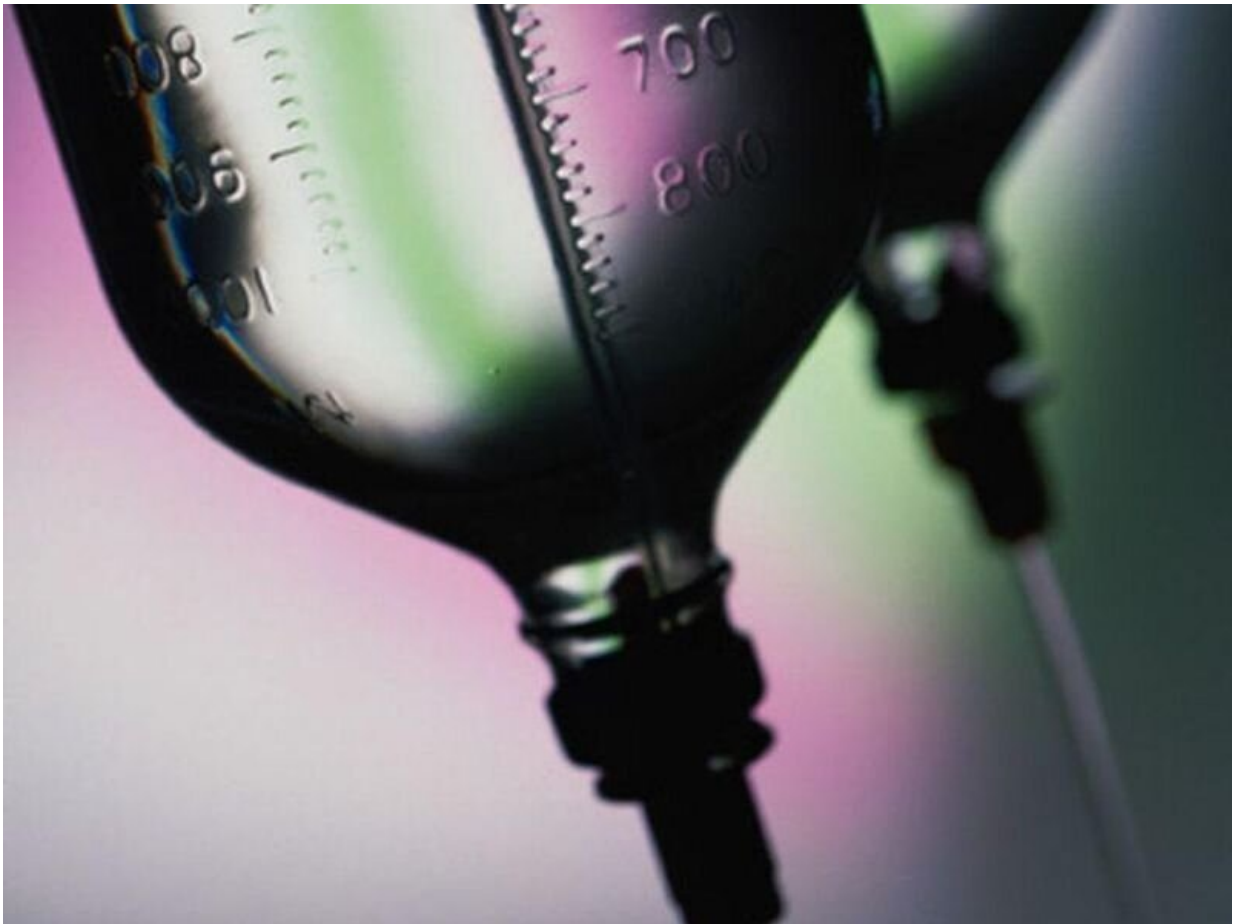


FDA approves third COVID-19 antibody treatment for emergency use

May 27 2021, by Ernie Mundell and Robin Foster Healthday Reporters



(HealthDay)—A third antibody treatment designed to keep high-risk

COVID-19 patients from winding up in the hospital was approved for emergency use by the U.S. Food and Drug Administration on Wednesday.

Importantly, in lab tests the newly authorized drug, dubbed sotrovimab, neutralized the highly infectious virus variant that is crippling India, as well as variants first spotted in Britain, South Africa, Brazil, California and New York.

"With the authorization of this monoclonal antibody treatment, we are providing another option to help keep high-risk patients with COVID-19 out of the hospital," Dr. Patrizia Cavazzoni, director of the FDA's Center for Drug Evaluation and Research, said in an agency news release. "It is important to expand the arsenal of monoclonal antibody therapies that are expected to retain activity against the circulating variants of COVID-19 in the United States."

Developed by GlaxoSmithKline (GSK), in concert with the American company Vir Biotechnology Inc., the drug should become available to Americans "in the coming weeks," company officials said in a statement.

"Sotrovimab is a critical new treatment option in the fight against the current pandemic and potentially for future coronavirus outbreaks as well," said George Scangos, Vir's chief executive.

Recently, the [federal government](#) paused shipments of Eli Lilly's antibody cocktail to eight states because of the high prevalence there of the variants first seen in South Africa and Brazil, *The New York Times* reported. Lab experiments have suggested that those variants can resist Lilly's treatment. (Regeneron's antibody cocktail appears to neutralize the variants, based on lab tests.)

GSK and Vir's treatment is a single drug, designed to mimic the

antibodies generated when the immune system fights off the coronavirus. Its emergency use authorization was based on a study of 583 volunteers who had started experiencing symptoms within the previous five days. The study found that those who got the GSK-Vir treatment showed an 85 percent reduction in their risk of hospitalization or death, compared with those who got a placebo.

Even as vaccination numbers rise and infection rates fall in the United States, the antibody treatments are likely to remain an important tool for preventing bad outcomes in high-risk patients, the *Times* said.

Last week, the FDA broadened the criteria that doctors can use to determine eligibility for antibody treatments, the *Times* reported. That opens the door for more [young people](#) with certain medical conditions and members of high-risk racial or ethnic groups to get the treatments.

"Ultimately, it gives prescribers a lot of latitude in what they can give this for," Dr. Walid F. Gellad, who directs the Center for Pharmaceutical Policy and Prescribing at the University of Pittsburgh, told the *Times*.

But the antibody cocktails from Lilly and Regeneron have not been used as widely as expected for a range of reasons, public health experts say.

They are cumbersome to administer because they require intravenous infusion, and patients often don't know to ask for them or where to find them. And many doctors were initially skeptical of the evidence supporting the treatments, though more clinical trials have since reported impressive results, the *Times* reported.

"There's still a role for these," Gellad said. "The problem is just people aren't getting them who could benefit from them, and having another one on the market doesn't necessarily solve that."

Fully vaccinated in U.S. Hits 50%

Half of America's adults are now fully vaccinated against the new coronavirus, U.S. officials announced Tuesday.

"This is a major milestone in our country's vaccination efforts," White House senior COVID-19 adviser Andy Slavitt said during a White House media briefing, noting that only 1% of Americans were vaccinated when President Joe Biden entered office in January.

Slavitt urged Americans who are still hesitant about vaccination to get their shots.

"Find whatever reason you want to get vaccinated. For those not sure yet, do your homework, talk to your doctor or your pharmacist. All concerns are reasonable, but do yourself a favor: Don't let some guy on Facebook answer your question when good answers are available," Slavitt said.

Biden has said there will be enough vaccines for every adult American by the end of this month, and all people aged 12 and up are now eligible to receive a shot. At least 25 states, plus Washington, D.C., have now fully vaccinated at least half of their adult residents, *CNN* reported.

At least 70% to 85% of the U.S. population will need to have immunity to COVID-19 to reach the threshold of protection needed to limit the virus' spread, health experts have said. Vaccinating children, teens and young adults could help officials reach that percentage, while leaving the young unvaccinated could give the virus a chance to spread, mutate and develop a strain resistant to existing vaccines, *CNN* reported.

Vaccinating children and adolescents will also help schools reopen more safely in the fall.

As the promising vaccination numbers were released, CDC Director Dr.

Rochelle Walensky offered a mix of hope and caution as Americans prepare to celebrate Memorial Day weekend, the traditional beginning of summer with friends and family.

"If you are vaccinated, you are protected, and you can enjoy your Memorial Day," Walensky said during the White House media briefing. "If you are not vaccinated, our guidance has not changed for you, you remain at risk of infection. You still need to mask and take other precautions."

The holiday arrives amid a national decline in coronavirus cases, hospitalizations and deaths. All across the country, mask mandates are easing, restrictions are lifting and many states have gone back to business as usual, the *Times* reported.

After countless Memorial Day events were scuttled last year because of the pandemic, vaccinated Americans may be looking forward to crowded beaches and packed backyard barbecues, Walensky acknowledged.

But she also urged those who remain unvaccinated to add a new activity to their Memorial Day rituals. "I want to encourage you to take this holiday weekend to give yourself and your family the gift of protection by getting vaccinated," she said. "We are on a good downward path, but we are not quite out of the woods yet."

Tough travel warnings for Japan

U.S. officials on Monday warned all Americans not to visit Japan because of a spike in coronavirus cases there just two months before the Tokyo Olympics are set to start.

The travel advisories, one issued by the U.S. Centers for Disease Control

and Prevention and one that came from the U.S. State Department, don't ban Americans from visiting Japan, but they could trigger higher travel insurance rates and may discourage some Olympic athletes and spectators from competing in or attending the games, the *Associated Press* reported.

"Travelers should avoid all travel to Japan," the CDC said in its alert. "Because of the current situation in Japan, even fully vaccinated travelers may be at risk for getting and spreading COVID-19 variants and should avoid all travel to Japan."

The State Department's warning was even more blunt.

"Do not travel to Japan due to COVID-19," it said in its announcement, which raised the department's travel alert from Level 3 (reconsider travel) to Level 4 (do not travel).

However, the U.S. Olympic & Paralympic Committee said it still anticipates that American athletes will be able to safely compete at the Tokyo Games.

"We feel confident that the current mitigation practices in place for athletes and staff... coupled with the testing before travel, on arrival in Japan, and during Games time, will allow for safe participation of Team U.S. athletes this summer," the committee said in a statement to *Reuters* on Monday.

Japanese Prime Minister Yoshihide Suga says he is determined to hold the Olympics in Tokyo beginning on July 23, after a one-year delay, and has made an ambitious pledge to finish vaccinating the country's 36 million older people by the end of July. There is fear of new variants spreading because such a tiny percentage of the Japanese population—estimated at 2% to 4%—is vaccinated, the *AP* said.

In the United States, the vaccination picture is improving by the day. As of Thursday, nearly 132 million Americans were fully vaccinated and 62% of adults had received at least one dose, according to the CDC. The U.S. Food and Drug Administration also recently approved the Pfizer vaccine for adolescents ages 12 to 15.

As of Thursday, the U.S. coronavirus case count neared 33.2 million, while the death toll neared 592,000, according to a tally from Johns Hopkins University. Worldwide, more than 168.4 million cases had been reported by Thursday, with nearly 3.5 million people dead from COVID-19.

More information: The U.S. Centers for Disease Control and Prevention has more on the [new coronavirus](#).

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