FDA: Spring will bring more supplies of effective COVID-19 therapies

FEB 16, 2022

Jennifer Lubell
Contributing News Writer

Monoclonal antibodies and antivirals have strengthened the COVID-19 response arsenal, but some are in short supply and not all are equipped to deal with the fast-spreading Omicron variant.

Efforts to boost production of therapeutics are underway, a Food and Drug Administration (FDA) official said during an episode of the AMA-sponsored webinar series, “COVID-19: What Physicians Need to Know.”

COVID-19 has killed nearly 900,000 people in the U.S. and 5 million worldwide. Recommended usage in therapeutics is an important step in counseling patients and providing the most timely and relevant information about defeating this virus, said AMA President Gerald E. Harmon, MD, who moderated the webinar. Physicians facing supply issues of hard-to-get antivirals such as Paxlovid (PDF) also want to know about the timeline of any new antivirals or antibody treatments, he said.

For doctors and other health professionals, “it’s been a very difficult winter and it’s not over yet,” acknowledged John Farley, MD, MPH, director of FDA’s Office of Infectious Diseases in the Center for Drug Evaluation and Research’s Office of New Drugs. Monitoring the situation with these drugs is a complex process that involves FDA, the Centers for Disease Control and Prevention and several branches of government, he added.

Distribution of therapeutics should improve over time. However, at least for the combination of antiviral nirmatrelvir and ritonavir tablets marketed as Paxlovid, “we have a period of continued short supply ahead,” said Dr. Farley, who joined two other FDA experts to discuss the efficacy of the treatments.
Update on monoclonal antibodies

Omicron accounts for 99% of all new COVID-19 cases in the United States, said Dr. Farley. Changes to the spike protein are a key characteristic of any SARS-CoV-2 variant. This has implications for the monoclonal antibody therapies because they need to bind to the spike protein of the virus to neutralize it, he said.

Two of the three existing monoclonal antibody therapies are ineffective against Omicron. New virology data suggest that REGEN-COV (casirivimab or imdevimab) and bamlanivimab and etesevimab administered together are not likely to be active against variants from the Omicron lineage, said Dr. Farley.

This is unfortunate, considering that many physicians use these therapies against COVID-19, he added.

Sotrovimab, authorized by the FDA to treat mild to moderate COVID-19, does exhibit some effectiveness against Omicron, although this therapy is in limited supply.

“We’re working hard to improve the supply of sotrovimab and I think that will improve over time,” said Dr. Farley.

Remdesivir as outpatient drug

Remdesivir (marketed as Veklury) is another important tool in the COVID-19 armamentarium, noted Dr. Farley. Many physicians are familiar with it and the drug performed well in several studies to reduce hospitalization or death. Until now, hospitals have been the main recipient of this drug. However, its manufacturer Gilead is working to expand its distribution plan and bring it to more outpatient facilities, he said.

Antivirals retain activity against Omicron

Dr. Farley also anticipates that Paxlovid will ramp up production this spring.

“The U.S. government and the company [Pfizer] are working as hard as they can to improve the supply of that product,” which is authorized by the FDA to treat mild-to-moderate COVID-19 in
patients 12 or older who weigh at least 40 kilograms and are at high risk of progressing to severe COVID-19.

In a clinical trial, the medication cut hospitalization and death by 88% when administered within five days of symptom onset.

Biochemical and cell culture data show that Paxlovid retains activity against Omicron. However, “there are no clinical data yet available for Paxlovid in patients infected with Omicron,” said Stephanie Troy, MD, senior medical officer in the FDA’s antivirals division in the Office of New Drugs.

The drug is not recommended for people with severe renal impairment and has multiple drug interactions, Dr. Troy said. Physicians and other health professionals should inform patients of contraindications and get a complete medication list from patients. Based on any drug interactions, it may be appropriate to seek out other authorized treatments, she added.

Merck’s molnupiravir (PDF) is another oral antiviral that appears to retain its activity against Omicron, said Aimee Hodowanec, MD, another senior medical officer in the FDA’s antivirals division. In a clinical trial, it reduced hospitalization and death by 33% compared to placebo and has no drug interactions based on limited data. However, it’s only intended for adults and could affect bone and cartilage growth.

Molnupiravir is not recommended for pregnant women. If a health professional determines that benefits outweigh risks, they should counsel the patient and direct them to Merck’s pregnancy surveillance program, Dr. Hodowanec said.

Visit the AMA COVID-19 resource center for clinical information, guides and resources, and updates on advocacy and medical ethics.

Also stay up to date with the National Institute of Health’s COVID-19 treatment guidelines.