FDA News Release

FDA approves new drug to treat influenza

For Immediate Release

October 24, 2018

Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm624290.htm)

Today, the U.S. Food and Drug Administration approved Xofluza (baloxavir marboxil) for the treatment of acute uncomplicated influenza (flu) in patients 12 years of age and older who have been symptomatic for no more than 48 hours.

“This is the first new antiviral flu treatment with a novel mechanism of action approved by the FDA in nearly 20 years. With thousands of people getting the flu every year, and many people becoming seriously ill, having safe and effective treatment alternatives is critical. This novel drug provides an important, additional treatment option,” said FDA Commissioner Scott Gottlieb, M.D. “While there are several FDA-approved antiviral drugs to treat flu, they’re not a substitute for yearly vaccination. Flu season is already well underway, and the U.S. Centers for Disease Control and Prevention recommends getting vaccinated by the end of October, as seasonal flu vaccine is one of the most effective and safest ways to protect yourself, your family and your community from the flu and serious flu-related complications, which can result in hospitalizations. Yearly vaccination is the primary means of preventing and controlling flu outbreaks.”

Flu is a contagious respiratory illness caused by **influenza viruses (/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm)**. When patients with the flu are treated within 48 hours of becoming sick, antiviral drugs can reduce symptoms and duration of the illness.

“When treatment is started within 48 hours of becoming sick with flu symptoms, antiviral drugs can lessen symptoms and shorten the time patients feel sick,” said Debra Birnkrant, M.D., director of the Division of Antiviral Products in the FDA’s Center for Drug Evaluation and Research. “Having more treatment options that work in different ways to attack the virus is important because flu viruses can become resistant to antiviral drugs.”

The safety and efficacy of Xofluza, an antiviral drug taken as a single oral dose, was demonstrated in two randomized controlled clinical trials of 1,832 patients where participants were assigned to receive either Xofluza, a placebo, or another antiviral flu treatment within 48 hours of experiencing flu symptoms. In both trials, patients treated with Xofluza had a shorter time to alleviation of symptoms compared with patients who took the placebo. In the second trial, there was no difference in the time to alleviation of symptoms between subjects who received Xofluza and those who received the other flu treatment.

The most common adverse reactions in patients taking Xofluza included diarrhea and bronchitis.

Xofluza was granted **Priority Review (/ForPatients/Approvals/Fast/ucm405405.htm)** under which the FDA's goal is to take action on an application within an expedited time frame where the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

The FDA granted approval of Xofluza to Shionogi & Co., Ltd.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA - Influenza (Flu) Antiviral Drugs and Related Information (/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm)**
- **CDC – About Flu (https://www.cdc.gov/flu/about/index.html)**

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