Xofluza approved for postexposure prevention of flu

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(HealthDay)—The approved indication for Xofluza (baloxavir marboxil)

has been expanded to include postexposure prevention of influenza for those who may have come in contact with someone who has the flu, the U.S. Food and Drug Administration announced Monday.

Xofluza was approved in 2018 to treat uncomplicated flu in patients 12 years and older who are symptomatic for no more than two days. The drug was previously only available in a tablet form but is now available in granule form for mixing in water.

The expanded approval decision was based on data from the Phase III BLOCKSTONE study, a randomized, double-blind, controlled trial of 607 individuals ages 12 years and older who were exposed to a household member with the flu. Individuals were randomly assigned to receive either a single dose of Xofluza (303 individuals) or placebo (304 individuals). One percent of those who received Xofluza compared with 13 percent who received placebo were infected with influenza and presented with fever and at least one respiratory symptom over 10 days. These data were published in the *New England Journal of Medicine* in July.

The most commonly reported side effects of Xofluza include diarrhea, bronchitis, nausea, sinusitis, and headache.

"This expanded indication for Xofluza will provide an important option to help prevent influenza just in time for a flu season that is anticipated to be unlike any other because it will coincide with the coronavirus pandemic," Debra Birnkrant, M.D., director of the Division of Antiviral Products in the FDA Center for Drug Evaluation and Research, said in an agency news release. "Americans will have to be more vigilant than ever as these viruses spread concurrently."

Approval was granted to Genentech U.S. Inc.

More information: More Information