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FDA NEWS RELEASE

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FDA approves first anti-diarrheal drug for HIV/AIDS patients
Fulyzaq is the second botanical drug approved by the agency

The U.S. Food and Drug Administration today approved Fulyzaq (crofelemer) to relieve symptoms of diarrhea in HIV/AIDS patients taking antiretroviral therapy, a combination of medicines used to treat HIV infection.

Diarrhea is experienced by many HIV/AIDS patients and is a common reason why patients discontinue or switch their antiretroviral therapies. Fulyzaq is intended to be used in HIV/AIDS patients whose diarrhea is not caused by an infection from a virus, bacteria, or parasite. Patients take Fulyzaq two times a day to manage watery diarrhea due to the secretion of electrolytes and water in the gastrointestinal tract.

Derived from the red sap of the Croton lechleri plant, Fulyzaq is the second botanical prescription drug approved by FDA. A botanical drug product is often a complex mixture derived from one or more plant materials with varying degrees of purification. In 2006, the FDA approved the first botanical prescription drug, Veregen (sinecatechins), a treatment for external genital and perianal warts.

"Currently, there are no FDA-approved therapies for HIV-associated diarrhea," said Julie Beitz, M.D., director of the Office of Drug Evaluation III in FDA's Center for Drug Evaluation and Research. "Fulyzaq may be helpful to HIV/AIDS patients with this troublesome condition."

Just as for other types of drugs, the safety and efficacy of a botanical drug product are established through clinical trials. In addition, manufacturers of a botanical drug product must ensure rigorous control of raw materials, and good agricultural and collection practices, together with analytical testing of the complex mixture.

The safety and efficacy of Fulyzaq were established in a clinical trial of 374 HIV-positive patients on stable antiretroviral therapy with a history of diarrhea lasting one month or longer. The median number of daily watery bowel movements was 2.5 per day. Patients who had diarrhea caused by an infection or a gastrointestinal disease were excluded from participating in the trials. Patients were randomly assigned to take Fulyzaq or a placebo twice daily.

The trial was designed to measure clinical response, defined as the number of patients who had two or fewer watery bowel movements weekly. Results showed that 17.6 percent of patients taking Fulyzaq experienced clinical response compared with 8 percent taking placebo. In some patients, a persistent anti-diarrheal effect was seen for 20 weeks.
Before treating patients with Fulyzaq, health care professionals should conduct proper testing to confirm the diarrhea is not caused by an infection or a gastrointestinal disease. Common side effects reported in patients taking Fulyzaq in the clinical trial were upper respiratory tract infection, bronchitis, cough, flatulence, and increased levels of the liver enzyme bilirubin.

Fulyzaq is distributed by Salix Pharmaceuticals, based in Raleigh, N.C. under license from Napo Pharmaceuticals, Inc.

Veregen is marketed by Florham Park, N.J.-based PharmaDerm.

For more information:

- FDA Approved Drugs: Questions and Answers[1]
- FDA: Drug Innovation[2]
- FDA: HIV and AIDS Activities[3]

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