FDA Approves First Drug to Treat Diarrhea in People With HIV

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The U.S. Food and Drug Administration (FDA) has approved Fulyzaq (crofelemer), the first drug to relieve symptoms of diarrhea that is a side effect of HIV antiretrovirals (ARVs). Intended for use among people with HIV who are taking ARVs and whose diarrhea is not caused by a virus, bacteria or parasite, the drug treats watery diarrhea that is a consequence of electrolyte secretion and water in the gastrointestinal tract.

The new drug is distributed by Salix Pharmaceuticals in Raleigh, North Carolina, according to an FDA statement. It is derived from the sap of the Croton lechleri plant, commonly known as the Peruvian dragon's blood tree.

The clinical trial that proved the safety and efficacy of Fulyzaq involved 374 HIV-positive participants who were all on stable ARV therapy and had a history of diarrhea lasting a month or longer, with a median of 2.5 watery bowel movements per day. Those whose diarrhea was caused by either an infection or a gastrointestinal disease were not admitted into the trials. With patients randomly assigned to take either Fulyzaq or a placebo two times a day, 17.6 percent of the treatment arm experienced two or fewer watery bowel movements each week while 8 percent of those on the placebo reached this clinical benchmark.

The most common side effects of Fulyzaq are upper respiratory tract infection, bronchitis, cough, flatulence and increased bilirubin levels.

For the FDA release, click here.

Editor's note: In October 2016, Napo Pharmaceuticals announced the launch of the new brand Mytesi.

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