FDA approves Linzess to treat constipation in children, teens

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The U.S. Food and Drug Administration approved Linzess (linaclotide)

as a once-daily treatment for pediatric patients ages 6 to 17 years with functional constipation.

The approval was based on data from 328 participants who were randomly assigned (1:1) to receive Linzess or placebo. A statistically significant benefit and clinically meaningful improvement was seen for 12-week spontaneous bowel movement frequency rate with Linzess compared with placebo, with Linzess-treated patients showing a greater than twofold least squares mean change from baseline in spontaneous bowel movements per week (2.6 versus 1.3). Diarrhea was the most common adverse event reported (4 percent of Linzess-treated patients versus 2 percent of placebo-treated patients).

"Pediatric functional constipation is an all-too-common issue that physicians see every day, yet despite the tremendous distress it causes to our patients and their families, we haven't had an FDA-approved prescription treatment to offer until now," Jeffrey S. Hyams, M.D., from the Connecticut Children's Medical Center and the University of Connecticut in Hartford, said in a statement. "The approval of Linzess for the treatment of functional constipation in pediatric patients ages 6 to 17 years old is a meaningful advancement for these young patients."

Expanded approval of Linzess was granted to Ironwood Pharmaceuticals.

More information: FDA Approval