New Drug Approvals

Generic Name (Trade Name—Company) | Uses/Notes
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March 1, 2017 | **FDA has approved** telotristat ethyl tablets in combination with somatostatin analog (SSA) therapy for treatment of adults with carcinoid syndrome diarrhea that SSA therapy alone has inadequately controlled.

Carcinoid syndrome is a cluster of symptoms sometimes seen in people with carcinoid tumors. These tumors are rare and often slow-growing. Most carcinoid tumors are found in the gastrointestinal tract. Carcinoid syndrome occurs in fewer than 10% of patients with carcinoid tumors, usually after the tumor has spread to the liver. The tumors in these patients release excess amounts of serotonin, resulting in diarrhea.

In a regimen with SSA therapy, telotristat ethyl is approved in tablet form to be taken orally three times daily with food. The agent inhibits the production of serotonin by carcinoid tumors and reduces the frequency of carcinoid syndrome diarrhea.

Its safety and efficacy were established in a 12-week, double-blind, placebo-controlled trial in 90 adult participants with well-differentiated metastatic neuroendocrine tumors and carcinoid syndrome diarrhea. These patients were having between 4 to 12 daily bowel movements despite use of SSA at a stable dose for at least 3 months. Participants remained on their SSA treatment and were randomized to add placebo or treatment with telotristat ethyl three times daily.

Those receiving telotristat ethyl added to their SSA treatment experienced a greater reduction in average bowel movement frequency than those on SSA and placebo. Specifically, 33% of participants randomized to add telotristat ethyl on to SSA experienced an average reduction of two bowel movements per day, compared with 4% of patients randomized to add placebo on to SSA.

The agent's most common adverse effects include nausea, headache, increased levels of the liver enzyme gamma-glutamyl transferase, depression, peripheral
edema, flatulence, decreased appetite, and fever. Telotristat ethyl may cause constipation, and the risk of developing constipation may be increased in patients whose bowel movement frequency is fewer than four bowel movements per day. In clinical trials, patients treated with a higher than recommended dosage developed severe constipation. One patient required hospitalization, and two other patients developed complications of either intestinal perforation or intestinal obstruction.

Patients should be monitored for severe constipation. If a patient experiences severe constipation or severe, persistent, or worsening abdominal pain, they should discontinue telotristat ethyl and contact their health care provider.

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