

FDA Approves New Medication for Treatment of Chronic Idiopathic Constipation

On January 19, 2017 the U.S. Food and Drug Administration approved a new medication for the treatment of Chronic Idiopathic Constipation (CIC) for adults: Trulance (plecanatide). The manufacturer, Synergy Pharmaceuticals claims the drug will be available towards the end of the first quarter in 2017. Currently there are only two other medications on the market that are approved for CIC: Linzess (linaclotide) and Amitiza (lubiprostone). With chronic constipation affecting nearly 42 million people and having no single medication that works for all patients, it is exciting to have another treatment option on the market for patients with CIC. In comparison to the current options for CIC, Trulance appears to have much lower incidence of diarrhea than Linzess, which is a common complaint of medications that treat CIC. This is a potential benefit to the use of Trulance over perhaps Linzess.

Trulance is a guanylate cyclase-C agonist that acts locally on the luminal surface of the intestinal epithelium. Its action as an agonist at this location results in increased concentration of intracellular and extracellular cyclic guanosine monophosphate (cGMP) which stimulates chloride and bicarbonate to be secreted into the intestinal lumen through the cystic fibrosis transmembrane conductance regulator (CFTR) ion channel. Trulance likely increases fluid secretion into the intestinal lumen and speeds up GI transit as seen in animal models. Trulance is administered orally once daily without regard to food. Two 12-week trials that were placebo-controlled and included 1,775 patients established the safety and efficacy of Trulance. These trials included patients who had constipation for 6 months or greater, including hard or lumpy stools for at least 25% of defecations and those who experienced abdominal pain or discomfort for at least 3 days per month for the last 3 months. It is reported that preliminary analysis of these trials indicated that Trulance met primary endpoints showing statistical significance for overall responders for both the 3 mg and 6 mg doses. The approval of Trulance gives patients suffering from CIC an additional treatment option with less burdensome adverse effects.

References:

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