

## Trulance™ (plecanatide) – New Drug Approval

- On January 19, 2017, [Synergy Pharmaceuticals announced the FDA approval of Trulance \(plecanatide\)](#) for the treatment of chronic idiopathic constipation (CIC) in adults.
- CIC is a complex, functional GI disorder defined by symptoms including fewer than three bowel movements a week and hard-to-pass or incomplete bowel movements, for which there is no identifiable cause. CIC affects approximately 33 million Americans and an estimated 14% of the global population.
- Trulance is a guanylate cyclase-C (GC-C) agonist that replicates the function of uroguanylin, an endogenous human gastrointestinal (GI) peptide. Activation of GC-C results in increased intestinal fluid and accelerated transit.
- The safety and efficacy of Trulance were based on data from two, 12- week clinical studies of 1,775 patients randomly assigned to placebo or Trulance.
  - Participants receiving Trulance were more likely to experience improvement in the frequency of complete spontaneous bowel movements than those receiving placebo (Trulance: 21% for both studies; placebo: 10% and 13% for studies 1 and 2, respectively;  $p < 0.005$  for both studies).
  - Patients taking Trulance also had improvements in stool frequency and consistency and straining,
- Trulance carries a boxed warning for risk of serious dehydration in pediatric patients.
- Trulance is contraindicated in patients < 6 years of age due to the risk of serious dehydration and in patients with known or suspected mechanical GI obstruction. Diarrhea is listed as a warning and precaution of Trulance.
- The most common adverse event ( $\geq 2\%$ ) with Trulance use was diarrhea.
- The recommended dose of Trulance is 3 mg orally once daily without regard to food.
  - For adult patients with swallowing difficulties, Trulance tablets can be crushed and administered orally either in applesauce or with water or administered with water via a nasogastric or gastric feeding tube. Mixing Trulance crushed tablets in other soft foods or in other liquids has not been tested.
- Synergy Pharmaceuticals plans to launch Trulance in the first quarter of 2017 as 3 mg tablets.