Trulance® (plecanatide) – New indication

- On January 25, 2018, Synergy Pharmaceuticals announced the FDA approval of Trulance (plecanatide) for the treatment of adults with irritable bowel syndrome with constipation (IBS-C).

- Trulance is also approved for the treatment of adults with chronic idiopathic constipation.

- IBS is a chronic gastrointestinal disorder characterized by recurrent abdominal pain and associated with two or more of the following: related to defecation, associated with a change in the frequency of stool, or associated with a change in the form of the stool. IBS can be subtyped by the predominant stool form: IBS-C, diarrhea (IBS-D) or mixed (IBS-M). Those within the IBS-C subtype experience hard or lumpy stools > 25% of the time they defecate, and loose or watery stools < 25% of the time.

    - It is estimated that the prevalence of IBS-C in the U.S. adult population is approximately 4 – 5%.

- The new indication for Trulance was demonstrated in two placebo-controlled, 12-week studies of 1,453 patients with IBS-C. The efficacy of Trulance was assessed using a responder analysis based on abdominal pain intensity and a stool frequency responder endpoint.

    - In the first study, 30% of Trulance-treated patients and 18% of placebo-treated patients were considered responders (treatment difference: 12% [95% CI: 6, 19]).
    - In the second study, 21% of Trulance-treated patients and 14% of placebo-treated patients were considered responders (treatment difference: 7% [95% CI: 2, 13]).

- Trulance carries a boxed warning for risk of serious dehydration in pediatric patients.

- The recommended dosage of Trulance for both indications is 3 mg orally once daily.