Symproic® (naldemedine) – New drug approval

- On March 24, 2017, Shionogi and Purdue Pharma announced the FDA approval of Symproic (naldemedine) for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.
    - Symproic is a Schedule II controlled substance.
    - The descheduling of Symproic is currently under evaluation by the U.S. Drug Enforcement Agency (DEA) based on a petition by Shionogi.
- Constipation is a commonly reported side effect associated with opioid treatment. The prevalence of OIC in patients with chronic non-cancer pain is estimated to range between 40 – 50%.
- Symproic is a peripherally-acting opioid receptor antagonist and is structurally related to naltrexone. It acts on tissues such as the gastrointestinal tract to decrease the constipating effects of opioids.
- The safety and efficacy of Symproic were demonstrated in 3 clinical trials that were part of the COMPOSE program enrolling patients with OIC and chronic non-cancer pain. Efficacy was assessed using a responder analysis. A responder was defined as a patient who had at least 3 spontaneous bowel movements (SBMs) per week and a change from baseline of at least 1 SBM per week for at least 9 out of the 12 weeks and 3 out of the last 4 weeks.
    - In study 1, 48% of Symproic-treated patients were responders vs. 35% of placebo patients (treatment difference = 13% [95% CI: 5, 21; p = 0.0020]).
    - In study 2, 53% of Symproic-treated patients were responders vs. 34% of placebo patients (treatment difference = 19% [95% CI: 11, 27; p < 0.0001]).
    - Symproic was also evaluated in a 52 week, placebo-controlled long-term safety trial.
- Symproic is contraindicated in patients with known or suspected gastrointestinal obstruction or at increased risk of recurrent obstruction, and in patients with a history of a hypersensitivity reaction to Symproic.
- Warnings and precautions of Symproic include gastrointestinal perforation and opioid withdrawal.
- The most common adverse reactions (≥ 2%) with Symproic use were abdominal pain, diarrhea, and nausea.
- The recommended starting dose of Symproic is 0.2 mg orally once daily with or without food.
    - Patients receiving opioids for < 4 weeks may be less responsive to Symproic.
    - Symproic should be discontinued if treatment with the opioid pain medication is discontinued.
- Shionogi and Purdue Pharma plan to launch Symproic in mid-summer 2017. Symproic will be available as 0.2 mg film-coated tablets.