Stelara® (ustekinumab) – New indication

- On October 21, 2019, Janssen announced the FDA approval of Stelara (ustekinumab), for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

- Stelara is also approved for the treatment of psoriasis, psoriatic arthritis, and Crohn's Disease.

- UC is a serious, chronic and progressive immune-mediated inflammatory disease of the large intestine, affecting approximately 910,000 people in the U.S.

    — Stelara is the first FDA approved biologic therapy for UC that targets the interleukin (IL)-12 and IL-23 cytokines. The IL-12 and IL-23 cytokines have been shown to play an important role in inflammatory and immune responses.

- The approval of Stelara for the new indication was based on two randomized, double-blind, placebo-controlled clinical studies in adult patients with moderately to severely active UC. The 8-week intravenous induction study (UC-1; N = 961) was followed by the 44-week subcutaneous randomized withdrawal maintenance study (UC-2; N = 523) for a total of 52 weeks of therapy.

    — In UC-1, a significantly greater proportion of patients treated with Stelara (at the recommended dose of approximately 6 mg/kg dose) were in clinical remission at week 8 vs. placebo (19% vs. 7%, respectively). The treatment difference was 12% (97.5% CI: 7, 18).
    — In UC-2, clinical remission was achieved in 26% and 45% of patients treated with placebo or Stelara, respectively. The treatment difference was 19% (95% CI: 9, 28).

- The most common adverse reaction (≥ 3%) with Stelara use for UC induction therapy was nasopharyngitis. The most common adverse reactions (≥ 3%) with Stelara use for UC maintenance therapy were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.

- The recommended induction dose of Stelara for the treatment of UC is a single intravenous infusion using a weight-based dosage regimen. The recommended maintenance dosage is a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

    — Refer to the Stelara drug label for complete dosing details for UC and for dosing recommendations for all its other indications.