Skyrizi® (risankizumab-rzaa) – New indication

- On June 18, 2024, AbbVie announced the FDA approval of Skyrizi (risankizumab-rzaa), for the treatment of moderately to severely active ulcerative colitis (UC) in adults.
- Skyrizi is also approved for the treatment of moderate-to-severe plaque psoriasis, active psoriatic arthritis, and moderately to severely active Crohn's disease.
- The approval of Skyrizi for the new indication was based on a 12-week induction study (UC-1) in 966 patients with moderately to severely active UC. Patients were randomized to Skyrizi or placebo. The primary endpoint was clinical remission defined using the modified Mayo score (mMS) at week 12.
    - Clinical remission was achieved in 24% of patients with Skyrizi vs. 8% of patients with placebo (difference 16, 95% CI: 12, 20; $p < 0.001$).
- The approval of Skyrizi for the new indication was also based on a maintenance study (UC-2) in 547 patients who received induction regimens in a previous study and demonstrated clinical response per mMS after 12 weeks. Patients were randomized to receive a maintenance regimen of Skyrizi or placebo at week 12 and every 8 weeks thereafter for up to an additional 52 weeks. The primary endpoint was clinical remission using mMS at week 52.
    - Clinical remission was achieved in 45% of patients with Skyrizi 180 mg (difference vs. placebo of 20, 95% CI: 11, 29; $p < 0.001$), 41% with Skyrizi 360 mg (difference vs. placebo of 16, 95% CI: 7, 25; $p < 0.001$), and 26% with placebo.
- The most common adverse reaction (≥ 3%) with Skyrizi use for induction therapy for UC was arthralgia. The most common adverse reactions for maintenance therapy were arthralgia, pyrexia, injection site reactions, and rash.
- The recommended induction dosage of Skyrizi for UC is 1,200 mg administered by intravenous infusion over a period of at least two hours at week 0, week 4, and week 8. The recommended maintenance dosage is 180 mg or 360 mg administered by subcutaneous injection at week 12, and every 8 weeks thereafter. The lowest effective dosage needed to maintain therapeutic response should be used.
    - Refer to the Skyrizi drug label for dosing for all its other indications.