Skyrizi® (risankizumab-rzaa) – New indication, new formulation approval

- On June 17, 2022, AbbVie announced the FDA approval of Skyrizi (risankizumab-rzaa), for the treatment of moderately to severely active Crohn's disease in adults.

- Skyrizi is also approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy and for the treatment of active psoriatic arthritis in adults.

- The approval of Skyrizi for the new indication was based on two 12-week induction studies (CD-1 and CD-2) in patients with moderately to severely active Crohn's disease. Patients were randomized to receive Skyrizi 600 mg, Skyrizi 1200 mg, or placebo as an intravenous (IV) infusion at week 0, week 4, and week 8. The co-primary endpoints were clinical remission and endoscopic response at week 12.

    - In CD-1 (511 patients received placebo or Skyrizi 600 mg), clinical remission was achieved in 25% of patients with placebo vs. 45% with Skyrizi 600 mg (difference of 21, 95% CI: 12, 29; $p < 0.001$). Endoscopic response was achieved in 12% of patients with placebo vs. 40% with Skyrizi 600 mg (difference of 28, 95% CI: 21, 35; $p < 0.001$).
    - In CD-2 (378 patients received placebo or Skyrizi 600 mg), clinical remission was achieved in 20% of patients with placebo vs. 42% with Skyrizi 600 mg (difference of 22, 95% CI: 13, 31; $p < 0.001$). Endoscopic response was achieved in 11% of patients with placebo vs. 29% with Skyrizi 600 mg (difference of 18, 95% CI: 10, 25; $p < 0.001$).
    - The Skyrizi 1200 mg dosage did not demonstrate additional treatment benefit over the 600 mg dosage and is not a recommended regimen.

- Skyrizi was also evaluated in a maintenance study (CD-3) in 247 patients who achieved clinical response after 12 weeks of induction treatment with Skyrizi in studies CD-1 and CD-2. Patients were randomized to receive a maintenance regimen of Skyrizi 360 mg by subcutaneous (SC) injection or placebo at week 12 and every 8 weeks thereafter for up to an additional 52 weeks. The co-primary endpoints were clinical remission and endoscopic response at week 52.

    - Clinical remission was achieved in 46% of patients with placebo vs. 57% with Skyrizi (difference of 14, 95% CI: 3, 26; $p < 0.05$).
    - Endoscopic response was achieved in 22% of patients with placebo vs. 48% with Skyrizi (difference of 31, 95% CI: 21, 41; $p < 0.05$).

- In addition to the new indication, two new formulations of Skyrizi were approved:

    - Skyrizi 360 mg/2.4 mL (150 mg/mL) single-dose prefilled cartridge for SC injection
    - Skyrizi 600 mg/10 mL (60 mg/mL) in single-dose vial for IV infusion.

- Skyrizi was previously only available as a SC injection in a 150 mg/mL single-dose prefilled pen, 150 mg/mL single-dose prefilled syringe, and a 75 mg/0.83 mL single-dose prefilled syringe.

- The most common adverse reactions (> 3%) with Skyrizi use for induction therapy for Crohn's disease were upper respiratory infections, headache, and arthralgia.

- The most common adverse reactions (> 3%) with Skyrizi use for maintenance therapy for Crohn's disease were arthralgia, injection site reactions, abdominal pain, anemia, pyrexia, back pain, arthropathy, and urinary tract infection.

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- The recommended induction dosage of Skyrizi is 600 mg administered by IV infusion over a period of at least one hour at week 0, week 4, and week 8. The recommended maintenance dosage of Skyrizi is 360 mg administered by SC injection at week 12, and every 8 weeks thereafter.
- Refer to the Skyrizi drug label for dosing for its other indications.
- AbbVie's launch plans for the new formulations of Skyrizi are pending.

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