Rinvoq® (upadacitinib) – New indication

- On March 16, 2022, AbbVie announced the FDA approval of Rinvoq (upadacitinib), for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
    - Rinvoq is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.
- Rinvoq is also approved for rheumatoid arthritis, psoriatic arthritis, and atopic dermatitis.
- The approval of Rinvoq for the new indication was based on two identical induction studies (UC-1, UC-2) in 988 patients with ulcerative colitis. Patients were randomized to receive either Rinvoq 45 mg once daily or placebo for 8 weeks. The primary endpoint was clinical remission defined using the modified Mayo score (mMS) at week 8, a 3-component Mayo score which consists of stool frequency, rectal bleeding, and findings on centrally read endoscopy score.
    - In study UC-1, the remission rate was 26% and 5% with Rinvoq and placebo, respectively (difference 22, 95% CI: 16, 27; $p < 0.001$).
    - In study UC-2, the remission rate was 33% and 4% with Rinvoq and placebo, respectively (difference 29, 95% CI: 23, 35; $p < 0.001$).
- Additionally, Rinvoq was evaluated for the maintenance treatment of ulcerative colitis in UC-3 in 451 patients. Patients who had achieved clinical response in a previous study were re-randomized to receive Rinvoq 15 mg, 30 mg, or placebo once daily for up to 52 weeks. The primary endpoint was clinical remission defined using mMS at week 52.
    - The remission rate was 12%, 42%, and 52% with placebo, Rinvoq 15 mg, and Rinvoq 30 mg, respectively. The treatment difference for Rinvoq 15 mg vs. placebo was 31% (95% CI: 22, 40; $p < 0.001$). The treatment difference for Rinvoq 30 mg vs. placebo was 39% (95% CI: 30, 48; $p < 0.001$).
- Rinvoq carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The most common adverse reactions (≥ 5%) with Rinvoq use during induction or maintenance treatment of ulcerative colitis were upper respiratory tract infections, increased blood creatine phosphokinase, acne, neutropenia, elevated liver enzymes, and rash.
- The recommended induction dose of Rinvoq for ulcerative colitis is 45 mg orally once daily for 8 weeks. The recommended dose of Rinvoq for maintenance treatment is 15 mg once daily.
    - A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease. Rinvoq should be discontinued if an adequate therapeutic response is not achieved with the 30 mg dosage. The lowest effective dosage needed to maintain response should be used.

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— Refer to the Rinvoq drug label for dosing for all its other indications.