Rinvoq® (upadacitinib) – New indication

- On May 18, 2023, the FDA announced the approval of AbbVie's Rinvoq (upadacitinib), for the treatment of adult patients with moderately to severely active Crohn's disease 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 Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.
- Rinvoq is also approved for treatment of rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis.
- Rinvoq is the first oral drug FDA approved for moderately to severely active Crohn's disease.
- The approval of Rinvoq for the new indication was based on two induction studies (CD-1 and CD-2) in 857 patients with moderately to severely active Crohn's disease. Patients were randomized to Rinvoq 45 mg or placebo for 12 weeks. The co-primary endpoints were the proportion of patients achieving clinical remission at week 12, and the proportion of patients achieving endoscopic response at week 12.
    - In CD-1, clinical remission was achieved in 36% and 18% of patients with Rinvoq and placebo, respectively (treatment difference 17, 95% CI: 9, 25; $p < 0.001$). Endoscopic response was achieved in 34% and 3% of patients with Rinvoq and placebo, respectively (treatment difference 30, 95% CI: 24, 36; $p < 0.001$).
    - In CD-2, clinical remission was achieved in 46% and 23% of patients with Rinvoq and placebo, respectively (treatment difference 24, 95% CI: 15, 32; $p < 0.001$). Endoscopic response was achieved in 46% and 13% of patients with Rinvoq and placebo, respectively (treatment difference 33, 95% CI: 26, 41; $p < 0.001$).
- In addition to the induction studies, Rinvoq was also evaluated in a maintenance study (CD-3) in 343 patients who responded to 12 weeks of Rinvoq induction treatment. Patients were re-randomized to receive a maintenance regimen of either Rinvoq 15 mg or 30 mg once daily or placebo for 52 weeks, representing a total of at least 64 weeks of therapy. The co-primary endpoints of clinical remission and endoscopic response were assessed at week 52.
    - Clinical remission was achieved in 42%, 55%, and 14% with Rinvoq 15 mg, Rinvoq 30 mg, and placebo, respectively. The treatment difference vs. placebo was 29% (95% CI: 18, 39; $p < 0.001$) and 40% (95% CI: 29, 51; $p < 0.001$) for Rinvoq 15 mg and 30 mg, respectively.
    - Endoscopic response was achieved in 28%, 41%, and 7% with Rinvoq 15 mg, Rinvoq 30 mg, and placebo, respectively. The treatment difference vs. placebo was 22% (95% CI: 13, 32; $p < 0.001$) and 34% (95% CI: 25, 44; $p < 0.001$) for Rinvoq 15 mg and 30 mg, respectively.
- Rinvoq carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.
- The most common adverse reactions (≥ 5%) with Rinvoq use were upper respiratory tract infections, anemia, pyrexia, acne, herpes zoster, and headache.

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- The recommended dose of Rinvoq for induction treatment of Crohn's disease is 45 mg orally once daily for 12 weeks. For maintenance treatment, the recommended dosage of Rinvoq 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.
    - Refer to the Rinvoq drug label for dosing for all its other indications.

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