Rinvoq® (upadacitinib) – New indication

- On December 14, 2021, AbbVie announced the FDA approval of Rinvoq (upadacitinib), for the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
    - Use of Rinvoq in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.
- Rinvoq is also approved for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- The approval of Rinvoq for the new indication was based on two randomized, double-blind, placebo-controlled studies in patients 18 years of age or older with moderately to severely active psoriatic arthritis. Study PsA-I was a 24-week trial in 1,705 patients who had an inadequate response or intolerance to at least one nonbiologic DMARD. Patients received Rinvoq 15 mg or upadacitinib 30 mg once daily, Humira® (adalimumab), or placebo, alone or in combination with background non-biologic DMARDs. At week 24, all patients randomized to placebo were switched to Rinvoq 15 mg or upadacitinib 30 mg once daily in a blinded manner. The primary endpoint was the proportion of patients who achieved an American College of Rheumatology ≥ 20% improvement (ACR20) at week 12.
    - ACR20 response was achieved in 71% with Rinvoq 15 mg vs. 36% with placebo (treatment difference 35, 95% CI: 28, 41).
- Study PsA-II was a 24-week trial in 642 patients who had an inadequate response or intolerance to at least one biologic DMARD. Patients received Rinvoq 15 mg or upadacitinib 30 mg once daily or placebo, alone or in combination with background non-biologic DMARDs. At week 24, all patients randomized to placebo were switched to Rinvoq 15 mg or upadacitinib 30 mg once daily in a blinded manner. The primary endpoint was the proportion of patients who achieved an ACR20 response at week 12.
    - ACR20 response was achieved in 57% with Rinvoq 15 mg vs. 24% with placebo (treatment difference 33, 95% CI: 24, 42).
- Rinvoq carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The recommended dose of Rinvoq for both of its indications is 15 mg orally once daily.