Rinvoq® (upadacitinib) – New indication

- On October 21, 2022, AbbVie announced the FDA approval of Rinvoq (upadacitinib), for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to tumor necrosis factor (TNF) blocker therapy.
    - Rinvoq is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.
- Rinvoq is also approved for the treatment of rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis, and ankylosing spondylitis.
- Non-radiographic axial spondyloarthritis is a chronic, progressive inflammatory rheumatic disease that causes joint inflammation, leading to back pain and stiffness, and cannot be detected by x-ray.
    - Rinvoq is the only JAK inhibitor approved for non-radiographic axial spondyloarthritis.
- The approval of Rinvoq for the new indication was based on Trial nr-axSpA, a randomized, double-blind, placebo-controlled study in 314 patients 18 years of age or older with active non-radiographic axial spondyloarthritis. Patients received Rinvoq 15 mg once daily or placebo. The primary endpoint was the proportion of patients achieving an Assessment of SpondyloArthritis international Society 40 (ASAS40) response at week 14.
    - At week 14, ASAS40 response was achieved in 44.9% of patients with Rinvoq vs. 22.3% with placebo (difference 22.5, 95% CI: 12.4, 32.5).
- Rinvoq carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The recommended dose of Rinvoq for the treatment of non-radiographic axial spondyloarthritis is 15 mg once daily.
    - Refer to the Rinvoq drug label for dosing for all its other indications.