Rinvoq® (upadacitinib) – New indication

- On April 29, 2022, AbbVie announced the FDA approval of Rinvoq (upadacitinib), for the treatment of adults with active ankylosing spondylitis 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 rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, and ulcerative colitis.
- 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 active ankylosing spondylitis. Trial AS-I was a 14-week study in 187 ankylosing spondylitis patients with an inadequate response to at least two nonsteroidal anti-inflammatory drugs (NSAIDs) or intolerance to or contraindication for NSAIDs and had no previous exposure to biologic DMARDs. Trial AS-II was a 14-week study in 420 ankylosing spondylitis patients with an inadequate response to 1 or 2 biologic DMARDs. The primary endpoint in both studies was the proportion of patients achieving an Assessment of SpondyloArthritis international Society 40 (ASAS40) response at week 14.
    - In Trial AS-I, 50.5% and 25.5% of patients treated with Rinvoq and placebo achieved ASAS40 response, respectively (treatment difference 25, 95% CI: 12, 38).
    - In Trial AS-II, 44.5% and 18.2% of patients treated with Rinvoq and placebo achieved ASAS40 response, respectively (treatment difference 26, 95% CI: 18, 35).
- 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 ankylosing spondylitis is 15 mg orally once daily.
    - Refer to the Rinvoq drug label for dosing for all its other indications.