Oral JAK Inhibitors (Xeljanz®/XR, Olumiant®, Rinvoq®) – Updated labeling

- On December 2, 2021, the FDA approved a class-wide update to the labeling for the oral JAK inhibitors consistent with the Drug Safety Communication issued on September 1, 2021 by the FDA.
    - The update will apply to Pfizer's Xeljanz/Xeljanz XR (tofacitinib), AbbVie's Rinvoq (upadacitinib), and Eli Lilly's Olumiant (baricitinib).
- Based on this class-wide update, the label for all three drugs will now include additional information about the risks of malignancy and thrombosis, and the addition of mortality and major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) risks within the *Boxed Warnings* and *Warnings and Precautions* sections.
    - This follows the final review of the post-marketing study, ORAL Surveillance, evaluating Xeljanz in patients with rheumatoid arthritis (RA). The results of this study showed a higher rate of MACE, malignancy, mortality, and thrombosis in Xeljanz-treated patients vs. tumor necrosis factor (TNF) blockers.
- The indication for Rinvoq was updated to treatment of adults with moderately to severely active RA who have had an inadequate response or intolerance to one or more TNF blockers.
    - Rinvoq was previously approved for this indication in patients with an inadequate response or intolerance to methotrexate.
- The indications for Xeljanz/Xeljanz were also updated to include inadequate response or intolerance to one or more TNF blockers. Previously, Xeljanz/Xeljanz XR were approved for:
    - Treatment of adult patients with moderately to severely active RA who have had an inadequate response or intolerance to methotrexate.
    - Treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs.
    - Treatment of adult patients with moderately to severely active ulcerative colitis, who have an inadequate response or who are intolerant to TNF blockers.
    - Treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older.
- The indication for Olumiant was not significantly updated as the use was already limited to treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more TNF antagonist therapies.