Xeljanz®/Xeljanz® XR (tofacitinib) – New indication

- On December 14, 2017, Pfizer announced the FDA approval of Xeljanz/Xeljanz XR (tofacitinib) for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).
    - Xeljanz/Xeljanz XR is also indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic DMARDs.
    - Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- The FDA approval of Xeljanz for the treatment of active PsA was based on data involving 816 patients from two clinical studies, OPAL Broaden and OPAL Beyond.
    - Both pivotal studies met their two primary efficacy endpoints, demonstrating statistically significant improvements in American College of Rheumatology 20 (ACR20) response and change from baseline in the Health Assessment Questionnaire–Disability Index (HAQ-DI) score, at three months in patients receiving Xeljanz in combination with a nonbiologic DMARD vs. placebo.
    - In OPAL Broaden, 50% of patients taking Xeljanz 5 mg twice daily achieved an ACR20 response, vs. 33% of patients taking placebo ($p \leq 0.05$).
    - In OPAL Beyond, 50% of patients achieved an ACR20 response with Xeljanz 5 mg twice daily, vs. 24% of patients taking placebo ($p \leq 0.05$).
    - In both studies, patients receiving Xeljanz demonstrated significantly greater improvement ($p \leq 0.05$) from baseline in HAQ-DI score vs. placebo.
- The safety profile observed in patients with active PsA treated with Xeljanz was consistent with the safety profile observed in RA patients.
- Xeljanz/Xeljanz XR carries a boxed warning for serious infections and malignancy.
- For both indications, the recommended dose of Xeljanz is 5 mg twice daily and the recommended dose of Xeljanz XR is 11 mg once daily.
    - For the treatment of PsA, Xeljanz/Xeljanz XR is used in combination with a nonbiologic DMARD.