## Xeljanz® (tofacitinib) – New indication, new formulation

- On September 28, 2020, Pfizer announced the FDA approval of Xeljanz (tofacitinib), for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.
    - Use of Xeljanz in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- Xeljanz is also approved for the treatment of adults with rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis.
- In addition to the new indication, the FDA also approved a new oral solution formulation for Xeljanz.
    - Tofacitinib is also available as immediate-release (Xeljanz) and extended-release (Xeljanz XR) tablets. Only Xeljanz tablets and oral solution are approved for pcJIA.
- The approval of Xeljanz for the new indication was based on a 44-week, two-part study (consisting of an 18-week, open-label, run-in phase, followed by a 26-week double-blind, placebo-controlled, randomized withdrawal phase) in 225 patients 2 years to 17 years of age with JIA. Patients received Xeljanz for 18 weeks (run-in phase) followed by randomization to either Xeljanz or placebo for 26 weeks (double-blind phase). The primary endpoint was the occurrence of disease flare at week 44 relative to the double-blind phase baseline at week 18.
    - Xeljanz treated patients experienced significantly fewer disease flares at week 44 vs. placebo-treated patients (31% vs. 55%; p = 0.0007).
- Xeljanz carries a boxed warning for serious infections, mortality, malignancy, and thrombosis.
- The most common adverse reactions with Xeljanz use for pcJIA are consistent with adverse reactions reported in adult rheumatoid arthritis patients.
- The recommended oral dose of Xeljanz for the treatment of pcJIA is based on body weight

| Body weight | Dosage |
|---|---|
| 10 kg ≤ body weight < 20 kg | 3.2 mg (3.2 mL oral solution) twice daily |
| 20 kg ≤ body weight < 40 kg | 4 mg (4 mL oral solution) twice daily |
| Body weight ≥40 kg | 5 mg (one 5 mg tablet or 5 mL oral solution) twice daily |

    - Refer to the Xeljanz drug label for dosing for all its other indications.
- Pfizer plans to launch Xeljanz 1 mg/mL oral solution by the end of the first quarter 2021.