Xeljanz®, Xeljanz XR (tofacitinib) – Safety update

- On February 4, 2021, the FDA announced that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR (tofacitinib) compared to another type of medicine called tumor necrosis factor (TNF) inhibitors.

- Xeljanz and Xeljanz XR are approved for the treatment of adult patients with:

    — Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate
    — Active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs and
    — Moderately to severely active ulcerative colitis, who have an inadequate response or who are intolerant to TNF blockers.

- Xeljanz and Xeljanz oral solution are approved for the treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older.

- Xeljanz and Xeljanz XR currently carry a boxed warning for serious infections, mortality, malignancy and thrombosis.

- The FDA required Pfizer to conduct a safety clinical trial in patients with RA who were 50 years of age or older and had at least one additional cardiovascular risk factor and were taking methotrexate to evaluate the risk of serious heart-related events, cancer, and infections. The trial studied two doses of Xeljanz (5 mg or 10 mg twice daily) vs. a TNF inhibitor.

    — Interim trial results showed an increased risk of blood clots and death with the higher 10 mg twice daily dosage, and as a result, the FDA approved a Boxed Warning to the Xeljanz drug label.
    — The clinical trial is now complete and initial results show a higher occurrence of serious heart-related events and cancer in RA patients treated with both doses of Xeljanz vs. patients treated with a TNF inhibitor. FDA is awaiting additional results from the trial.

- Patients should not stop taking Xeljanz or Xeljanz XR without first consulting with their health care professionals, as doing so may worsen their condition. Patients should talk to their health care professionals if they have any questions or concerns.

- Health care professionals should consider the benefits and risks of Xeljanz or Xeljanz XR when deciding whether to prescribe or continue patients on the medicine.

- The FDA will evaluate the clinical trial results that have been received to date and will work with the drug manufacturer to obtain further information as soon as possible. The FDA will communicate their final conclusions and recommendations when they have completed their review or have more information to share