Xeljanz®, Xeljanz XR (tofacitinib) – New Boxed Warning

- On July 26, 2019, the FDA announced that new warnings will be added to the tofacitinib (Xeljanz, Xeljanz XR) drug label regarding an increased risk of pulmonary embolism and death with the 10 mg twice daily dose in patients with ulcerative colitis (UC).

- In addition, the approved use of tofacitinib for UC will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines.

- Interim data from an ongoing safety trial of tofacitinib in patients with rheumatoid arthritis (RA) showed that those treated with tofacitinib 10 mg twice daily had an increased occurrence of blood clots and death vs. patients treated with tofacitinib 5 mg twice daily or a tumor necrosis factor (TNF) blocker.

- Tofacitinib is approved to treat RA, psoriatic arthritis (PsA), and UC.

    — The 10 mg twice daily dose of tofacitinib is not approved for RA or PsA. This dose is only approved for UC for initial treatment and for long-term use in limited situations. While the increased risks of blood clots and of death were seen in patients taking this dose for RA, these risks may also apply to those taking tofacitinib for UC.
    — The tofacitinib 5 mg immediate-release tablet is approved for the treatment of RA and for maintenance treatment of UC. The tofacitinib 10 mg immediate-release tablet is approved for the induction treatment in patients with UC.
    — The 11 mg extended-release tablet is approved for RA and PsA.

- Healthcare providers should discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis. Patients should be counseled about thrombosis risks and be advised to seek immediate medical attention if they experience any unusual symptoms or symptoms of thrombosis.

- Tofacitinib should be reserved to treat UC for patients who have failed or do not tolerate TNF blockers. Tofacitinib should be avoided in patients who may have a higher risk of thrombosis. When treating UC, use tofacitinib at the lowest effective dose and limit the use of the 10 mg twice daily dosage to the shortest duration needed.

- Patients should tell their healthcare provider if they have a history of blood clots or heart problems. Patients should not change or stop their Xeljanz therapy without first discussing with their healthcare provider, as doing so may worsen their condition. Patients should seek immediate medical attention if they experience symptoms of pulmonary embolism or other unusual symptoms including sudden shortness of breath, chest pain, swelling of a leg or arm, leg pain or tenderness or red/discolored skin in the painful or swollen leg or arm.

- The FDA will reassess these safety issues when the safety trial has completed and final, verified data are available. The FDA will update the public when additional information is available.

- A prior FDA announcement of the initial Xeljanz safety update can be found here.