February 5, 2021 **COM-2021-009**

DRUG SAFETY NOTIFICATION

DATE: FEBRUARY 4, 2021

DRUG NAME: XELJANZ, XELJANZ XR (TOFACITINIB)

DRUG INDICATION: ARTHRITIS AND ULCERATIVE COLITIS

SAFETY TOPIC: INITIAL SAFETY TRIAL RESULTS FIND INCREASED RISK OF SERIOUS HEART-RELATED PROBLEMS AND CANCER WITH XELJANZ, XELJANZ XR (TOFACITINIB)

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate with you with the latest up-to-date information on drug safety. For this reason, we are notifying you that the U.S. Food and Drug Administration (FDA) is alerting that preliminary results from a safety clinical trial showed an increased risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR (tofacitinib) compared to tumor necrosis factor (TNF) inhibitors. The FDA will evaluate the clinical trial results received to date, work with the drug manufacturer to obtain further information, and will communicate final conclusions and recommendations after completing their review or have more information to share.

Recommendations for healthcare professionals:

- Advise patients that they should not stop taking tofacitinib without first consulting with their healthcare provider, because doing so may worsen their condition.
- Advise patients to talk with their healthcare provider if they have any questions or concerns.
- Consider the benefits and risks of tofacitinib when deciding whether to initiate or continue patients on the drug.
- Continue to follow the recommendations in the tofacitinib prescribing information.

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- Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:
    - Complete and submit the MedWatch Online Voluntary Reporting Form online.
    - Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Additional information can be found at FDA's Drug Safety and Availability portal.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- Serious heart problems and cancer with Xeljanz (tofacitinib). U.S. Food and Drug Administration. (2021). Retrieved February 4, 2021, from https://www.fda.gov/drugs/drug-safety-and-availability/initial-safety-trial-results-find-increased-risk-serious-heart-related-problems-and-cancer-arthritis.