Pfizer Saudi Limited
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SAUDI ARABIA

6 May 2019

Direct Healthcare-Professional Communication (DHPC)

Communication of new safety information: Increased risk of pulmonary embolism and overall mortality with higher dose of XELJANZ® (tofacitinib) for rheumatoid arthritis

Dear Healthcare Provider,

Pfizer, in agreement with the Saudi Food and Drug Authority, would like to inform you of the following:

Summary:

- An increased risk of pulmonary embolism and overall mortality has been seen in a study with tofacitinib 10 mg twice daily in rheumatoid arthritis.
- Prescribers should continue to adhere to the authorized dose of 5 mg twice daily for the treatment of rheumatoid arthritis.
- Patients receiving tofacitinib should be monitored for the signs and symptoms of pulmonary embolism, and be advised to seek medical attention immediately if they experience them.

Further information:

On February 19, Pfizer announced it has taken steps to transition rheumatoid arthritis (RA) study patients who were on tofacitinib 10 mg twice daily to tofacitinib 5 mg twice daily in the post-marketing study A3921133. This action was taken as the result of notification from the tofacitinib Rheumatology Data Safety Monitoring Board (DSMB) of an increase in the frequency of pulmonary embolism and overall mortality in patients in the trial who were taking the 10 mg twice daily dose of tofacitinib. This RA study was designed to assess the risk of cardiovascular (CV) events and therefore in contrast to previous tofacitinib studies, patients were required to be at least 50 years of age and have at least one CV risk factor. All patients entered the study on stable doses of background methotrexate. Similar results to RA study A3921133 have not been identified in Pfizer analyses of other tofacitinib RA clinical trials or routine monitoring of post-marketing safety data, including our statistical analyses of the FDA Adverse Event Reporting System (FAERS) database. The 10 mg twice daily dose of tofacitinib is not approved for RA in Saudi Arabia.

We are communicating now, given the serious nature of the safety issue, to ensure that patients taking tofacitinib are aware that the Regulatory authorities still believes the benefits of taking tofacitinib for its approved uses continue to outweigh the risks. Patients taking tofacitinib for its approved uses should continue to take their medication as directed by their health care

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professional. Today's safety alert underscores the importance of monitoring and addressing safety questions that arise in the post-market setting.

Health care professionals should follow the recommendations in the tofacitinib prescribing information for the specific condition they are treating. Monitor patients for the signs and symptoms of pulmonary embolism and advise them to seek medical attention immediately if they experience them.

Patient safety is of the utmost importance to Pfizer and the company continually monitors the safety of its medicines. As such we continue to work with regulatory agencies around the world on this safety signal. We wanted you to be aware of these emerging data from this RA study and its 10 mg twice daily dose group so that you can consider this when counseling your patients on the use of Xeljanz.

For more information, please see the Xeljanz local full prescribing information enclosed or contact Pfizer Medical Information via:

MedInfoMEandAfrica@pfizer.com
https://pmiform.com/HCP/MID-EAST

Call for reporting:

As a reminder, there is a need to report any suspected adverse reactions to the

National Pharmacovigilance and Drug Safety Center (NPC):
By email: npc.drug@sfda.gov.sa
Or by fax: +966 11 2057662
Or by online: https://ade.sfda.gov.sa/

Pharmacovigilance department in the company:
Email: SAU.AEReporting@Pfizer.com

Sincerely Yours,

M. Fathy

Mohamed Fathy, MD
Medical Director – Saudi Arabia