09-March-2023

Direct Healthcare Professional Communication

Olumiant (Baricitinib): Updated recommendations to minimise the risks of malignancy, major adverse cardiovascular events, serious infections, venous thromboembolism and mortality with use of Janus kinase inhibitors (JAKi).

Dear Healthcare Professional,

Eli Lilly and Company (Lilly) would like to inform you of the following:

Summary

- **An increased incidence of malignancy, major adverse cardiovascular events (MACE), serious infections, venous thromboembolism (VTE) and mortality has been observed in patients with rheumatoid arthritis (RA) with certain risk factors using JAKi treatment compared to TNFα inhibitors.**
- **These risks are considered class effects and relevant across all approved indications of JAKi in inflammatory and dermatologic diseases.**
- **These JAKi should only be used if no suitable treatment alternatives are available in patients:**
    - **65 years of age and older;**
    - **who are current or past long-time smokers;**
    - **with other cardiovascular or malignancy risk factors.**
- **JAKi should be used with caution in patients with VTE risk factors other than those listed above.**
- **Dosing recommendations are revised for some patient groups with risk factors.**
- **Periodic skin examination is recommended for all patients.**
- **Prescribers should discuss with patients the risks associated with the use of JAKi.**

Further information on the safety concerns and the recommendations

The JAK inhibitors, like Olumiant (baricitinib), were approved for the treatment of several chronic inflammatory disorders (rheumatoid arthritis (RA), psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, ulcerative colitis, atopic dermatitis, and alopecia areata). The approved use differs for the different products, as outlined in the respective product information."

Preliminary findings from an Observational study (B023) involving Olumiant (Baricitinib), as well as results from the Oral Surveillance Study which involved another JAK inhibitor also suggested an increased risk of major cardiovascular events and VTE in patients with RA treated with Olumiant compared with those treated with TNF-alpha inhibitors.

The Warning and Precautions section of the Product Information will be updated based on:

• recommended by the Pharmacovigilance Risk Asessment Committee (PRAC) to minimize the risk of serious side effects with Janus Kinase (JAK) inhibitors used to treat several chronic inflammatory disorders. These side effects include cardiovascular conditions, blood clots, cancer and serious infections.

• These medicines should be used in the following patients only if no suitable treatment alternatives are available: those aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past and those at increased risk of cancer.

• JAK inhibitors should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism, VTE) other than those listed above. Further, the doses should be reduced in patient groups who are at risk of VTE, cancer or major cardiovascular problems, where possible.

The Saudi Food and Drug Authority (SFDA) has approved the information in this letter.

Call for reporting

To report adverse events among patients taking OLUMIANT® (Baricitinib), please contact:

-The National Pharmacovigilance and Drug Safety Center NPC:

- SFDA Call Center: 19999
- Fax: +966-11-205-7662
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa
- :

- Pharmacovigilance department in Eli Lilly and Company (Lilly):

- Email: Saudi_Pharmacovigilance@lilly.com
- Office: +966 11 461 7845
- 24/7 mobile: +966 56 786 8843
- Webpage: lillysaudi-reporting.com