فرع شركة جونسون أند جونسون ميدل إيست

Direct Healthcare Professional Communication

10-Jul-2019

DARZALEX® (daratumumab): New Identified Risk of Hepatitis B Reactivation

Dear Healthcare Professional,

In Agreement with the Saudi Food and Drug Authority (SFDA), Johnson & Johnson Middle East FZ Branch would like to inform you about a new adverse drug reaction (ADR)/important identified risk of Hepatitis B (HBV) reactivation associated with the use of DARZALEX® (daratumumab).

Summary

Hepatitis B virus (HBV) reactivation, in some cases fatal, has been reported in patients treated with DARZALEX® (daratumumab).

Recommendations

- **HBV screening should be performed in all patients before initiation of treatment with DARZALEX® (daratumumab). Patients already under treatment with daratumumab and for which HBV serology in unknown should also be tested for HBV.**
- **For patients with evidence of positive HBV serology, monitor for clinical and laboratory signs of HBV reactivation during, and for at least six months following the end of DARZALEX® (daratumumab) treatment. Manage patients according to clinical guidelines.**
- **In patients who develop reactivation of HBV while on DARZALEX® (daratumumab), suspend treatment with DARZALEX® (daratumumab) and any concomitant steroids, chemotherapy, and institute appropriate treatment. Resumption of DARZALEX® (daratumumab) treatment in patients whose HBV reactivation is adequately controlled should be discussed with physicians with expertise in managing HBV.**

Background

A recent cumulative review of data from clinical trials and post-marketing cases has identified reports of HBV reactivation in patients treated with DARZALEX® (daratumumab). As of 15 November 2018, DARZALEX® (daratumumab) has been received by approximately 4407 patients in the setting of clinical trials, and an estimated world-wide post-marketing exposure of 34,316 person-years. The overall frequency of HBV reactivation in DARZALEX® (daratumumab) clinical trials, including serious and non-serious reports, is uncommon (0.2%). The majority of clinical trial cases were considered non-serious, although fatal HBV reactivation cases have been reported in clinical trials and in the post-marketing setting. DARZALEX® (daratumumab) has been continued once HBV reactivation has been controlled with antiviral medication.

The role of DARZALEX® (daratumumab) therapy in the reported cases of HBV reactivation is confounded by the underlying medical condition given that patients with multiple myeloma are immunosuppressed.

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In several cases patients were also receiving concomitant medications associated with viral reactivation. However, as the relationship cannot be ruled out, the Prescribing Information and the Patient Information Leaflet for DARZALEX® (daratumumab) will be updated to reflect the new safety information.

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

Call for Reporting

Healthcare professionals should report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system.

SFDA (National Pharmacovigilance and Drug Safety Department)
Email: npc.drug@sfda.gov.sa
Telephone: 8002490000
Fax: +966 11 2057662
Online: http://ade.sfda.gov.sa

Company Contact Points

If you have further questions or require additional information, please contact our Local Safety Department at:

Email: GCC-PV2@its.jnj.com
Fax: +966 11 2153190

Yours faithfully,

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Hesham Atef
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