Direct Healthcare Professional Communication

27-October-2020

Dear Healthcare Professional,

Janssen Pharmaceutical Company in agreement with the Egyptian Health Authority would like to inform you about a possible risk of Hepatitis C virus (HCV) reactivation associated with the use of DARZALEX® (daratumumab).

Summary

The current clinical data do not suggest that there is a causal relationship between daratumumab and Hepatitis C re-activation. However, due to the high incidence, further monitoring of this potential risk is required

Recommendations

• HCV screening should be performed in all patients before initiation of treatment with DARZALEX® (daratumumab).

• For patients with evidence of positive HCV serology, monitor for clinical and laboratory signs of HCV 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 HCV 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 HCV reactivation is adequately controlled should be discussed with physicians with expertise in managing HCV.

Call for reporting

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

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