AM Mangion Ltd

Registered Office:
A.M. Mangion Limited
Mangion Building,
New Street off Valletta Road,
Luqa LQA 6000 - MALTA

Tel: (+356) 2397 6000
Fax: (+356) 2397 6613
Email: admin@ammangion.com.mt
Website: www.ammangion.com.mt
Bankers HSBC Bank Malta PLC - St. Julians
Registration: C4112
VAT Reg. No.: MT12619204

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Pomalidomide (Imnovid): New important advice - hepatitis B virus status to be established before initiating treatment with pomalidomide

Dear Healthcare professional,

Celgene Europe Limited in agreement with the European Medicines Agency and the Malta Medicines Authority would like to inform you of the following:

Summary

- **Reactivation of hepatitis B has been reported rarely following treatment with pomalidomide plus dexamethasone in patients previously infected with the hepatitis B virus.**
- **Some of these cases have progressed to acute hepatic failure and resulted in discontinuation of pomalidomide.**
- **Hepatitis B virus status should be established before initiating treatment with pomalidomide.**
- **For patients who test positive for HBV infection, consultation with a physician with expertise in the treatment of hepatitis B is recommended.**
- **Caution should be exercised when using pomalidomide in combination with dexamethasone in patients previously infected with HBV, including patients who are anti-HBc positive but HBsAg negative.**
- **Previously infected patients should be closely monitored for signs and symptoms of active HBV infection throughout therapy.**

Further information on the safety concern and the recommendations

Imnovid in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

Cases of hepatitis B reactivation, some of which progressed to hepatic failure, have been reported rarely (less than 1/1,000) following treatment with pomalidomide plus dexamethasone. They generally occurred early during therapy with pomalidomide, with most reports during the first treatment cycle.

Patients treated with pomalidomide usually have existing risk factors for viral reactivation including old age, underlying progressive multiple myeloma and prior treatment with multiple immunosuppressive treatments. However, the immunosuppressive effect of pomalidomide in combination with dexamethasone may further increase the risk of viral reactivation in these patients.

Call for reporting

Please be reminded that adverse reactions associated with the use of Imnovid should be reported to:

Medicines Authority Post-licensing Department, 203, Level 3,Rue D'Argens, Gzira GZR1368, Malta or at www.medicinesauthority/adrportal

▼ This medicinal product is subject to additional monitoring. This is intended to facilitate early identification of new safety information.

Company contact point

If you have further questions or require further information, please contact your local Celgene representative at
AM Mangion Ltd, Mangion Building, New Street off Valletta Road, Luqa LQA 6000 – Malta or on Phone number 00 356 2397600 or email at rp@ammangion.com.mt