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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Lenalidomide (Revlimid®): New important advice regarding viral reactivation

Dear Healthcare professional,

Celgene Europe Limited in agreement with the European Medicines Agency and the Medicines Authority would like to inform you of the following concern about the immunomodulator, lenalidomide:

Summary

- **Cases of viral reactivation have been reported following treatment with lenalidomide, particularly in patients previously infected with the herpes zoster or hepatitis B viruses (HBV).**
- **Some cases of HBV reactivation progressed to acute hepatic failure and resulted in death.**
- **Hepatitis B virus status should be established before initiating treatment with lenalidomide.**
- **A physician with expertise in the treatment of hepatitis B should be consulted for patients who test positive for HBV infection,.**
- **Previously infected patients should be closely monitored for signs and symptoms of viral reactivation, including active HBV infection, throughout therapy.**

Further information on the safety concern and the recommendations

Viral reactivation, including herpes zoster and hepatitis B viruses, has been reported during the postmarketing period for lenalidomide. Cases of hepatitis B reactivation have been reported very rarely (<1/10,000), but in 4 cases they progressed to hepatic failure. In these 4 cases, lenalidomide was discontinued and the patients required antiviral treatment. Previously infected patients should be closely monitored throughout therapy for signs and symptoms of viral reactivation, including active HBV infection.
Reactivation of herpes zoster led in some cases to disseminated herpes zoster, meningitis herpes zoster or ophthalmic herpes zoster necessitating antiviral treatment and the permanent discontinuation or temporary interruption of treatment with lenalidomide.
Patients treated with lenalidomide usually have pre-existing risk factors for viral reactivation, including old age, underlying progressive disease and prior or concomitant treatment with immunosuppressive treatments including stem cell transplant. The immunosuppressive effect of lenalidomide may further increase the risk of viral reactivation in these previously infected patients.

Revlimid is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant and in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. Further, Revlimid is indicated for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other

Directors:
A.M. Mangion B.Pharm (Chairman)
J. Mangion B.Pharm (Hons), M.B.A. (UF) (CEO)
K. Mangion
R. Vella

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therapeutic options are insufficient or inadequate and for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.

Call for reporting

Please be reminded that adverse reactions associated with the use of Revlimid should be reported to Medicines Authority. ADR report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal *and sent to postlicensing.medicinesauthorithy@gov.mt*

▼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 – email* pv@ammangion.com *or call 00 356 2397 6407*