16th January 2017

**Direct Health Care professional communication**

**Lenalidomide** (Revlimid™): **New important advice regarding viral reactivation**

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Dear Healthcare professional,

Celgene would like to inform you of the following concern of 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 reactivation of herpes zoster and hepatitis B viruses, has been reported during the post marketing 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 in combination with dexamethasone for the treatment of patients with multiple myeloma who have received at least one previous drug treatment.

Revlimid™ is indicated for the treatment of patients with anemia requiring transfusions resulting from myelodysplastic syndrome with low or intermediate risk 1 associated with a deletion 5q cytogenetic abnormality with or without other cytogenetic abnormalities.

The Information in this letter has been approved by the Saudi Food and Drug Authority.

Revlimid™ Summary of Product Characteristics and Patient Information Leaflet will be updated to include the appropriate information based on the above mentioned safety updates.

**Call for reporting**

*Please be reminded that adverse reactions associated with the use of Revlimid™ should be reported in accordance with the national spontaneous reporting system*

**To report any undesirable effect(s):**

Saudi Food and Drug Authority: National Pharmacovigilance and Drug Safety Center (NPC)
- Fax: +966-11-205-7662
- Toll-free: 8002490000
- Email: npc.drug@sfda.gov.sa
- Online: http://ade.sfda.gov.sa/

If you have further questions or require further information, please contact the local agent Al Salehiya:

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Yours faithfully,

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