Direct Healthcare Professional Communication

22 April 2016

Dear Healthcare Professional

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

Celgene Europe Limited in agreement with the European Medicines Agency and the Medicines and Healthcare Products Regulatory Agency 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

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

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. Please report:

- All suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- All suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website – https://yellowcard.mhra.gov.uk/

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Adverse reactions associated with the use of pomalidomide may also be reported to Celgene:
Celgene Drug Safety, Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB
Telephone: 0808 238 9908
Fax: 0844 801 0468
email: drugsafetyuk@celgene.com

Communication information

If you have any further questions or require further information, please contact your local Celgene representative at:
Celgene Medical Information, Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB
Telephone: 0844 801 0045
Fax: 0844 801 0046
email: medinfo.uk.ire@celgene.com

Yours faithfully

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Celgene Limited