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5th April 2011

Direct Healthcare Professional Communication on the potential risk of second primary malignancies in patients treated with Revlimid® (lenalidomide)

Dear Healthcare Professional:

Celgene Europe Limited, in agreement with the European Medicines Agency and the Irish Medicines Board (IMB), wishes to inform you about important new information on the clinical safety of Revlimid® (lenalidomide).

- A higher incidence of second primary malignancies in patients treated with lenalidomide compared to controls has been observed in clinical studies conducted outside of the authorised indication. Based on this observation, a review of the benefit-risk of lenalidomide in the authorised indication is being undertaken by the Committee for Medicinal Products for Human Use (CHMP).
- Revlimid is authorised in the European Union (EU) for use in combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy.
- At present, there is no recommendation to delay, modify or restrict the use of lenalidomide for patients treated according to the EU-authorised indication.
- Use of lenalidomide for indications other than the authorised indication falls outside the scope of the current benefit-risk review. The use of lenalidomide in unlicensed indications is not recommended; Healthcare Professionals should carefully consider the balance of risk and benefit of any off-label use.
- Trials currently being conducted using lenalidomide as an experimental drug are under periodic safety monitoring and the current review does not affect enrolment/participation in these trials.
- Healthcare Professionals are advised to be vigilant for the occurrence of second primary malignancies, especially in unlicensed indications, and to report such events promptly according to EU and national requirements.
- Further information will be communicated, following the conclusion of the CHMP evaluation, as necessary.

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.

Adverse events (and cases of suspected or confirmed pregnancy and foetal exposure) should be reported. Adverse event report forms and pregnancy reporting forms are included in the Healthcare Professionals Information Pack, which can be found on www.celgene.ie. Completed forms should be forwarded to Celgene Drug Safety using the contact details below:

BEFORE OFFICE MOVE 15th APRIL 2011:
Celgene Limited
Morgan House
Madeira Walk
Windsor
Berkshire
SL4 1EP
United Kingdom

AFTER OFFICE MOVE 15th APRIL 2011:
Celgene Limited
1 Longwalk Rd
Stockley Park
Uxbridge
UB11 1DB

Tel: 1800 936 217
Fax: 1800 936 477
Email: drugsafetyuk@celgene.com

Any suspected adverse reaction may also be reported direct to the IMB using the online form at www.imb.ie or using the freepost Yellow Card reporting system.

Further information
If you have any further questions or require further information, please contact your local Celgene representative at

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Yours sincerely

Medical Director
Dr Michael Thompson