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Dear **[Healthcare Professional]**

Revlimid® (lenalidomide)

New Preclinical Safety Information on Teratogenicity from Ongoing Primate Embryofoetal Development Study: EU SmPC Update

Celgene, in agreement with the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and national competent authorities wishes to inform you about the following new safety information relating to Revlimid® (lenalidomide):

- Preliminary results of an ongoing study show that lenalidomide is teratogenic in animals and is expected to be teratogenic in humans
- The SmPC for Revlimid has been updated, to reflect these preclinical results and clearly state that a teratogenic effect of lenalidomide in humans is expected
- Healthcare Professionals are advised to carefully follow the pregnancy prevention measures as specified in the **Pregnancy Prevention Programme** and the SmPC to avoid any foetal exposure to lenalidomide during pregnancy

Revlimid® (lenalidomide) is authorised in combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one previous therapy.

Important preliminary results have been obtained from an ongoing primate embryofoetal development study conducted with lenalidomide (final results expected March 2009). Malformations (short limbs, bent digits, wrist and/or tail, supernumerary or absent digits) were observed in the offspring of female monkeys who received lenalidomide during pregnancy. Thalidomide produced similar types of malformations in the same study.

Although preliminary, these results show that lenalidomide is teratogenic in animals, in a similar way as thalidomide, and is expected to be teratogenic in humans.

Prior to these findings, the EU Summary of Product Characteristics (SmPC) stated that Revlimid was a potential human teratogen and the Revlimid Pregnancy Prevention Programme was put in place to provide guidance to healthcare professionals and patients to avoid foetal exposure.

In light of these findings, the SmPC for Revlimid has been updated, to reflect these preclinical results and clearly state that a teratogenic effect of lenalidomide in humans is expected. Educational Healthcare Professional's Kit and Educational brochures for patients will also be revised to reflect this latest information.

Celgene wishes to remind Healthcare Professionals that they must carefully follow the strict pregnancy prevention measures as specified in the **Pregnancy Prevention Programme** and the SmPC to avoid any foetal exposure to lenalidomide during pregnancy.

Women of childbearing potential as defined in the SmPC should use one effective method of contraception for at least 4 weeks before therapy, during therapy, during dose interruptions and 4 weeks after therapy has finished. A pregnancy test must be performed before initiating treatment, monthly thereafter and 4 weeks after the end of treatment.

Full details, including measures to be taken by male patient to avoid foetal exposure, are also provided in the Educational Healthcare professional's kit.

The practical implementation of the Risk Management Programme in the UK will not be affected.

Should you have any questions related to the use of Revlimid, please contact Celgene (details below).

Call for Reporting

Healthcare professionals should report any adverse event suspected to be associated with the use of Thalidomide Pharmion to the Medicines and Healthcare products Regulatory Agency using a Yellow Card available directly from the MHRA, CHM Freepost, London SW8 5BR, or electronically via the MHRA website (www.yellowcard.gov.uk). Suspected adverse reactions may also be reported to Celgene by phone on 08448 010 045 (Medical Information), by fax on 08448 010 046 or e-mail at drugsafetyUK@celgene.com.

The content of this communication has been approved by the Committee for Medicinal products for Human Use (CHMP) and the MHRA.

Yours sincerely,



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