

Revlimid (lenalidomide): Ongoing Safety Review - increased risk of developing new malignancies

ISSUE: FDA is informing the public that we are aware of results from clinical trials conducted inside and outside the United States that found that patients treated with Revlimid (lenalidomide) may be at an increased risk of developing new types of cancer compared to patients who did not take the drug. FDA is currently reviewing all available information on this potential risk and will communicate any new recommendations once it has completed its review.

BACKGROUND: Revlimid is used to treat a type of blood disorder known as myelodysplastic syndrome. Revlimid is also used along with other drugs to treat people with the cancer known as multiple myeloma.

RECOMMENDATION: At this time, there is no recommendation to delay, modify or restrict the use of Revlimid for patients being treated according to the FDA-approved indications. FDA is currently reviewing all available information on this potential risks and will communicate any new recommendations once it has completed its review.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.