

IND SAFETY REPORT: INITIAL WRITTEN REPORT**TO: Division of Drug Oncology Products, Center for Drug Evaluation and Research, FDA****FAX: 301-796-9845**1. IND NUMBER
610102. AGENT NAME
CCI-779 (temsirrolimus, Torisel™)3. DATE
December 29, 20094. SPONSOR
Division of Cancer Treatment and Diagnosis, National Cancer Institute5. REPORTER'S NAME, TITLE, AND INSTITUTION
L. Austin Doyle, MD-Senior Investigator for Investigational Therapeutics 2, Investigational Drug Branch, CTEP, DCTD, NCI6. PHONE NUMBER
301-496-11967. FAX NUMBER
301-402-04288. PROTOCOL NUMBER (AE #)
GOG-0248 (AE# 1763564)9. PATIENT IDENTIFICATION
083-0248-00210. AGE
6811. SEX
Female

12. DESCRIPTION OF ADVERSE EVENT

The patient is a 68-year-old female with endometrioid endometrial adenocarcinoma who developed grade 4 hypomagnesemia while on a phase 2 trial utilizing the investigational agent temsirolimus. She began the first course of the investigational therapy on April 23, 2009, and received her last dose of temsirolimus on November 12, 2009 (Cycle 5, Day 35). On October 21, 2009 (Cycle 5, Day 13), the patient presented to the clinic for a routine blood draw which showed a magnesium level of 0.6 mg/dL (reference range: 1.6-2.6 mg/dL) from a baseline value of 1.5 mg/dL on April 17, 2009. A repeat laboratory evaluation on November 11, 2009 (Cycle 5, Day 34), showed a magnesium of 2.1 mg/dL. On December 9, 2009 (Cycle 6, Day 20), the patient's magnesium remained normal at 1.7 mg/dL. The patient continues on study. Additional information has been requested from the investigational site. There is a reasonable possibility that the experience may have been caused by the drug.

13. DOSE, ROUTE, AND SCHEDULE

Cycle = 6 weeks
Temsirrolimus 25 mg IV over 30 minutes weekly

14. DATES OF TREATMENT

The patient began the investigational therapy on April 23, 2009, and received the last dose of temsirolimus on November 12, 2009 (Cycle 5, Day 35).

15. ACCRUAL AND IND EXPERIENCE

Number of patients enrolled in NCI-sponsored clinical trials using temsirolimus = 1852.
There have been 2 other cases of hypomagnesemia reported to the NCI through AdEERS as serious adverse events for temsirolimus.

16. COMMENTS

AT THIS TIME, NO OTHER INFORMATION IS AVAILABLE. IF UPON FURTHER INVESTIGATION RELEVANT INFORMATION BECOMES AVAILABLE, THEN A FOLLOW-UP REPORT WILL BE SUBMITTED IN ACCORDANCE WITH 21CFR312.32(d)(2).

DISCLAIMER per 21 CFR 312.32(e): THIS SAFETY REPORT DOES NOT NECESSARILY REFLECT A CONCLUSION OR ADMISSION BY THE CTEP IDB SENIOR INVESTIGATOR/SPONSOR THAT THE INVESTIGATIONAL AGENT/THERAPY CAUSED OR CONTRIBUTED TO THE ADVERSE EXPERIENCE BEING REPORTED.

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