

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
61010

2. AGENT NAME
CCI-779 (temsirolimus, Torisel™)

3. DATE
September 9, 2009

4. SPONSOR
Division of Cancer Treatment and Diagnosis, National Cancer Institute

5. REPORTER'S NAME, TITLE, AND INSTITUTION
L. Austin Doyle, MD-Senior Investigator for Investigational Therapeutics 2, Investigational Drug Branch, CTEP, DCTD, NCI

6. PHONE NUMBER
301-496-1196

7. FAX NUMBER
301-402-0428

8. PROTOCOL NUMBER (AE #)
GOG-0248 (AE# 1699372)

9. PATIENT IDENTIFICATION
021-0248-004

10. AGE
64

11. SEX
Female

12. DESCRIPTION OF ADVERSE EVENT

The patient was a 64-year-old female with endometrioid endometrial adenocarcinoma who suddenly expired while on a phase 2 trial utilizing the investigational agent temsirolimus or the combination of hormonal therapy plus temsirolimus. She began the first course of the investigational therapy on June 15, 2009, and received her last dose of temsirolimus on August 31, 2009 (Cycle 2, Day 36). On September 2, 2009 (Cycle 2, Day 38), the patient was found dead in her bed by a family member. There is no further information about the cause of the patient's death at this time. 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
Temsirolimus 25 mg IV over 30 minutes weekly**

14. DATES OF TREATMENT

The patient began the investigational therapy on June 15, 2009, and received the last dose of temsirolimus on August 31, 2009 (Cycle 2, Day 36).

15. ACCRUAL AND IND EXPERIENCE

Number of patients enrolled in NCI-sponsored clinical trials using temsirolimus = 1724. There have been 4 other incidences of sudden death and 20 other incidences of death NOS reported to the NCI through AdEERS as serious adverse events for temsirolimus.

16. COMMENTS

**Also administered on this protocol:
Megestrol acetate: 80 mg PO BID × 3 weeks followed by
Tamoxifen: 20 mg PO BID × 3 week**

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.