

**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

**April 8, 2011**

4. SPONSOR

**Division of Cancer Treatment and Diagnosis, National Cancer Institute**

5. REPORTER'S NAME, TITLE, AND INSTITUTION

**L. Austin Doyle, M.D., Senior Investigator for Investigational Therapeutics 2, Investigational Drug Branch, CTEP, DCTD, NCI**

6. PHONE NUMBER

**301-496-1196**

7. FAX NUMBER

**301-402-0428**

8a. PROTOCOL NUMBER (AE #)

**NCIC-199 (AE# 1698752)**

8b. AE GRADE: AE

**Grade 5: Death: Death NOS**

9. PATIENT IDENTIFICATION

**CAVK0003**

10. AGE

**67 years**

11. SEX

**Female**

12. DESCRIPTION OF ADVERSE EVENT

**The patient was a 67-year-old female with squamous cell cervical cancer who expired while on a phase 2 trial utilizing the investigational agent temsirolimus. She began the first course of the investigational therapy on November 26, 2010, and received her last dose of temsirolimus on March 4, 2011 (Cycle 3, Day 15). On March 7, 2011 (Cycle 3, Day 18), the patient was admitted to the hospital for nausea and vomiting of three days duration. She was treated with IV ondansetron. On March 21, 2011, the patient developed deep vein thrombosis, and expired on March 28, 2011. 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 = 28 Days****Temsirolimus: 25 mg IV over 30 minutes on Days 1, 8, 15, and 22.**

14. DATES OF TREATMENT

**The patient began the investigational therapy on November 26, 2010, and received her last dose of temsirolimus on March 4, 2011 (Cycle 3, Day 15).**

15. ACCRUAL AND IND EXPERIENCE

**Number of patients enrolled in NCI-sponsored clinical trials using temsirolimus = 2638**

**There have been 105 other cases of death NOS and 4 other cases of sudden death 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 21CFR 312.32 (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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