

IND SAFETY REPORT: FOLLOW-UP #1

TO: *Division of Biologic Oncology Products, Center for Drug Evaluation and Research, FDA*

FAX: 301-796-9849

301-796-9845

Division of Drug Oncology Products, Center For Drug Evaluation and Research, FDA

1. IND NUMBER 7921 61010	2. AGENT NAME Bevacizumab (rhuMab VEGF) (704865) CCI-779 (tamsirolimus, Torisel TM)	3. DATE July 15, 2009
--------------------------------	---	---------------------------------

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

5. REPORTER'S NAME, TITLE, AND INSTITUTION
Helen Chen, MD-Associate Branch Chief for Investigational Therapeutics 3,
Investigational Drug Branch, CTEP, DCTD, NCI
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 #)
E2804 (AE# 1257729)

9. PATIENT IDENTIFICATION
28147

10. AGE
62

11. SEX
Male

12. DESCRIPTION OF ADVERSE EVENT

The patient was a 62-year-old male with renal cell adenocarcinoma who expired while on a phase 2 trial utilizing the investigational agents sorafenib, bevacizumab and tamsirolimus. He had not started the sorafenib arm of the study. The patient began the investigational therapy on April 30, 2009, and received his last dose of bevacizumab on May 14, 2009 (Cycle 1, Day 15) and the last dose of tamsirolimus on May 21, 2009 (Cycle 1, Day 22). On May 25, 2009 (Cycle 1, Day 26), the patient was found dead in his home by his friend. At this time, the cause of death is unknown. The result of an autopsy is pending. 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.
Tamsirolimus 25 mg IV over 30 minutes on Days 1, 8, 15, and 22
Bevacizumab 10 mg/kg IV over 30-90 minutes on Days 1 and 15

14. DATES OF TREATMENT

The patient began the investigational therapy on April 30, 2009, and received the last dose of bevacizumab on May 14, 2009 (Cycle 1, Day 15) and the last dose of tamsirolimus on May 21, 2009 (Cycle 1, Day 22).

15. ACCRUAL AND IND EXPERIENCE

Number of patients enrolled in NCI-sponsored clinical trials using bevacizumab = 21421 and for tamsirolimus = 1665. There have been 15 other incidences of death NOS and 4 other incidences of sudden death reported to the NCI through AdEERS as serious adverse events for tamsirolimus; and 52 other incidences of death NOS and 34 other incidences of sudden death reported to the NCI through AdEERS as serious adverse events for bevacizumab.

16. COMMENTS

FOLLOW-UP:

Based upon further investigation, the Senior Investigator at the Investigational Drug Branch has decided not to file this adverse event expeditiously.

0002