

IND SAFETY REPORT: FOLLOW-UP #1TO: *Division of Biologic Oncology Products, Center for Drug Evaluation and Research, FDA*

FAX: 301-796-9849

1. IND NUMBER
79212. AGENT NAME
Bevacizumab (rhuMAb VEGF)3. DATE
May 4, 20114. SPONSOR
Division of Cancer Treatment and Diagnosis, National Cancer Institute5. REPORTER'S NAME, TITLE, AND INSTITUTION
Helen Chen, MD-Associate Branch Chief for Investigational Therapeutics 3,
Investigational Drug Branch, CTEP, DCTD, NCI6. PHONE NUMBER
301-496-11967. FAX NUMBER
301-402-04288a. PROTOCOL NUMBER (AE #)
CALGB-90601 (AE # 1740963)8b. AE GRADE: AE
Grade 5: Death NOS9. PATIENT IDENTIFICATION
12234110. AGE
50 yrs11. SEX
Male

12. DESCRIPTION OF ADVERSE EVENT

The patient was a 50-year-old male with transitional cell carcinoma of the urothelial tract who expired while on a phase 3 trial utilizing the investigational agent bevacizumab/placebo in combination with cisplatin and gemcitabine. He began the first dose of the investigational therapy on September 9, 2010, and received the last dose of bevacizumab/placebo on March 3, 2011 (Cycle 9, Day 1), the last doses of cisplatin on December 30, 2010 (Cycle 6, Day 1), and the last dose of gemcitabine on January 6, 2010 (Cycle 6, Day 8). As per site phone conversation, the patient was taken off the study due to disease progression on March 3, 2011. He expired on April 5, 2011. At this time, there is no other information available. 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 = 21 days
Bevacizumab/placebo 15 mg/kg IV over 30-90 minutes on Day 1

14. DATES OF TREATMENT The patient began the investigational therapy on September 9, 2010, and received the last dose of bevacizumab/placebo on March 3, 2011 (Cycle 9, Day 1).

15. ACCRUAL AND IND EXPERIENCE Number of patients enrolled in NCI-sponsored clinical trials using bevacizumab = 31,666. There have been 172 other cases of deaths reported to the NCI as serious adverse events through AdeERS for bevacizumab.

16. COMMENTS The following was also administered:
Cisplatin 70 mg/m² IV on Day 1 and Gemcitabine 1000 mg/m² IV over 30 minutes on Days 1 and 8 for Cycles 1-6.**FOLLOW-UP: BASED UPON FURTHER INVESTIGATION, THE SENIOR INVESTIGATOR HAS DECIDED THAT THIS ADVERSE EVENT IS UNRELATED TO THE INVESTIGATIONAL AGENT/THERAPY.**

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