

IND SAFETY REPORT: INITIAL WRITTEN REPORT**TO: Division of Biologic Oncology Products, Center for Drug Evaluation and Research, FDA****FAX: 301-796-9849**

1. IND NUMBER

7921

2. AGENT NAME

Bevacizumab (rhuMab VEGF)

3. DATE

December 28, 2009

4. SPONSOR

Division of Cancer Treatment and Diagnosis, National Cancer Institute

5. REPORTER'S NAME, TITLE, AND INSTITUTION

Kevin Conlon, MD-Senior Investigator for Investigational Therapeutics 3, CTEP, DCTD, NCI

6. PHONE NUMBER

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8. PROTOCOL NUMBER (AE #)

E1305 (AE # 1858857)

9. PATIENT IDENTIFICATION

13038

10. AGE

52

11. SEX

Female

12. DESCRIPTION OF ADVERSE EVENT

The patient was a 52-year-old female with head and neck squamous cell carcinoma who expired while on a phase 3 trial utilizing the investigational agent bevacizumab in combination with cisplatin and docetaxel. She began the first and only course of the investigational treatment on December 16, 2009. The site reported to CTEP that the patient died on December 24, 2009 (Cycle 1, Day 9). The event was reported as Death, NOS. At this time, there is no other information about the cause of the patient's death. 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 15 mg/kg IV over 30-90 minutes on Day 1**14. DATES OF TREATMENT **The patient began the investigational therapy on December 16, 2009. This was her only dose of bevacizumab.**15. ACCRUAL AND IND EXPERIENCE **Number of patients enrolled in NCI-sponsored clinical trials using bevacizumab = 24,451. There have been 67 other cases of death NOS and 48 other cases of sudden death reported to the NCI as serious adverse events through AdEERS for bevacizumab.**16. COMMENTS **The following was also administered:****Cisplatin 75 mg/m² IV over 1-2 hours on Day 1 and Docetaxel 75 mg/m²/day IV over 1 hour on Day 1. First and only dose of each administered on December 16, 2009.****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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