

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 February 24, 2011
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		6. PHONE NUMBER 301-496-1196
		7. FAX NUMBER 301-402-0428
8a. PROTOCOL NUMBER (AE #) E1305 (AE# 1442953)	8b. AE GRADE: AE Grade 5: Death not associated with CTCAE term: Death NOS	
9. PATIENT IDENTIFICATION 13098	10. AGE 53 yrs	11. SEX Male
12. DESCRIPTION OF ADVERSE EVENT The patient was a 53-year-old male with squamous cell carcinoma of the head and neck who expired suddenly while on a phase 3 trial utilizing the investigational agent bevacizumab in combination with docetaxel and cisplatin. He began the first course of the investigational therapy on December 16, 2010, and received the last doses of bevacizumab, docetaxel, and cisplatin on January 26, 2011 (Cycle 3, Day 1). On February 14, 2011 (Cycle 3, Day 20), the site observed the patient's name in the local newspaper obituary. Further investigation revealed that he was found dead at home alone on February 12, 2011 (Cycle 3, Day 18). The patient's death certificate is still pending. An autopsy was not done. There is no additional information regarding 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 = 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, 2010, and received the last dose of bevacizumab on January 26, 2011 (Cycle 3, Day 1).		
15. ACCRUAL AND IND EXPERIENCE Number of patients enrolled in NCI-sponsored clinical trials using bevacizumab = 31,449. There have been 118 other cases of death NOS and 50 other cases of sudden death reported to the NCI as serious adverse events through AdEERS for bevacizumab.		
16. COMMENTS Also administered on this protocol: Docetaxel: 75 mg/m² IV over 1 hour on Day 1 Cisplatin: 75 mg/m² IV over 1-2 hours on Day 1		
<p>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).</p> <p>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.</p>		

0002