

**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  
**September 22, 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 #)  
**CALGB-40502 (AE# 1037258)**

8b. AE GRADE: AE  
**Grade 4: Wound infection**

9. PATIENT IDENTIFICATION  
**125323**

10. AGE  
**43 yrs**

11. SEX  
**Female**

12. DESCRIPTION OF ADVERSE EVENT

**The patient is a 43-year-old female with metastatic invasive breast carcinoma who experienced a grade 4 wound infection while on a phase 3 trial utilizing the investigational agent bevacizumab in combination with nab-paclitaxel. She began the first course of the investigational therapy on March 28, 2011 and received the last doses of bevacizumab and nab-paclitaxel on July 21, 2011 (Cycle 5, Day 1). On July 27, 2011, the patient presented to the emergency room with a 7-day history of progressive right gluteal pain and swelling. She was admitted to the hospital for a perineal abscess, and started on vancomycin and analgesics. Later that day, she underwent an incision and drainage of the perineal abscess with debridement of the abscess cavity and necrotic tissue over an area of 60 cm, as well as some debridement of the necrotic tissue down to the level of the subcutaneous fat. Penrose drains were placed to facilitate drainage, and she was sent to the recovery room in stable condition. The patient received more antibiotics and was discharged from the hospital on August 3, 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  
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 March 28, 2011, and received the last dose of bevacizumab on July 21, 2011 (Cycle 5, Day 1).**

15. ACCRUAL AND IND EXPERIENCE

**Number of patients enrolled in NCI-sponsored clinical trials using bevacizumab = 34,421. Infection is a known event for bevacizumab.**

16. COMMENTS

**Also administered on this protocol: Nab-Paclitaxel: 150 mg/m<sup>2</sup> IV over 30 minutes on Days 1, 8, and 15.**

**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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