

IND SAFETY REPORT: FOLLOW-UP #1

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

FAX: 301-796-9845

301-796-9849

1. IND NUMBER
59699
7921

2. AGENT NAME
BMS 247550 (ixabepilone, Ixempra)
Bevacizumab (rhuMAb VEGF)

3. DATE
November 12, 2009

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

5. REPORTER=S NAME, TITLE, AND INSTITUTION
Richard Piekarz, MD-Senior Investigator for Investigational Therapeutics 2,
Investigational Drug Branch, CTEP, DCTD, NCI
Kevin Conlon, MD-Senior Investigator for Investigational Therapeutics 3,
Investigational Drug Branch, CTEP, DCTD, NCI

6. PHONE NUMBER
301-496-1196

7. FAX NUMBER
301-402-0428

8. PROTOCOL NUMBER (AE #)
CALGB-40502 (AE # 1857033)

9. PATIENT IDENTIFICATION
116917

10. AGE
56

11. SEX
Female

12. DESCRIPTION OF ADVERSE EVENT
The patient was a 56-year-old female with invasive breast carcinoma who died while on a phase 3 study using the investigational agents bevacizumab and ixabepilone. She began her first course of treatment on August 12, 2009, and received her last dose of bevacizumab and ixabepilone on August 26, 2009, (Cycle 1, Day 15). A family member of the patient notified the hospital that the patient died on September 21, 2009. No further information is available at this moment. Additional information has been requested from the investigational site. There is a reasonable possibility that the adverse event may have been caused by the drug.

13. DOSE, ROUTE, AND SCHEDULE
Ixabepilone 16 mg/m² IV over 1 hour on Days 1, 8, and 15
Bevacizumab 10 mg/kg IV over 30-90 min on Days 1 and 15

14. DATES OF TREATMENT
The patient began the investigational therapy on August 12, 2009, and received the last dose of bevacizumab and ixabepilone on August 26, 2009 (Cycle 1, Day 15).

15. ACCRUAL AND IND EXPERIENCE
The number of patients enrolled in NCI-sponsored clinical trials using bevacizumab = 23,109 and the number of patients enrolled in NCI-sponsored clinical trials using ixabepilone is 1,867. There have been 66 death NOS incidences reported to the NCI through AdEERS as serious adverse events for bevacizumab and 1 death NOS incidences reported to the NCI through AdEERS as serious adverse events for ixabepilone

16. COMMENTS

Follow-up # 1:
Based upon further investigation, the Senior Investigator at the Investigational Drug Branch has decided not to file this report expeditiously to the FDA.

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