

## IND SAFETY REPORT: INITIAL WRITTEN REPORT

**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**

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1. IND NUMBER <b>59699</b>  <b>7921</b>	2. AGENT NAME <b>BMS 247550 (ixabepilone, Ixemptra)</b>  <b>Bevacizumab (rhuMAb VEGF)</b>	3. DATE <b>September 30, 2009</b>
4. SPONSOR <b>Division of Cancer Treatment and Diagnosis, National Cancer Institute</b>		
5. REPORTER=S NAME, TITLE, AND INSTITUTION <b>Richard Piekarz, MD-Senior Investigator for Investigational Therapeutics 2, Investigational Drug Branch, CTEP, DCTD, NCI</b>  <b>Kevin Conlon, MD-Senior Investigator for Investigational Therapeutics 3, Investigational Drug Branch, CTEP, DCTD, NCI</b>		6. PHONE NUMBER <b>301-496-1196</b>  7. FAX NUMBER <b>301-402-0428</b>
8. PROTOCOL NUMBER (AE #) <b>CALGB-40502 (AE # 1857033)</b>		
9. PATIENT IDENTIFICATION <b>116917</b>	10. AGE <b>56</b>	11. SEX <b>Female</b>
12. DESCRIPTION OF ADVERSE EVENT <b>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.</b>		
13. DOSE, ROUTE, AND SCHEDULE <b>Ixabepilone 16 mg/m<sup>2</sup> IV over 1 hour on Days 1, 8, and 15</b>  <b>Bevacizumab 10 mg/kg IV over 30-90 min on Days 1 and 15</b>		
14. DATES OF TREATMENT <b>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).</b>		
15. ACCRUAL AND IND EXPERIENCE <b>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</b>		
16. COMMENTS  <b>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).</b>  <b>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.</b>		

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