

**IND SAFETY REPORT: INITIAL WRITTEN REPORT**

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

**FAX: 301-796-9845**

1. IND NUMBER  
**70116**  
**58443**

2. AGENT NAME  
**CC-5013 (lenalidomide, Revlimid®)**  
**PS-341 (bortezomib; Velcade®)**

3. DATE  
**March 27, 2009**

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

5. REPORTER'S NAME, TITLE, AND INSTITUTION  
**Howard Streicher, MD – Senior Investigator for Investigational Therapeutics 3, Investigational Drug Branch, CTEP, DCTD, NCI**

6. PHONE NUMBER  
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7. FAX NUMBER  
**301-402-0428**

8. PROTOCOL NUMBER (AE #)  
**S0777 (1673759)**

9. PATIENT IDENTIFICATION  
**215542**

10. AGE  
**61**

11. SEX  
**Male**

12. DESCRIPTION OF ADVERSE EVENT

**The patient was a 61-year-old male with multiple myeloma who died while on a phase 3 trial using the investigational agents lenalidomide in combination with bortezomib. He began investigational therapy with lenalidomide and bortezomib on March 13, 2009, and received the last dose of lenalidomide on March 15 (Cycle 1, Day 3), and the last dose of bortezomib on March 13, 2009 (Cycle 1, Day 1). On March 15, 2009, the patient was found dead in his home. An autopsy was performed; results are pending. The patient had a history of coronary artery disease and was scheduled for coronary artery bypass graft surgery in April. There is a reasonable possibility that the experience may have been caused by the drug. Additional information has been requested from the investigational site.**

13. DOSE, ROUTE, AND SCHEDULE

**Cycle = 21 days**  
**Lenalidomide 25 mg PO on days 1-14**  
**Bortezomib: 1.3 mg/m<sup>2</sup> IVP on days 1, 4, 8, and 11**

14. DATES OF TREATMENT

**The patient started investigational treatment on March 13, 2009, and received the last dose of lenalidomide on March 15, 2009 (Cycle 1, Day 3), and the last dose of bortezomib on March 13, 2009 (Cycle 1, Day 1).**

15. ACCRUAL AND IND EXPERIENCE

**Number of patients enrolled in NCI-sponsored clinical trials using lenalidomide = 1541, and bortezomib = 2733. Other incidences reported to the NCI through AdEERS as serious adverse events: 4 sudden deaths and 6 death NOS for lenalidomide; 10 sudden deaths and 14 death NOS for bortezomib.**

16. COMMENTS

**Also administered on this protocol: Dexamethasone 20 mg PO on days 1, 2, 4, 5, 8, 9, 11, and 12; Last administered March 14, 2009; Aspirin 325 mg PO daily**

**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.**