

**IND SAFETY REPORT: FOLLOW-UP #1**

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

**May 28, 2009**

4. SPONSOR

Division of Cancer Treatment and Diagnosis, National Cancer Institute

5. REPORTER'S NAME, TITLE, AND INSTITUTION

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6. PHONE NUMBER

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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

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**UPON FURTHER REVIEW OF THE ADDITIONAL INFORMATION RECEIVED, THE SENIOR INVESTIGATOR AT THE INVESTIGATIONAL DRUG BRANCH HAS DECIDED NOT TO FILE THIS REPORT EXPEDITIOUSLY TO THE FDA.**

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