

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

January 30, 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 (1358268)

9. PATIENT IDENTIFICATION

211743

10. AGE

57

11. SEX

Female

12. DESCRIPTION OF ADVERSE EVENT

The patient was a 57-year-old female with multiple myeloma who died suddenly while on a phase 3 trial using the investigational agent lenalidomide in combination with bortezomib. She began investigational therapy with lenalidomide and bortezomib on August 14, 2008, and received her last dose of lenalidomide on August 23, 2008 (Cycle 1, Day 10), and her last dose of bortezomib on August 21, 2008 (Cycle 1, Day 8). The patient was started at a reduced dose of lenalidomide due to an increased creatinine level and was hospitalized for days 1-8 of treatment. She was discharged on August 21, 2008. While hospitalized, in addition to the protocol treatment, she also received Lovenox® from August 11, 2008, to August 16, 2008. On August 23, 2008, at home, the patient called for her family and when they came into her room she fell backwards and was unresponsive. EMS was called and when they arrived they found the patient to be in asystole and attempted to resuscitate her. The patient was pronounced dead upon arrival to the hospital emergency room. An autopsy was performed and the results are pending. Additional information has been requested from the investigational site.

13. DOSE, ROUTE, AND SCHEDULE

Lenalidomide 25 mg PO on days 1-14, every 21 days

Bortezomib: 1.3 mg/m² IVP on days 1, 4, 8, and 11, every 21 days

14. DATES OF TREATMENT

The patient started investigational treatment on August 14, 2008, and received the last dose of lenalidomide on August 23, 2008 (Cycle 1, Day 10), and the last dose of bortezomib on August 21, 2008 (Cycle 1, Day 8).

15. ACCRUAL AND IND EXPERIENCE

Number of patients enrolled in NCI-sponsored clinical trials using lenalidomide = 1278, and bortezomib = 2512. Other incidences reported to the NCI through AdEERS as serious adverse events: 2 sudden deaths and 6 death NOS for lenalidomide; 9 sudden deaths and 16 death NOS for bortezomib.

16. COMMENTS

The patient started lenalidomide at 5mg PO daily; Total dose = 50 mg.

Also administered on this protocol: Dexamethasone 20 mg PO daily on days 1, 2, 4, 5, 8, 9, 11, and 12; Last administered August 22, 2008; Aspirin 325 mg PO daily

FOLLOW-UP: BASED UPON FURTHER INVESTIGATION, THIS ADVERSE EVENT IS CONSIDERED UNRELATED TO THE INVESTIGATIONAL AGENT/THERAPY.

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