

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
74019

2. AGENT NAME
Sunitinib malate (SU011248 L-malate; Sutent[®])

3. DATE
June 23, 2009

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

5. REPORTER=S NAME, TITLE, AND INSTITUTION
Pamela Harris, MD –Senior Investigator for Investigational Therapeutics 1, Investigational Drug Branch, CTEP, DCTD, NCI

6. PHONE NUMBER
301-496-1196

7. FAX NUMBER
301-402-0428

8. PROTOCOL NUMBER (AE #)
CALGB-30607 (AE # 1491694)

9. PATIENT IDENTIFICATION
115788

10. AGE
63

11. SEX
Male

12. DESCRIPTION OF ADVERSE EVENT

The patient is a 63-year-old male with non-small cell lung cancer who experienced a grade 3 muscle weakness, while on a phase 3 trial using the investigational agent sunitinib. The patient began his first cycle of treatment on May 18, 2009, and received his last dose of sunitinib on June 2, 2009 (Cycle 1, Day 16). On June 3, 2009 (Cycle 1, Day 17), the patient presented to the emergency room complaining of fever, fatigue and weakness. He was admitted to the hospital on the same day. While he was hospitalized, the patient had severe thrombocytopenia and grade 2 hypoxia. On June 3, 2009, a CT scan showed no evidence of pulmonary embolus, a lower extremity Dopplers ultrasound was negative, a chest X-rays showed no evidence of pneumonia, and an EKG was essentially unremarkable with no acute issues. The chemotherapy was held, and the patient was discharged on June 5, 2009. The patient returned on June 8, 2009, for oncology follow-up and Cycle 2, Day 1 evaluation. His platelet count was 39,000/mm³ (reference range: 150,000-400,000/mm³), and Cycle 2 was held. He was to return to the clinic in one week for re-evaluation. Additional information has been requested from the investigational site. There is a reasonable possibility that the experience may have been caused by the drug.

13. DOSE, ROUTE, AND SCHEDULE

Cycle = 21 days
Sunitinib: 37.5 mg/m² or placebo PO QD

14. DATES OF TREATMENT

The patient started the investigational therapy on May 18, 2009, and received the last dose of sunitinib on June 2, 2009 (Cycle 1, Day 16).

15. ACCRUAL AND IND EXPERIENCE

Number of patients enrolled in NCI-sponsored clinical trials using sunitinib = 1805.
There have been eight other incidences of muscle weakness NOS reported to the NCI through AdEERS as serious adverse events for sunitinib.

16. COMMENTS

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.

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