

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
February 19, 2010

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 #)
7898 (AE# 1788898)

9. PATIENT IDENTIFICATION
2511716

10. AGE
57

11. SEX
Male

12. DESCRIPTION OF ADVERSE EVENT

The patient is a 57-year-old male with adenocarcinoma of the esophagus who experienced a grade 4 cerebrovascular ischemia while on a phase 1 trial using the investigational agent sunitinib malate. He began his first course of treatment on June 10, 2009 and received the last dose of sunitinib malate on September 1, 2009 (Cycle 2, Day 22). On September 2, 2009, the patient was admitted to the hospital with confusion, ataxia, and blurred vision. An MRI of the brain revealed a markedly increased signal involving the left occipital lobe, a mildly increased signal in a gyriform-like pattern, and a single focus of increased signal involving the deep white matter of the left cerebral hemisphere. The patient was transferred to the research hospital on September 3, 2009. An MRA was performed to confirm the diagnosis of cerebrovascular accident, as shown by the prior MRI. The patient received 2 units of packed red blood cells due to his anemia. Neurology consultation was done, which recommended an echocardiogram with bubble study, lower extremity Doppler® ultrasound, and initiation of aspirin therapy. His symptoms began to improve and he was discharged on September 4, 2009. 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 = 6 weeks
Sunitinib malate: 50 mg PO daily, Weeks 1, 2, 4, and 5**

14. DATES OF TREATMENT

The patient started the investigational therapy on June 10, 2009, and received the last dose of sunitinib malate on September 1, 2009, (Cycle 2, Day 22).

15. ACCRUAL AND IND EXPERIENCE

**Number of patients enrolled in NCI-sponsored clinical trials using sunitinib malate = 2322
There have been 13 other cases of cerebrovascular ischemia reported to the NCI through AdEERS as serious adverse events for sunitinib malate.**

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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