

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
July 27, 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 I, Investigational Drug Branch, CTEP, DCTD, NCI

6. PHONE NUMBER
301-496-1196

7. FAX NUMBER
301-402-0428

8. PROTOCOL NUMBER (AE #)
7713 (AE # 1168449)

9. PATIENT IDENTIFICATION
062-021

10. AGE
52

11. SEX
Female

12. DESCRIPTION OF ADVERSE EVENT
The patient is a 52-year-old female with endometrioid endometrial adenocarcinoma who experienced a grade 4 pulmonary embolism while on a phase 2 trial using the investigational agent sunitinib. She began her first course of treatment on May 4, 2009, and received the last dose of sunitinib on July 3, 2009 (Cycle 2, Day 19). On July 21, 2009 (Cycle 2, Day 37), a chest CT scan revealed an embolism in the right lower lobe pulmonary artery and the right lower lobe posterior and lateral segmental branches. The patient was asymptomatic. The patient is currently receiving treatment for this event. Additional information has been requested from the investigative site. There is a reasonable possibility that the experience may have been caused by the drugs

13. DOSE, ROUTE, AND SCHEDULE
**Cycle = 6 weeks
Sunitinib: 50 mg PO daily for 4 weeks**

14. DATES OF TREATMENT
The patient started the investigational therapy on May 4, 2009, and received the last dose of sunitinib on July 3, 2009 (Cycle 2, Day 19).

15. ACCRUAL AND IND EXPERIENCE
**Number of patients enrolled in NCI-sponsored clinical trials using sunitinib = 1958.
There have been 23 other cases of thrombosis/thrombus/emboli 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 FOLLOWUP REPORT WILL BE SUBMITTED IN ACCORDANCE WITH 21 CFR312.32(d)(2).

DISCLAIMER per 21CFR 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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