

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
740192. AGENT NAME
Sunitinib malate (SU011248 L-malate; Sutent®)3. DATE
January 19, 2011

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

8a. PROTOCOL NUMBER (AE #)

GOG-0231C (AE# 1423773)

8b. AE GRADE: AE

Grade 4: Secondary Malignancy: Myelodysplastic Syndrome

9. PATIENT IDENTIFICATION

094-0231C-005

10. AGE

61 yrs

11. SEX

Female

12. DESCRIPTION OF ADVERSE EVENT

The patient is a 61-year-old female with leiomyosarcoma of the uterus who experienced grade 4 myelodysplastic syndrome after completing a phase 2 study utilizing the investigational agent sunitinib malate. She began the investigational therapy on March 19, 2007, and received her last dose of sunitinib malate on July 10, 2007 (Cycle 3, Day 28). On December 27, 2010, the patient was evaluated for intermittent nose-bleeds, increasing fatigue, intermittent night sweats, and low-grade fever of 1-month duration. She had a white blood cell count of $5.2 \times 10^9/L$ (reference range: $5.0-10.0 \times 10^9$), hemoglobin of 6.7 g/dL (reference range: 12.0-16.0 g/dL), and a platelet count of 9×10^9 (reference range: $150-400 \times 10^9$). The patient was admitted to the hospital for further evaluation, and was transfused with 4 units of platelets and 2 units of packed red blood cells within a 24-hour period. A bone marrow biopsy the following day, showed trilineage myelodysplasia. She was transferred to the bone marrow transplant unit for further management. CT scans of the chest, abdomen, and pelvis were negative for an acute process. On December 31, 2010, the patient developed a fever of 101° F, and she was started on ciprofloxacin. She also received an additional unit of platelets. After a lengthy discussion with the patient and her husband, they both agreed to participate in another study. She was discharged home that day with plans for follow-up. 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 \times 4 weeks, then 2 weeks rest, continuous**

14. DATES OF TREATMENT

The patient started the investigational therapy on March 19, 2007, and received the last dose of sunitinib malate on July 10, 2007 (Cycle 3, Day 28).

15. ACCRUAL AND IND EXPERIENCE

Number of patients enrolled in NCI-sponsored clinical trials using sunitinib malate = 2834**There has been 1 other case of secondary malignancy reported to the NCI through AdEERS as a serious adverse event 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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