

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
July 1, 20104. SPONSOR
Division of Cancer Treatment and Diagnosis, National Cancer Institute5. REPORTER'S NAME, TITLE, AND INSTITUTION
Pamela Harris, MD – Senior Investigator for Investigational Therapeutics 1, Investigational Drug Branch, CTEP, DCTD, NCI6. PHONE NUMBER
301-496-11967. FAX NUMBER
301-402-04288. PROTOCOL NUMBER (AE #)
CALGB-30607 (AE# 1272083)8b. AE GRADE: AE
Grade 5: Sudden death9. PATIENT IDENTIFICATION
12092710. AGE
54 years11. SEX
Female12. DESCRIPTION OF ADVERSE EVENT
The patient was a 54-year-old female with non-small cell lung carcinoma who died suddenly while on a phase 3 trial using the investigational agent sunitinib malate. She began her first course of treatment on June 8, 2010, and received the last dose of sunitinib malate on June 27, 2010 (Cycle 1, Day 20). On June 28, 2010 (Cycle 1, Day 21), the clinical site received a call from an outside emergency department stating that the patient had been admitted in full arrest. CPR was started but she suddenly was noted to be coughing out blood. She expired on the same day. 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 malate: 37.5 mg or Placebo PO QD**14. DATES OF TREATMENT
The patient started the investigational therapy on June 8, 2010 and received the last dose of sunitinib malate on June 27, 2010 (Cycle 1, Day 20).15. ACCRUAL AND IND EXPERIENCE
**Number of patients enrolled in NCI-sponsored clinical trials using sunitinib malate=2503
There have been four other cases of sudden death and five other cases of death NOS 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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