

**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  
**March 5, 2009**4. SPONSOR  
**Division of Cancer Treatment and Diagnosis, National Cancer Institute**5. REPORTER=S NAME, TITLE, AND INSTITUTION  
**S. Percy Ivy, MD -Associate Chief 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-30704 (1140081)**9. PATIENT IDENTIFICATION  
**113728**10. AGE  
**46**11. SEX  
**Female**

## 12. DESCRIPTION OF ADVERSE EVENT

The patient was a 46-year-old female with non-small cell lung cancer who experienced a grade 5 hemorrhage, pulmonary/upper respiratory: broncopulmonary NOS, while on a phase 2 trial using the investigational agent sunitinib. She began her first course of treatment on November 19, 2008, and received the last dose of sunitinib on February 9, 2009, (Cycle 4, Day 12). The patient began cycle 4 of treatment on January 29, 2009 with dose reduced to 25 mg due to grade 3 LFT abnormalities which subsequently resolved. On February 10, 2009, the patient called the treating physicians to report one episode of coughing up a quarter size clot of blood. The patient was on a road trip with her brother so she could not return for evaluation. The treating physicians advised the patient to stop the sunitinib and to go to the Emergency Room. On February 10, 2009, at 10 PM the treating physicians received a call from a hospital Emergency Room reporting that patient passed away after having massive hemoptysis. The patient was not able to be intubated due to massive amount of blood. She became asystolic and then experienced cardiopulmonary arrest. Her brother who was with her requested resuscitation attempts to be stopped. 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/m<sup>2</sup> PO QD**

## 14. DATES OF TREATMENT

**The patient started the investigational therapy on November 19, 2008, and received the last dose of sunitinib on February 9, 2009 (Cycle 4, Day 12).**

## 15. ACCRUAL AND IND EXPERIENCE

**Number of patients enrolled in NCI-sponsored clinical trials using sunitinib = 1622**  
**There have been no other incidences of hemorrhage, pulmonary/upper respiratory: Broncopulmonary NOS reported to the NCI through AdEERS as serious adverse vents 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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