

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 7, 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 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 (AE#1877573)		
9. PATIENT IDENTIFICATION 115514	10. AGE 44	11. SEX Female
12. DESCRIPTION OF ADVERSE EVENT The patient was a 44-year-old female with non-small cell lung cancer who expired from cardiac ischemia/infarction while on a phase 2 trial using the investigational agent sunitinib in combination with pemetrexed. The patient began her first cycle of treatment on April 20, 2009, and received her last dose of pemetrexed on June 2, 2009 (Cycle 3, Day 1) and her last dose of sunitinib on June 16, 2009 (Cycle 3, Day 15). On June 18, 2009 (Cycle 3, Day 17), the patient presented to a hospital complaining of dyspnea. Her cardiac enzymes were elevated and her ECG changes were consistent with a myocardial infarction. She became hypotensive for which she was given normal saline, dopamine, epinephrine, Levophed® and Neosynephrine®. She rapidly developed atrial fibrillation and ventricular tachycardia. Resuscitation efforts resulted in normal sinus rhythm, and the patient was transferred to another hospital. A bedside echocardiogram showed dramatically lowered left ventricular function. Her liver enzymes were elevated, and she developed disseminated intravascular coagulation. She finally became asystolic despite transcuteaneous pacing with full pressor and ventilatory support. She was pronounced dead at 12:45 pm that same day (June 18, 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 = 21 days Sunitinib: 37.5 mg PO daily		
14. DATES OF TREATMENT The patient started the investigational therapy on April 20, 2009. She received the last dose of sunitinib on June 16, 2009 (Cycle 3, Day 15).		
15. ACCRUAL AND IND EXPERIENCE Number of patients enrolled in NCI-sponsored clinical trials using sunitinib = 1833. There have been nine other cases of cardiac ischemia/infarction reported to the NCI through AdeERS as serious adverse events for sunitinib.		
16. COMMENTS Also administered on this protocol: Pemetrexed 500 mg/m² IV over 10 min on Day 1; last administered on June 2, 2009 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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