

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
611352. AGENT NAME
STI571 (imatinib, Gleevec®)3. DATE
August 29, 20114. SPONSOR
Division of Cancer Treatment and Diagnosis, National Cancer Institute5. REPORTER'S NAME, TITLE, AND INSTITUTION
**Naoko Takabe, MD, PhD - Senior Investigator for Investigational Therapeutics 1,
Investigational Drug Branch, CTEP, DCTD, NCI**6. PHONE NUMBER
301-496-11967. FAX NUMBER
301-402-04288a. PROTOCOL NUMBER (AE #)
8603 (AE# 1255424)8b. AE GRADE: AE
Grade 5: Sudden Death9. PATIENT IDENTIFICATION
3532065310. AGE
31 years11. SEX
Female

12. DESCRIPTION OF ADVERSE EVENT

The patient was a 31-year-old female with synovial sarcoma who died suddenly while on a phase 1b/2 study utilizing the investigational agent imatinib in combination with everolimus. She began the first course of treatment on August 5, 2011, and received the last dose of imatinib on August 19, 2011 (Cycle 1, Day 15) and the last dose of everolimus on August 18, 2011 (Cycle 1, Day 14). No further information is available at this time. 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 = 28 days
Imatinib: 400 mg PO daily**

14. DATES OF TREATMENT

The patient began the investigational therapy on August 5, 2011, and received her last dose of imatinib on August 19, 2011 (Cycle 1, Day 15).

15. ACCRUAL AND IND EXPERIENCE

**Number of patients enrolled in NCI-sponsored clinical trials using imatinib = 4285
There has been 1 other case of sudden death, and 23 other cases of death NOS reported to the NCI through AdEERS as serious adverse events for imatinib.**

16. COMMENTS:

**Also administered on this protocol:
Everolimus: 10 mg PO QD**

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.