

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
March 23, 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 #)
7735 (AE# 1274440)9. PATIENT IDENTIFICATION
14696-4210. AGE
5011. SEX
Male

12. DESCRIPTION OF ADVERSE EVENT

The patient is a 50-year-old male with follicular thyroid carcinoma who experienced grade 4 laryngeal edema while on a phase 2 trial using the investigational agent sunitinib malate. He began his first course of treatment on October 23, 2007 and received the last dose of sunitinib malate on March 11, 2010 (Cycle 20, Day 28). The patient, who had complained of shortness of breath and inability to swallow, was sent to the emergency room on March 17, 2010 (Cycle 20, Day 34). He underwent a laryngoscopy and was found to have significant sub-vocal cord stenosis and edema. He became more stridorous and was intubated. He was taken to the operating room on March 19, 2010, for a tracheotomy. It was felt that a CT scan of the neck's soft tissues was consistent with scar tissue and possibly recurrent tumor overlying and adjacent to the entire anterior tracheal wall. It was felt that this patient's tracheotomy would be long-term because of his vocal cord paralysis, which was likely not reversible at this point. The tracheotomy and tracheobronchoscopy were well tolerated. The patient was sent to the intensive care unit in stable condition with a stable airway. 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 × 4 weeks**

14. DATES OF TREATMENT

The patient started the investigational therapy on October 23, 2007 and received the last dose of sunitinib malate on March 11, 2010 (Cycle 20, Day 28).

15. ACCRUAL AND IND EXPERIENCE

**Number of patients enrolled in NCI-sponsored clinical trials using sunitinib = 2332
There have been no other cases of laryngeal edema 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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