

**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 <b>61010</b>	2. AGENT NAME <b>CCI-779 (temsirolimus, Torisel™)</b>	3. DATE <b>December 9, 2009</b>
4. SPONSOR <b>Division of Cancer Treatment and Diagnosis, National Cancer Institute</b>		
5. REPORTER'S NAME, TITLE, AND INSTITUTION <b>L. Austin Doyle, MD-Senior Investigator for Investigational Therapeutics 2, Investigational Drug Branch, CTEP, DCTD, NCI</b>		6. PHONE NUMBER <b>301-496-1196</b>
		7. FAX NUMBER <b>301-402-0428</b>
8. PROTOCOL NUMBER (AE #) <b>GOG-0248 (AE# 1607186)</b>		
9. PATIENT IDENTIFICATION <b>083-0248-001</b>	10. AGE <b>47</b>	11. SEX <b>Female</b>
12. DESCRIPTION OF ADVERSE EVENT <b>The patient is a 47-year-old female with endometrioid endometrial adenocarcinoma who developed a grade 3 periumbilical lesion with ulceration while on a phase 2 trial utilizing the investigational agent temsirolimus. She began the first course of the investigational therapy on March 26, 2009, and received her last dose of temsirolimus on November 5, 2009 (Cycle 6, Day 15). On November 18, 2009 (Cycle 6, Day 28), the patient presented to the emergency room complaining of excruciating pain under her pannus and in her mons with ambulation. The pain was uncontrolled with oral Dilaudid®. Physical examination revealed a 6 cm periumbilical lesion with an excoriated ulcerated base with purulent discharge. There was also a markedly excoriated diffuse rash-type weeping lesion extending onto the thighs and mons pubis. Of note, the patient has a history of poorly controlled diabetes mellitus and morbid obesity. The patient was admitted to the hospital for a complicated wound infection and started on IV vancomycin, Diflucan®, Dilaudid®, sliding scale insulin, and Glucovance®. Wound cultures grew MRSA and <i>Corynebacterium</i> species. The pain was controlled with oxycodone and the wound was managed by wound care. On November 25, 2009, the patient was discharged home on IV antibiotics managed by Home Health. Additional information has been requested from the investigational site. There is a reasonable possibility that the experience may have been caused by the drug.</b>		
13. DOSE, ROUTE, AND SCHEDULE <b>Cycle = 6 weeks; Temsirolimus 25 mg IV over 30 minutes weekly</b>		
14. DATES OF TREATMENT <b>The patient began the investigational therapy on March 26, 2009, and received the last dose of temsirolimus on November 5, 2009 (Cycle 6, Day 15).</b>		
15. ACCRUAL AND IND EXPERIENCE <b>Number of patients enrolled in NCI-sponsored clinical trials using temsirolimus = 1813. There have been 7 other cases of ulceration reported to the NCI through AdEERS as serious adverse events for temsirolimus.</b>		
16. COMMENTS <b>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 21CFR312.32(d)(2).</b> <b>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.</b>		

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