

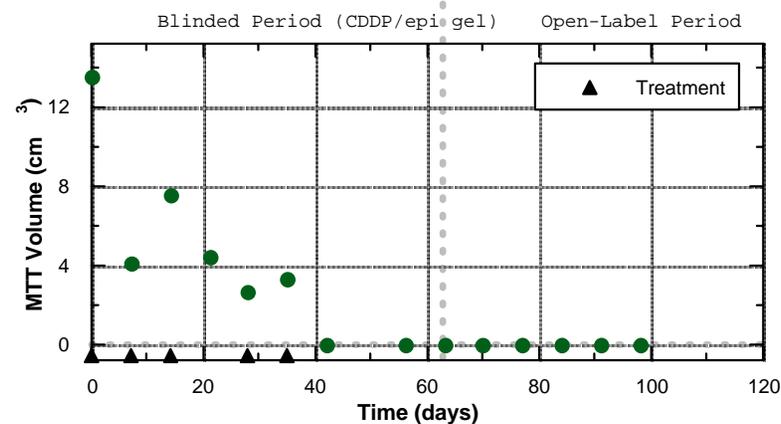
**History** A 44-year-old white man, was diagnosed with squamous cell carcinoma of the base of the tongue in 8/95. He underwent chemotherapy with cisplatin/5-FU (8/17/95, cisplatin 100 mg/m<sup>2</sup> x 1 dose, 5-FU 1000 mg/m<sup>2</sup> per day x 5 days; 9/11/95, cisplatin 100 mg/m<sup>2</sup> x 1 dose, 5-FU 1000 mg/m<sup>2</sup> per day x 5 days). A partial response was obtained. He subsequently underwent multiple therapeutic interventions: chemotherapy with cisplatin/5-FU (10/9/95, cisplatin 100 mg/m<sup>2</sup> x 1 dose, 5-FU 1000 mg/m<sup>2</sup> per day x 5 days); partial parotidectomy and left neck dissection (10/31/95); radiotherapy (12/15/95 to 2/15/96, 6700 cGy x 1 treatment per day); glossectomy, right neck dissection, and tracheotomy (3/5/96). A complete response was obtained. However, approximately 1 year later a biopsy (5/29/97) demonstrated the presence of squamous cell carcinoma. He underwent chemotherapy with cisplatin/5-FU (6/10/97, cisplatin 100 mg/m<sup>2</sup> x 1 dose, 5-FU 1000 mg/m<sup>2</sup> per day x 5 days). Stable disease was noted. On 7/10/97, 2 years after the original diagnosis, the patient was screened for study enrollment.

TREATMENT GROUP		CDDP/epi gel
	1° Tx GOAL	BLINDED PERIOD OUTCOME
Investigator	Wound care	SAME
Patient	Wound care	SAME
	TUMOR RESPONSE	PATIENT BENEFIT
During the Blinded Period	CR	No
Any Time During the Study	CR	No

**Baseline MTT** The MTT (volume 13.5 cm<sup>3</sup>) was cervical, located at the midline pre-tracheal. The tumor occurred in a previously radiated field. Both the investigator and the patient selected wound care as their primary treatment goals.

**Blinded Period** The patient received 5 CDDP/epi gel treatments to the MTT over 36 days. The patient had a complete MTT response but did not achieve benefit from CDDP/epi gel treatment. The tumor response was first observed on Day 22, lasted 85 days, and was continuing at last observation. The investigator and patient treatment goal, wound care, was assessed as unchanged by both the patient and the investigator. The investigator's secondary treatment goals, prevention of invasion of a vital structure and/or blood vessel and prevention of tracheal obstruction, were achieved for 91 days and 98 days, respectively, extending into the extended follow-up phase. The patient discontinued the blinded period on Day 64.

**Extended Follow-Up Phase** The patient continued to have a complete MTT response but did not achieve benefit from CDDP/epi gel treatment. The investigator and the patient's treatment goal, wound care, was not achieved (the patient's scores worsened). The investigator's secondary treatment goals, prevention of invasion of a vital structure and/or blood vessel and prevention of tracheal obstruction, continued to be achieved. The patient received 3 CDDP/epi gel treatments over 15 days to a cervical tumor (non-MTT) that emerged during the extended follow-up phase. This tumor increased in size from a volume of 1.13 cm<sup>3</sup> to 1.69 cm<sup>3</sup> and was classified as having



progressive disease. The patient discontinued the study on Day 106.

**Local Cytotoxic Effects** The MTT showed evidence of moderate ulceration prior to treatment. After CDDP/epi gel treatment, eschar peaked at "moderate" from Days 8 to 15 and necrosis peaked at "moderate" from Day 8 to Day 78. Ulceration remained "moderate" for nearly all assessments from Day 8 to Day 71, then was reduced to "mild" for 3 assessments, then increased to "moderate" at the final assessment on Day 99. Both necrosis and eschar were "mild" at the final assessment.

**Serious Adverse Events** The patient experienced no serious, treatment-related adverse events.

**Other Significant Adverse Events** There were no severe, treatment-related adverse events.

**Other Disease/Intercurrent Illness** The patient had a history of alcoholic hepatitis and childhood tonsillectomy and adenoidectomy (date unknown).