

Letter to the Editor

Phase II Trial of VP16-213 in Squamous Cell Carcinoma of the Head and Neck

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FROM AUGUST 1983 to October 1984, a phase II study of etoposide (VP16-213) was conducted in 19 consecutive patients with histologically proven squamous cell carcinoma of the head and neck, progressing after first line treatment (surgery and/or radiotherapy, chemotherapy). All patients had measurable or evaluable lesions, were aged below 70 years, had performance status 3 and adequate renal and liver function and bone marrow reserve.

VP16-213 was administered 150 mg/m² on days 1, 3, 5 every 3 weeks, diluted in 500 ml of physiological saline and infused over 30 min. Response and toxicity were classified according to Miller *et al.* [1].

Patients' characteristics are summarized in Table 1. Forty cycles of chemotherapy were administered, with a median number of 2 cycles

per patient. Among 19 patients entered, 2 died after the first cycle of chemotherapy because of progression of the disease, 1 died as a consequence of severe leukopenia induced by the first course and a fourth patient was lost to follow up.

Sixteen patients are evaluable for toxicity (see Table 2). Leukopenia and alopecia were the most important side effects (18.7% of grade 3-4 leukopenia, 50% of grade 3 alopecia). Among the 15 patients evaluable for response, 3 attained stable disease (lasting 5, 4 and 3 months) whilst 12 showed progression.

In this phase II trial, patients were heavily pre-treated; VP16-213 showed significant toxicity without demonstrating activity, as reported by Felman *et al.* [2]. We conclude that VP16-213, at the dosage and schedule employed in this study, had no activity in patients with head and neck carcinoma relapsing after first line therapy. Its activity in more favorable patients or in combination chemotherapy remains to be determined.

Table 1. Patients' characteristics (n = 19)

Males/females:	18/1
Median age (years):	61 (range: 28-70)
P.S. 1:11 2:6 3:2	
Primary site of tumors	Oral cavity: 8
	Oropharynx: 5
	Hypopharynx: 2
	Larynx: 3
	Nasopharynx: 1
Previous treatments	Surgery: 8
	Radiotherapy: 19
	Chemotherapy: 19

Table 2. Toxicity (n = 16)

Side effect	Grade			
	1	2	3	4
Leukocytes	5	2	2	1
Hemoglobin	4	1	1	—
Platelets	—	1	—	—
Vomiting	—	3	—	—
Hair loss	1	1	8	—
Renal	1	—	—	—

REFERENCES

1. Miller AB, Hoogstraten B, Staquet M, Winkler A. Reporting results of cancer treatment. *Cancer* 1981, **47**, 207-214.
2. Felman IE, Grumberg SM, Kirit V, Gala KV, Owens JC. Phase II trial of etoposide (VP16) in squamous cell carcinoma of the head and neck. *Proc Am Soc Clin Oncol* 1983, C-631 abstract.