

Table III. Efficacy of antineoplastons versus standard treatment in patients with glioblastoma multiforme

Study	Median age (y)	Median time from primary diagnosis (mo)	Baseline mean KPS	Response (%)			MTP (mo)	MST (mo)
				CR	PR	CR+PR		
Barker et al. ^[28]							6.3	
Prados et al. ^[29]	48.5	7.2					2.85	7.96
Temodal II ^[30]	54	9	80	1.4	6.5	7.9	2.2	5.4
Temodal 091 ^[30]	51	7.7	80		5	5	3.49	7.3
Procarbazine 091 ^[30]	51	7.7	80		5	5	2.11	5.82
Burzynski et al. CAN-1 study	41.5	5	70	14	21	35	6.72	17.44
Burzynski et al. All patients	44	5.2	69	17.6	17.6	35.2		

CR = complete response; KPS = Karnofsky performance status; MST = median time of survival from first day of treatment; MTP = median time to progression from first day of treatment; PR = partial response.

Only three patients diagnosed with primitive neuroectodermal tumour were included in the study. Among them, one is alive today and in complete remission, and two have died.

Only one patient diagnosed with malignant meningioma was included in the CAN-1 study. This patient obtained a complete response without recurrence.

The CAN-1 protocol indicated that the best results were obtained in anaplastic and low grade gliomas. The results in the treatment of highly malignant GBM, medulloblastoma, and malignant meningioma were also interesting, and warrant further clinical studies.

The response to antineoplastons depends on the dosage and duration of treatment. With the exception of one patient, all cases of progressive disease occurred within the first year of treatment. Most progressive disease occurred on a total dose of A10 lower than 55kg, and of AS2-1 lower than 3kg.

Over 100 clinical trials with various chemotherapy regimens have been conducted in patients with recurrent brain tumours. The general consensus in the medical community is that such tumours cannot be cured by chemotherapy and the response rate is only modest. Complete responses are almost never seen, and the total response rate usually includes stable disease. Although some studies report significant responses, the duration of im-

provement is short. Ultimately, almost all of these patients die from their brain tumours.

As an example, in the study by Sandberg-Wollheim et al. with PCV [procarbazine, CCNU (lomustine), vincristine] chemotherapy plus radiation therapy after surgical resection of the tumour, 94% of patients died.^[22] The patient population was heterogeneous. The results of the most important trials in similar patient populations are tabulated and compared with the CAN-1 protocol in table II.

Two of the studies reported here involved patients newly diagnosed with brain tumours who received combination chemotherapy and radiation therapy after extensive resection of the tumour (Sandberg-Wollheim et al.^[22] and Hildebrand et al.).^[23] The remaining studies, including CAN-1, accrued patients who were more difficult to treat, that is, those who failed radiation therapy or chemotherapy. Among them, treatment consisted of a combination chemotherapy (Jeremic et al.),^[24] tamoxifen (Couldwell et al.),^[25] and 13-*cis*-retinoic acid (Yung et al.).^[26] In all the studies, most patients had high grade gliomas; however, a small percentage of patients were diagnosed with low grade tumours.

The results of the CAN-1 study showed the highest complete and partial response rates of all tabulated studies and the lowest rate of progressive disease. No complete responses were reported, ex-