

Table I. Pretreatment characteristics of patients in the CAN-1 study

Characteristic	No.	Percentage
Gender		
Male	22	61.1
Female	14	38.9
Age (y)		
<18	9	25
>18	27	75
Median	38.5	
Tumour histology		
Glioblastoma multiforme	14	36.9
Anaplastic glioma	13	36.1
Astrocytoma, low grade	5	13.9
Others	4	11.1
Previous therapies		
Radiation	26	72.2
Chemotherapy	15	41.6
Karnofsky performance status at admission		
Median	75	

15 to 17mg of PG. The combined concentration of the active ingredients PN and PG is 80 g/L \pm 3 g/L. Both formulations were supplied, free of charge, by the Burzynski Clinic.

Pretreatment evaluation included a complete medical history and physical examination, standard laboratory test and a magnetic resonance imaging (MRI) scan.

Patients received daily intravenous injections of antineoplastons A10 and AS2-1 through a Broviac, Groshong or equivalent catheter. Gradually escalating doses of the two antineoplastons were given by intermittent injections (6 times a day) using a portable Provider® 6000 dual-channel pump (Abbott Laboratories, North Chicago, IL, USA). Patients over 18 years of age received injections at a rate of 250 ml/h. Those aged between 2 and 18 years received injections at the rate of 50 to 100 ml/h. The daily dose was increased until the highest tolerated dosage was reached, not exceeding 15.7 and 0.9 g/kg/day of A10 and AS2-1, respectively. Patients with high grade tumours usually received the highest tolerated dosage.

The average dosages for antineoplastons A10 and AS2-1 were 7.7 and 0.36 g/kg/day, respectively. The maximum total dose of A10 and AS2-1

during treatment was 548.8 and 59.6kg, respectively, with approximately 66% of the patients taking from 10 to 150kg of A10 and from 1 to 15kg of AS2-1. The median duration of daily A10 and AS2-1 treatment was 661 days (from 91 to 3874 days).

During the first 2 weeks of therapy, antineoplastons were administered at the Burzynski Clinic where patient and family members received training in standard care of the catheter and programming of the pump. The patient's history, physical examination, laboratory test and MRI were repeated periodically during the course of treatment. Between visits to the clinic, the patients were under the care of their local co-investigator.

Response criteria required complete disappearance of all contrast-enhanced tumour(s) on imaging studies for 4 weeks or longer for designation of complete response. More than 50% reduction was required in the sum of the products of the greatest perpendicular diameters of contrast-enhanced tumour(s) for at least 4 weeks and no appearance of new lesions for designation of partial response. Stable disease was defined as less than 50% change (either greater or smaller) in the sum of the products of the greatest perpendicular diameters of the contrast-enhanced tumour(s) for a minimum of 12 weeks. Progressive disease was defined as a greater than 50% increase in the sum of the products of the greatest perpendicular diameters of the contrast-enhanced tumour(s) compared with the nadir evaluation or appearance of new lesions.

Additional drugs known not to have antitumour activity were given for a short time. They included the following: anti-inflammatory agents, anticonvulsants, anti-infectives, antihistamines, antitussives, expectorants, mucolytics, blood formation and coagulation agents, cardiovascular agents, tranquillisers, antidepressants, diuretics, electrolytes, gastrointestinal agents, hormones, smooth muscle relaxants, bronchodilators, uricosurics, and vitamins. Corticosteroids were given to 83% of patients. Of patients with complete and partial responses, 69% discontinued corticosteroid therapy for at least 7 days before having an MRI scan to