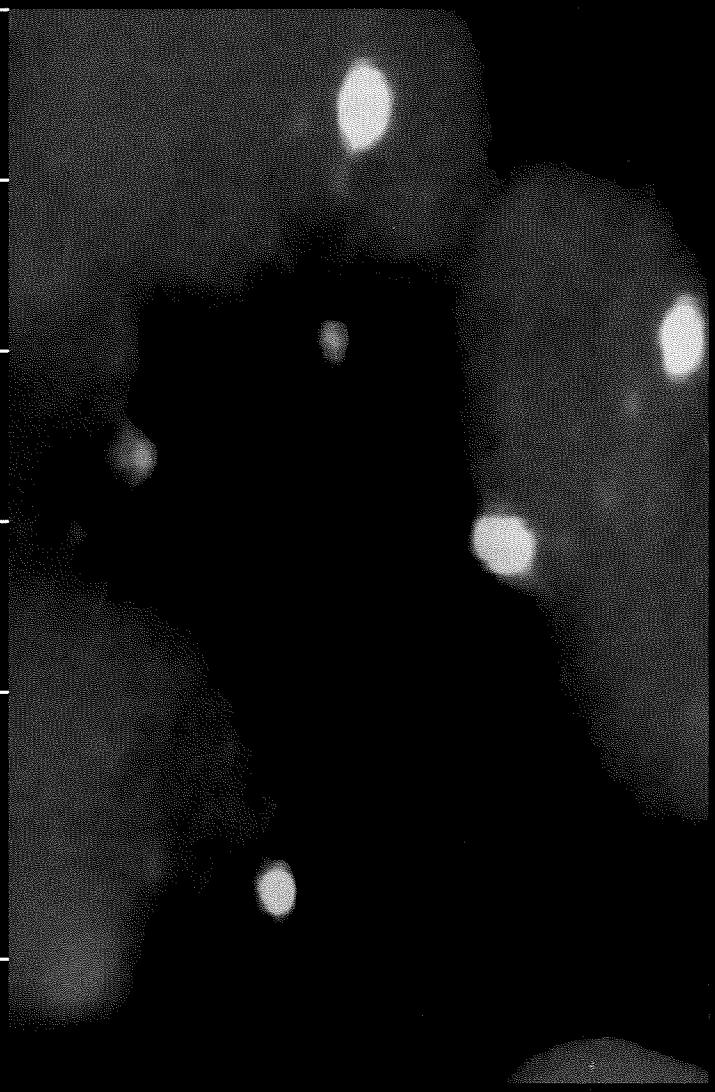
Official Journal of the Society for Neuro-Oncology since 1997

NEURO-ONCOLOGY

Volume 10
Issue 5
October 2008



neuro-oncology.dukejournals.org

MA-20. PHASE II STUDY OF ANTINEOPLASTONS A10 AND AS2-1 (ANP) IN PATIENTS WITH NEWLY DIAGNOSED ANAPLASTIC ASTROCYTOMA: A PRELIMINARY REPORT

Stanislaw Burzynski[1], Robert Weaver[2], Tomasz Janicki[2], Gregory Burzynski[2], Shiney Samuel[2], and Barbara Szymkowski[2]; [1]Burzynski Clinic, Houston, TX, USA; [2]TX, USA

Antineoplastons (ANP) are synthetic analogs of naturally occurring phenylacetylglutamine, phenylacetylisoglutamine, and phenylacetate. Two phase II trials have been performed to evaluate the efficacy and toxicity of ANP in newly diagnosed and recurrent anaplastic astrocytoma (AA). This study describes the treatment of a group of 20 evaluable patients with newly diagnosed AA. The prognosis for patients with AA is poor. Their 5-year survival rate is less than 30% even with the most aggressive therapies, including surgery and adjuvant radiation therapy and chemotherapy, which clearly indicates that more effective treatments are needed. The study was monitored by the FDA and the institutional review board. All patients in our study were diagnosed with AA, and their ages ranged from 22 to 64 years (median, 40). No patients received radiation or chemotherapy before starting ANP, but six patients underwent surgery and 14 had biopsy only. ANP was administered intravenously daily through a subclavian central venous catheter by a double-channel infusion pump. The median duration of treatment was 5.7 months and the median average dosage of A10 was 5.69 g/kg/day, and the median average dosage of AS2-1 was 0.28 g/kg/day. The treatment was well tolerated with only two cases of grade 3 toxicity, possibly related to ANP (shortness of breath and generalized weakness). Complete response was achieved in 25%, stable disease in 40%, and progressive disease in 35% of patients. The overall survival rate at 2 years was 45%. The median progression-free survival time based on K-M was 12.6 months. In this study, the patients achieved a substantially higher percentage of complete response compared to the study of ANP in recurrent AA (25% versus 16%). ANP is a multi-targeted therapy affecting signal transduction, the cell cycle, the TCA cycle, and apoptosis. In conclusion, ANP is well tolerated and provides encouraging results in the treatment of newly diagnosed AA and merits further investigation compared with standard treatment in a randomized phase III trial.

Reprinted from *Neuro-Oncology*, Volume 10, Number 5, October 2008
Published by Duke University Press. To subscribe, call (888) 387-5765