

PHASE II STUDY OF ANTINEOPLASTONS A10 AND AS2-1 IN ADULT PATIENTS WITH PRIMARY MALIGNANT BRAIN TUMORS.

Special Exception to Protocol BT-21

Treatment Summary

PATIENT: Treadwell, James N.
PATIENT ID NUMBER: JNT-BT-21-CE
DIAGNOSIS: 1. Glioblastoma Multiforme.
2. Lymphadenopathy (hilar, mediastinal and retroperitoneal) of unknown etiology.
RESULTS: Complete response
SPONSOR: Burzynski Research Institute, Inc.
CHIEF INVESTIGATOR: S. R. Burzynski, M.D., Ph.D.
CO-INVESTIGATOR (in house): Stanislaw R. Burzynski, M.D., Ph.D.
CO-INVESTIGATOR (local): George A Luiken, MD

TREATMENT HISTORY:

The patient is a 64 year old Caucasian male from Coronado, California, who was in good health until March 2004, when he began to experience severe headaches. He had increased intensity of the headaches with some diminished cognition and MRI of the head on April 26, 2004 demonstrated an abnormal contrast enhancing area in the left frontal lobe. On April 27, 2004, he underwent a left frontal craniotomy and near total tumor excision with a small amount of residual tumor remaining inferiorly in the resection cavity on the post surgical MRI and pathology revealed glioblastoma multiforme. On May 26, 2004, he underwent a second resection of the tumor and Gliadel wafer placement. Postoperative MRI of the head demonstrated no residual area suspicious for cancer. From June 22, 2004 to August 4, 2004, he received brain radiation for a total dose of 6000 cGy in 30 sessions. From June 23, 2004 to August 20, 2004, he received three cycles of chemotherapy with Temodar. From August 16, 2004 to September 6, 2004, he was treated with a daily dose of Accutane. MRI of the brain and MR spectroscopy on September 8, 2004 revealed a mass lesion within the left insular cortex, which nearly doubled in size and exerted a mass effect on the lateral ventricle and a stable enhancing nodular lesion in the surgical bed. On September 14, 2004, he was placed on Decadron 4.0mg PO q.d. despite the fact that it was prescribed b.i.d. and he has not increased the dose as of today.

On September 24, 2004, the patient was admitted for administration of Antineoplastons according to Protocol BT-21 based on special exception. He gradually increased Antineoplaston A10 to 10.9gkg/day and AS2-1 to 0.33g/kg/day. On April 9, 2005, he decided to discontinue antineoplastons permanently.

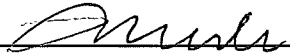
Treadwell, James N.

JNT-BT-21-CE

RESULTS OF TREATMENT:

MRI of the head on April 26, 2005 revealed a 69% decrease of the left insular enhancing lesion compared to the baseline study. Follow-up MRI of the head on July 5, 2005 revealed a further 27% decrease of the brain lesion, which increased the overall decrease of the lesion to 77% when compared to the baseline study. PET scan of the brain on February 8, 2005 demonstrated the disappearance of the hypermetabolic activity in the left temporal lobe region. Follow-up PET scan of the brain of July 15, 2005 again revealed no hypermetabolic uptake; therefore, his response was classified as a complete response. He has had multiple follow-up MRIs of the brain which have all shown no tumor recurrence, the last being September 30, 2008.

Date: 01-Jul-09



Stanislaw R. Burzynski, M.D., Ph.D.