Burzynski CLINIC
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PHASE II STUDY OF MAINTENANCE TREATMENT WITH ANTINEOPLASTONS A10 AND AS2-1 CAPSULES FOR PATIENTS WITH MALIGNANCIES IN COMPLETE RESPONSE FOLLOWING INITIAL INTRAVENOUS TREATMENT WITH ANTINEOPLASTONS A10 AND AS2-1.

Protocol BT-34

Treatment Summary

PATIENT:	**Gettino, Sophia B.**
PATIENT ID NUMBER:	**SBG-BT-34-02**
DIAGNOSIS:	**PNET (Pinealoblastoma)**
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):	

The patient is now a 13-year-old Caucasian female, who was initially 10 months old when she presented with a history of inability to move her head and look up. She was noted to have an increased head circumference, increased pressure of the anterior fontanelle, decreased eating, impaired coordination, progressive regression in her gross motor developmental milestones, irritability, lethargy, and she had relatively poor balance for her age. There was no history of vomiting or seizures, and she was otherwise healthy at the time of her diagnosis. The MRI of the brain on December 18, 1996 showed obstructive triventricular hydrocephalus secondary to a large heterogeneous cystic pineal region mass measuring 2-3 cm, which enhanced with gadolinium. A biopsy was performed and the diagnosis was confirmed as pinealoblastoma. A shunt was placed on December 20, 1996 with debulking of the tumor. The pathology confirmed pinealoblastoma, neuroectodermal tumor. The day after the surgery, an MRI of the brain of the left parietal and posterior cerebellar areas showed a subtle, ill-defined enhancement without a focal nodule or mass and mild to moderate hydrocephalus of the third and lateral ventricles. The CT scan of the head two days later showed the ventricular catheter entering the left frontal lobe and transversing the right frontal horn with the tip lying near the right anterior aspect of the foramen of Monroe. A PET scan of the head on December 28, 1996 confirmed that the ventricular system was decreased in size compared to previous films; however, there was still moderate hydrocephalus with the shunt in place. MRI of the brain on January 7, 1997 demonstrated a ring-enhancing mass in the previous area of tumor resection consistent with recurrent pinealoblastoma, a large amount of hemorrhage, bilateral subdural hematomas, hydrocephalus, and a shunt tube in the right lateral ventricle.

MRI of the spine of this same date was not completed because of technical difficulties; however, a report showed multiple metastases. Her primary care physician explained to the parents that because of her age, sudden onset of symptoms and pathologic findings, her prognosis, unfortunately, was very grave. The option of chemotherapy was presented in a pilot study; however, the parents wished to explore other treatment options before making a

decision and came to our clinic for further evaluation and treatment.

On February 27, 1997 the patient was admitted for administration of IV Antineoplastons A10 and AS2-1 according to Protocol BT-12. The dosage of Antineoplaston A10 was gradually increased to 20.8 g/kg/day and AS2-1 to 0.65 g/kg/day. She discontinued antineoplastons on March 6, 2003 due to complete response. She was enrolled in Protocol BT-34 on March 7, 2003 due to complete response and permanently terminated from the study on November 8, 2003 due to persistent complete response.

RESULTS OF TREATMENT
Follow-up MRIs of the brain demonstrated a gradual decrease of the pineal region enhancing tumor since baseline. PET scans of the brain on September 6, 2002 and February 24, 2003 demonstrated no hypermetabolic uptake in the brain stem parenchyma, especially in the region of the pineal gland, suggesting no recurrent disease. CT/PET scan of the brain February 19, 2008 compared with December 4, 2003 revealed no significant interval change with stable dilatation of the left occipital horn and unchanged calcification involving the pineal gland region but no abnormal activity present to suggest the presence of any recurrence of the disease.

Please see attached tabulation for detailed tumor measurements.

Date: 02-Jul-09

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