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9432 Katy Freeway, Suite 200, Houston, TX 77055
Phone: 713-335-5697 Fax: 713-935-0649

PHASE II STUDY OF ANTINEOPLASTONS A10 AND AS2-1 IN ADULT PATIENTS WITH ANAPLASTIC ASTROCYTOMA.

Protocol BT-08

Treatment Summary

PATIENT:	**Gold, Jodi L.**
PATIENT ID NUMBER:	**JLG-BT-08-11**
DIAGNOSIS:	**1. Anaplastic Astrocytoma.** **2. Chronic depression.**
RESULTS:	**Complete response.**
SPONSOR:	**Burzynski Research Institute, Inc**
CHIEF INVESTIGATOR:	**S. R. Burzynski, M.D., Ph.D.**
CO-INVESTIGATOR (in house):	**Robert A. Weaver, M.D., C.P.I.**
CO-INVESTIGATOR (local):	**Pullen, William MD**

TREATMENT SUMMARY:

The patient is a 31-year-old white female, who was in good health until May 1, 2000, when after deep massage, she felt weak and had a minor fall while at the gym. Two days later, she noted some right upper extremity clumsiness and also some limping while walking. She sought medical attention from her chiropractor, who referred her to a neurologist, who direct MRI of the brain on May 10, 2000, which revealed a 2.0 cm mass on the left parietal lobe. CT of the chest, abdomen and pelvis performed on May 11, 2000 was normal. Consequently, on May 15, 2000, she underwent stereotactic biopsy of the left parietal tumor by Dr. Rich and pathology examination revealed anaplastic astrocytoma. After surgery, she was placed on Decadron 4.0 mg po q.d. and Dilantin 300 mg po q.d. She developed a rash of the skin after taking these medications, so this was switched to Tegretol and she developed more pronounced pruritic rash on her body. The antiseizure regimen was stopped from this point. Repeated MRI of the brain performed on June 1, 2000 was again consistent with tumor on the parietal left lobe. The patient has not had any chemotherapy or radiation for her condition to date.

On June 6, 2000, the patient was admitted to Phase II Study of Antineoplastons in Patients with Anaplastic Astrocytoma according to Protocol BT-8. The dose of Antineoplaston A10 was gradually increased to 330 mL and AS2-1 to 40 mL 6x a day IV. This dosage corresponds to 12.47 g/kg/day of Antineoplaston A10 and 0.4 g/kg/day of AS2-1. The patient's other medications include Decadron 2 mg po q12h, potassium chloride 40 mEq po t.i.d., contraceptive 1 tab po q.d., Synthroid 150 mcg po q.d., Paxil 40 mg po q.d., Pepcid 20 mg po b.i.d. On June 30, 2000, the patient's transaminases increased to 112 U/L of SGOT and 154 U/L of SGPT. On July 5, 2000, the dose of antineoplastons was reduced by 25% because laboratory tests of July 3, 2000 revealed progressive worsening in SGOT of 152 U/L and SGPT of 437 U/L. On July 6, 2000, the patient was taken off antineoplastons because of further increase in SGOT and SGPT, where SGOT was 157 U/L and SGPT was 529 U/L respectively.

Repeated laboratory tests on July 7, 2000 revealed almost complete normalization of SGOT of 22 U/L, SGPT reduced to 334 U/L. On July 10, 2000, normal SGOT of 22 U/L and SGPT of 169 U/L was noted; therefore, the patient was started back on 160 mL of Antineoplaston A10 and 30 mL of AS2-1 6x a day IV. The dose of Antineoplaston A10 was escalated in 20 mL increments daily and laboratory tests of July 12, 2000 progressive worsening in SGOT and SGPT, and antineoplastons were discontinued temporarily on July 13, 2000. Once again, normalization of SGOT 22 U/L and progressive improvement in SGPT of 190 U/L was noted and the blood tests of July 17, 2000. The patient was started on desensitization protocol with Antineoplaston A10 and AS2-1 on July 18, 2000 and she received 10 mL of Antineoplaston A10 and 2 mL of AS2-1 96x a day IV. Repeated blood tests of July 21, 2000 revealed marked elevation of SGOT of 607 U/L, SGPT of 1950 U/L, respectively and antineoplastons were once again discontinued, and complete resolution of the patient's SGOT was noted by July 28, 2000 and significant improvement in SGPT of 283 U/L was noted. Subsequently, on July 29, 2000, the patient received 80 mL of Antineoplaston A10 and 20 mL of AS2-1 6x a day IV. On July 31, 2000, antineoplastons were maintained and AS2-1 was increased to 30 mL, and significant elevation of SGOT of 2100 U/L and SGOT of 3768 U/L was observed. Antineoplastons were again discontinued. Repeated laboratory tests of August 4, 2000 revealed improvement of SGOT of 56 U/L, SGPT of 1006 U/L and on August 5, 2000, almost complete normalization of SGOT of 37 U/L and SGPT of 667 U/L was seen. It was decided that Antineoplaston A10 and AS2-1 IV be discontinued and the patient was started on Antineoplaston A10 and AS2-1 capsules on August 5, 2000 and received 500 mg of each, Antineoplaston A10 and AS2-1 6x a day po. She did not report any side effects to these formulations. The next day on August 6, 2000, the patient received 1.0 g of Antineoplaston A10 and AS2-1 6x a day po. On August 7, 2000, the dose of antineoplastons was increased to 1.5 g 6x a day po of each, Antineoplaston A10 and AS2-1. Repeated laboratory of August 7, 2000 revealed normalization of SGOT of 31 U/L and SGPT reduced by 50% to 335 U/L. On September 14, 2000, the dose of antineoplastons was increased to 2.0 g of each, Antineoplaston A10 and AS2-1 6x a day. On September 15, 2000, antineoplaston A10 was decreased to 1.5 g po 6x a day. On January 23, 2001, antineoplaston AS2-1 was increased to 2.5 g po 6x a day. On March 2, 2001, she increased antineoplaston A10 to 2 g po 6x a day and decreased antineoplaston AS2-1 to 2 g po 6x a day. On March 10, 2001 she decreased both antineoplastons A10 and AS2-1 to 1.5 g of each po 6x a day. She continued on this dose until June 5, 2001, when she decided to gradually withdraw the antineoplastons and they were discontinued on November 1, 2001.
As of July 3, 2000, the patient showed complete response based on MRI.

RESULTS OF TREATMENT:

Follow-up MRI of the head with and without contrast of July 3, 2000 revealed complete resolution of two contrast enhancing nodules. Another follow-up MRI of the head of July 31, 2000 continues to demonstrate no enhancing nodules. The patient's condition was classified as complete response. The following MRI's on these dates did not show any tumor recurrence: September 11, 2000, October 11, 2000, November 29, 2000, January 16, 2001, February 26, 2001, June 25, 2001, September 24, 2001, December 10, 2001, March 11, 2002, June 24, 2002, December 9 2002, June 11, 2003, December 10, 2003, April 30, 2004, October 1, 2004, May 26, 2005, June 12, 2006, April 19, 2007, and March 18, 2008. The PET scan of the head on June 8, 2000 was negative.

As of March 10, 2009, the patient remains in complete response and on February 28, 2009 she delivered a healthy baby boy.

Please see attached tabulation for detailed tumor measurements.

Date: 10-Mar-09

Robert A. Weaver, M.D., C.P.I.