



S. R. BURZYNSKI

**PHASE II STUDY OF ANTINEOPLASTON A10 AND AS2-1
IN PATIENTS WITH REFRACTORY MALIGNANCIES
PROTOCOL CAN-1, NON-HODGKIN'S LYMPHOMA**

TREATMENT SUMMARY

PATIENT: SIEGEL, Mary Jo
DIAGNOSIS: Non-Hodgkin's lymphoma small cleaved cell, low grade, Stage IV.
RESULTS: Complete response.
SPONSOR: Burzynski Research Institute, Inc.
PRINCIPAL INVESTIGATOR: S. R. Burzynski, M.D., Ph.D.

Treatment History:

The patient is a 45-year-old white female, who was in good health until February, 1991 when she was diagnosed with small cleaved cell non-Hodgkin's lymphoma. At the time of diagnosis she developed severe pain in the abdomen and intestinal obstruction. She underwent laparotomy with resection of portion of small intestine and mesenteric lymph nodes. In September, 1991, she was found to have involvement of the bone marrow.

The patient came under my care on April 3, 1992. Initially her treatment program included administration of Antineoplaston A10 and AS2-1 capsules in the dose range of 7 g of A10 and 8 g of AS2-1 daily. On April 6, 1992 a low dose of alpha-interferon was added to the treatment (1.2 MU s.c. q.o.d.). On November 16, 1992 the treatment with oral formulations of Antineoplastons was discontinued and the patient began taking Antineoplaston A10 and AS2-1 intravenous infusions administered through a subclavian vein catheter and an ambulatory infusion pump. She was taking 0.5 g/kg/d of A10 and 0.38 g/kg/d of AS2-1. The treatment resulted in complete response, as documented by physical examinations, CT scan and bone marrow biopsy of November 16, 1993. Antineoplaston infusions and alpha-interferon were discontinued on May 3, 1994. On May 18, 1994 the patient began taking Antineoplaston AS2-1 capsules 0.25 g/kg/d. The treatment was discontinued on July 26, 1995. Approximately two years later after her complete response was documented and four months after discontinuation of treatment, the CT scan of October 19, 1995 was suspicious for small lymph nodes on the neck indicating recurrence. The patient restarted the treatment with Antineoplaston AS2-1 and A10 capsules, on November 7, 1995, which resulted in disappearance of the enlarged lymph nodes on the neck by physical examination and CT scan.

The dosage of A10 was 0.11 g/kg/day and AS2-1, 0.18 g/kg/day.

On April 29, 1996 she was admitted to the study under Protocol CAN-1

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Adverse Drug Experiences

The patient experienced mild electrolyte changes during the treatment. On January 7, 1993, she had hypocalcemia of 8.0 mg/dL (grade 1), possibly related to her diet. On February 11, 1993, she had hypernatremia of 147 mEq/L (grade 1). She had hyperglycemia of 119 mg/dL on July 14, 1992 (grade 1), possibly due to Medrol. She experienced slight changes in blood counts. On August 24, 1993, she had thrombocytopenia of $148 \times 10^3/\text{mm}^3$ (grade 1), possibly due to alpha-interferon. She had leukopenia of $2.2 \times 10^3/\text{mm}^3$ on July 14, 1992 and granulocytopenia of $1.6 \times 10^3/\text{mm}^3$ on the same date (grade 1) both possibly due to alpha-interferon. Her hemoglobin decreased to 10.9 g/dL on January 7, 1993 (grade 1), possibly due to alpha-interferon. The patient complained of headaches on April 7, 1992 (grade 1), possibly due to alpha-interferon.

Results of Treatment

The CT scan of August 12, 1992, showed multiple contiguous lymph nodes measuring 1.5 cm in diameter were demonstrated along the entire right jugular vein along the posterior aspect. They extended up to the submandibular region. Several lymph nodes were demonstrated bilaterally on the neck adjacent to the thyroid. The largest, on the right, measured approximately 1.5 cm and the largest on the left was less than 1 cm in diameter. Several lymph nodes were demonstrated in the left supraclavicular region; the largest of which measured 1.5 cm in diameter. The CT scan of the chest, of August 12, 1992, revealed left supraclavicular lymph node measuring approximately 1.9 cm x 1.0 cm. The right axillary lymph node measured 1.0 cm x 1.0 cm. The left paratracheal lymph node measured 0.8 cm x 0.8 cm. There were tiny pulmonary opacities measuring less than 0.3 cm in diameter seen in the periphery of the lungs; 1 in the left lower lobe and 2 in the right lower lobe. The CT scan of the abdomen and pelvis of August 12, 1992 revealed hypervascular lesion measuring 2.0 cm x 2.0 cm in the lateral segment of the left hepatic lobe, which enhanced after contrast administration. The patient had diffuse mesenteric, pericaval, and periaortic adenopathy. The follow-up CT scan of the chest, abdomen, and pelvis on January 8, 1993 have shown decrease of the size of the right axillary lymph nodes and the 2.0 cm lesion in the liver was unchanged and probably represented hemangioma. The left periaortic adenopathy decreased from the largest node size of 2.0 cm to 1.2 cm. The smaller lymph nodes did not change significantly compared to prior examination. Multiple small mesenteric lymph nodes were not changed. The CT scan of the abdomen and pelvis on May 21, 1993 revealed a 2 cm lesion in the liver unchanged. Multiple mesenteric lymph nodes showed interval decrease in size. The largest periaortic lymph node measured 1 cm in diameter. The next CT scan of the abdomen and pelvis on October 21, 1993 showed 2 cm hypodense lesion in the liver unchanged, previously described hyperdense lesion in the medial segment of the liver was no longer seen. Multiple, less than 1 cm in diameter,

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aortocaval lymph nodes were not changed. There was no longer any significant mesenteric lymphadenopathy. The follow-up CT scan of the chest, abdomen, and pelvis of March 24, 1994 did not show any evidence of mediastinal or hilar adenopathy. The visible lymph nodes were within normal limits. Except for hemangioma in the liver, the liver appeared normal. There was no evidence of residual lymphoma.

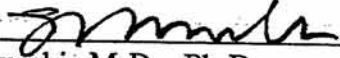
The CT scan of the chest and upper abdomen of March 7, 1995 did not show any significant lymphadenopathy. The follow-up CT scan of October 19, 1995 revealed possible new lymphadenopathy on the lower neck with the largest lymph node measuring approximately 1.0 cm x 1.5 cm.

The CT scan of March 8, 1996 revealed resolution of recurrent lymphadenopathy.

The repeated CT of December 3, 1996, did not show any recurrence. The patient's response was classified as complete response.

December 27, 1996

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S. R. Burzynski, M.D., Ph.D.

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