Protocol # 97-C-0050: A Pilot Study of Tumor-Specific Peptide Vaccination and IL-2 with or without Autologous T Cell Transplantation in Recurrent Pediatric Sarcomas

This protocol will study the safety , feasibility and efficacy of tumor-specific peptide vaccination administered with IL-2 therapy with or without autologous T cell infusions in patients with recurrent Ewing's sarcoma family of tumors (ESFT) and alveolar rhabdomyosarcoma (AR).

Eligibility Criteria:

- Previous Therapy:
  Arm A: Patients may be enrolled on Arm A only at the time of initial tumor diagnosis, prior to any cytoreductive therapy. Cell harvest will take place at this time. Immuno-therapy may then be given at any time after tumor recurrence, if other entry criteria are intact.
  Arm B: Patients enrolled on Arm B must have had tumor recurrence during or after receiving first line cytoreductive therapy. Patients are eligible if they have received up to 2 post-recurrence salvage regimens. Patients who have received more than 2 post-recurrence salvage regimens are eligible if peripheral CD4+T cell number is greater than 400 cells/mm^3.
- Confirmation of ESFT or AR and documentation of measurable disease
- Tumor specific fusion protein documented by RT-PCR (Arm A : may enroll prior to documentation of RT-PCR, but must have documentation prior to immunotherapy administration.)
- Age ≤30 years at the time of diagnosis; weight greater than 10 kg
- Life expectancy greater than 8 weeks; ECOG rating of 0 to 2, Adequate liver, renal, metabolic, and bone marrow parameters, Ejection fraction greater than 40% via MUGA scan or fractional shortening of > 27% via echocardiography.
- Recovery from acute toxicities of previous cytoreductive therapy.
- Patients with previously irradiated/currently inactive CNS disease.
- **Exclusion Criteria:**
- Women of childbearing age must not be pregnant or lactating; pregnancy tests must be obtained in women of appropriate age
- Oral corticosteroid therapy
- HIV infection, Hepatitis B or C infection; Patients with recurrent CNS disease after irradiation will not receive IL-2.

Pre-treatment Evaluation:

- History and physical exam, including general labs and immunologic evaluation (including measurement of DTH using candida antigen and tetanus toxoid) as per protocol.
- Diagnostic imaging (CXR, CT, MRI of known disease sites, CT of chest/head, bone scan)
- Bilateral bone marrow aspiration and biopsy required if involvement of BM was evident at initial presentation.
- Patients should bring all summaries of previous treatment, most recent lab work, copies of most recent radiologic scans and original pathology slides to NIH.
- If possible, send frozen tissue for RT-PCR so that a second biopsy is not required.

General Treatment Plan:

- Apheresis must occur at NIH; all cellular products will have processing, manipulation and cryopreservation at NIH. Autologous T Cell transplantation will be performed for Arm A only. Peptide-pulsed APC vaccine, IL-2 therapy (with or without T cell infusion) will be repeated approximately every 2 weeks as per protocol schema for a total of six immunotherapy cycles with IL-2 continuing for an additional 4 weeks.

Hospitalization:

- Patients will be treated as an outpatient, unless clinically contraindicated.

Toxicity/Accrual:

- This protocol is open to accrual.
- Dose limiting toxicities have not been noted as of this time.
- Patients meeting eligibility criteria can be referred to the Pediatric Oncology Branch, NCI for evaluation and treatment on this trial.