Protocol # 97-C-0052
A Pilot Study of Tumor-Specific Peptide Vaccination and IL-2 with Autologous T Cell Transplantation in Metastatic Pediatric Sarcomas

This protocol will study the safety, feasibility and efficacy of tumor-specific peptide vaccination, autologous T cell infusion, and IL-2 patients administered in the setting of minimal residual disease after cytotoxic therapy in with high risk Ewing's sarcoma family of tumors (ESFT) and alveolar rhabdomyosarcoma (AR).

Eligibility Criteria:
•Previous Therapy: Patients may be enrolled at the time of presentation with metastatic Ewing's sarcoma or alveolar rhabdomyosarcoma. Alternatively, patients may be enrolled at the time of tumor recurrence if the recurrence is at least one year after completion of initial chemotherapy and CD count is > 400 cells / mm^3.
•Confirmation of ESFT or AR
•Tumor specific fusion protein documented by RT-PCR
•Age : less than 30 years at the time of initial diagnosis; Weight greater than 15 kg
The following criteria must be met at the time post-chemotherapy immunotherapy is initiated:
•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** shortening fraction > 27% via echocardiography
•At least 6 weeks and recovery from acute toxicities of previous cytoreductive therapy

Exclusion Criteria:
Women of childbearing age must not be pregnant or lactating; pregnancy tests must be obtained in women of appropriate age
Concurrent cytoreductive or oral corticosteroid therapy for at least 2 weeks prior to first immunotherapy cycle
Concomitant estrogen therapy at the time of immunotherapy portion of the protocol
HIV infection, Hepatitis B or C infection
Active CNS metastases at the time of immunotherapy

Evaluation (this will occur pre-chemotherapy and again post-chemotherapy):
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, bone scan)
Bilateral bone marrow aspiration and biopsy required. For patients with recurrent disease, this is required only 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:
An initial apheresis and cryopreservation of cells will occur at NIH prior to initiation of cytoreductive therapy. Patients may return to local hospital for therapy as directed by local MD. After completion of cytoreductive therapy, patients return to NIH for T cell infusion, peptide-pulsed APC vaccine, and IL-2 therapy which will be repeated 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.

Patients meeting eligibility criteria can be referred to the Pediatric Oncology Branch, NCI for evaluation and treatment on this trial by calling 301-402-5940, 301-496-0486, 301-496-4257.