EWING SARCOMA

Title: COG AEWS1031: A Phase III Randomized Trial of Adding Vincristine-topotecan-cyclophosphamide to Standard Chemotherapy in Initial Treatment of Non-metastatic Ewing Sarcoma.

Purpose: To find if adding the drug combination VTC to the standard five-drug chemotherapy for Ewing sarcoma will get rid of the cancer better than the standard five-drug chemotherapy by itself.

Eligibility: Patients who are 50 years of age or younger with newly diagnosed, biopsy confirmed, extracranial, non-metastatic Ewing sarcoma or PNET of bone or soft tissue are eligible for this study. For the purpose of this study, chest wall tumors with ipsilateral pleural effusions, ipsilateral positive pleural fluid cytology or ipsilateral pleural based secondary tumor nodules will be considered localized disease. Patients with regional node involvement, based on clinical suspicion confirmed by pathologic documentation are considered to be non-metastatic. Tumors arising in the bony skull (extra-dural) are considered to be extracranial. Patient eligibility will be based on a diagnosis of Ewing sarcoma or PNET by institutional pathologist. No prior chemotherapy or radiation therapy is allowed. Patients should only have had a ibopsy of the primary tumor without an attempt or accomplished as long as adequate imaging was obtained prior to surgery. Patients whose tumors arise in the intra-dural soft tissue are not eligible. Patients with pathologic diagnoses other than Ewing sarcoma are not eligible. Pregnant women will not be entered on this study as fetal toxicities and teratogenic effects have been noted for several of the study drugs.

Principal Investigator: Joseph M. Wiley, M.D.

Phase: III

For more information, contact: Stephanie Entrup

Telephone Number: 410-601-8393

Email: sentrup@lifebridgehealth.org