UPDATE ON MSTS TRIALS

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THREE COG NEWLY ACTIVATED STUDIES:

Osteosarcoma:

AOST1322: Phase II study of eribulin in recurrent osteosarcoma.

Ewings:

AEWS1221: Randomized Phase II Selection Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody AMG 479 to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma. (Tentative start date October 2014)

NRSTS:

ARST1321 (open NR-STS): Pazopanib Neoadjuvant Trial In Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613)

There are three new trials opening this Fall 2014. Please contact Dr. Randall if you would like additional information (r.lor.randall@hci.utah.edu).

NEW COOPERATIVE TRIAL

Tom Scharschmidt, MD, FACS
Assistant Professor, *Division of Musculoskeletal Oncology Department of Orthopaedic Surgery Wexner Medical Center/James Cancer Hospital*
Director, *Bone Tumor Clinic Nationwide Childrens Hospital*

A new cooperative group trial for soft tissue sarcoma has been launched as a collaboration between COG and NRG. It is the first trial to encompass all age groups and sub-types of sarcoma. Accrual is vital to support the trial! Please see specifics below and discuss with your sarcoma team to get the protocol open at your institution!
Any questions can be directed to Tom Scharschmidt at thomas.scharschmidt@osumc.edu.

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COG-NRG ARST1321: Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC#737754; IND#118613)

Primary Objectives

- To identify the dose of pazopanib that is feasible when given in combination with radiation or chemoradiation in pediatric and adult patients newly diagnosed with unresected intermediate- and high-risk NRSTS.
- To compare the rates of near complete pathologic response (> 90% necrosis) with the addition of pazopanib to preoperative chemoradiation versus preoperative chemoradiation alone for potentially resectable > 5 cm, Grade 3 intermediate to high risk chemotherapy-sensitive NRSTS in the Phase II portion of the study for this cohort.
- To compare the rates of near complete pathologic response (> 90% necrosis) with the addition of pazopanib to preoperative radiotherapy versus preoperative radiotherapy alone for potentially resectable intermediate to high risk adult and pediatric NRSTS in the Phase II portion of the study for this cohort (using a Phase II decision rule to go onto the Phase III portion of the study).
- To compare the rates of event-free survival (EFS) with the addition of pazopanib to preoperative radiotherapy versus preoperative radiotherapy alone for localized intermediate to high risk adult and pediatric NRSTS in the Phase III portion of the study for this cohort if the Phase II decision rule is passed.

Patient Population

- Stage T2a/b (> 5 cm) and Grade 3 (see Appendix III); One of the following chemosensitive histologies as defined inNewly diagnosed and histopathologically confirmed, potentially resectable NRSTS of the extremity and trunk will be eligible for the chemotherapy or non-chemotherapy cohort based on:
  - Evidence of chemotherapy sensitivity of the histologic sarcoma subtype based on existing evidence from prior clinical trials
  - Sufficient risk of metastatic disease to warrant chemotherapy based on size and grade and
  - Medically deemed able or unable to undergo chemotherapy

Target Accrual

340

Status

Activated July 11, 2014

Protocol Documents

Available via the NCI Cancer Trails Support Unit (CTSU) web site: www.ctsu.org

UPDATE ON MSTS TRIALS (cont.)

AOST 1322

Primary Aims

To estimate the 4 month progression free survival rate and objective response rate in patients with recurrent osteosarcoma who are administered eribulin therapy on Day 1 and Day 8 of 21 day cycles.

Secondary Aims

To investigate the pharmacokinetics (PK) of eribulin in subjects with recurrent osteosarcoma.

To further describe the tolerability of single agent eribulin.

INCLUSION CRITERIA

Patients must be equal to or greater than 12 years of age but less than 50 years of age at the time of enrollment.

Patients must have had histologic verification of osteosarcoma at original diagnosis.

Patients must have measurable disease, documented by clinical, radiographic, or histologic criteria, and have relapsed or become refractory to conventional therapy.