**EA3132 Available Through ECOG-ACRIN Cancer Research Group**

Phase II Randomized Trial of Radiotherapy with or without Cisplatin for Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN) with TP53 Sequencing

**Patient Population**

See Section 3 for Complete Eligibility Details

**Pre-Registration (Step 0):**
- Age ≥ 18 years
- Pathologically proven diagnosis of squamous cell carcinoma (including variants such as verrucous carcinoma, spindle cell carcinoma, carcinoma NOS) of the head/neck (oral cavity, oropharynx, hypopharynx or larynx); pathologic stage III or IVA (AJCC 8): T3-T4a, N0-1, M0 or T1-T2, N1-3, M0
- Patient has undergone total resection of the primary tumor with curative intent (note: submit tissue ASAP after surgery in order to meet the 8 week deadline for Step 1 registration; full assay minimum turnaround time is 17-24 days)
- For oropharynx primary tumors, patient must have negative HPV status of the tumor as determined by p16 protein expression using IHC
- No positive margins (not superceded by an additional margin of tumor-negative tissue), nodal extracapsular extension, and/or gross residual disease post surgery
- Patients with a history of curatively treated malignancy must be disease-free for at least 2 years (exceptions for carcinoma in situ of cervix/non-melanomatous skin cancer); must not have received chemotherapy/ investigational therapy within 2 years of surgical resection of the primary tumor
- No previous irradiation to the H&N that would result in overlap in radiation fields for the current disease
- No patients with recurrent disease or multiple primaries

**Randomization (Step 1):** Site must be notified that the central determination of p53 mutation status of the surgical tumor tissue has been completed/assay has been completed
- The gross total resection of the primary tumor with curative intent was completed within 8 weeks prior to randomization; must have an exam by a H&N surgeon, chest x-ray (or chest CT or CT/PET of the chest or MRI) within 8 weeks of randomization
- ECOG PS 0-1 and adequate lab values

**Treatment Plan**

See Section 5 for Complete Treatment Details

**Administration Schedule (Arms A and B):**
- Protocol treatment must begin within 5 working days after registration and randomization to adjuvant treatment arm
- IMRT is mandatory; use of IGRT is optional (margin reduction is not permitted even when IGRT is used)
- The prescribed radiotherapy dose will be 60 Gy in 2 Gy once-daily fractions (total of 30 fractions)
  - Radiotherapy should begin on a Monday, Tuesday, or Wednesday and be completed as SOC according to institutional practices
  - Treatment of PTV60 followed by a 6 Gy boost is not permitted
- Arm B- Patients will receive cisplatin 40 mg/m² administered intravenously over 1-2 hours once a week for 6 weeks
  - Use actual body weight for all patients
  - Patients must receive vigorous hydration and diuresis (see protocol for pre-medications)

**Technical Factors:**
- All patients will be treated with IMRT using megavoltage photon radiation
- All therapy units used must have their calibrations verified by IROC Houston (RPC)
- Credentialing is required for IMRT

**Localzation, Simulation, and Immobilization:**
- Patients must have an immobilization device for the head and neck made prior to the treatment planning CT scan
- The treatment planning CT scan can be performed with or without IV contrast
- Slice thickness should be ≤ 3 mm
- IGRT is recommended; weekly verification imaging is required

**Patient Enrollment**

All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org/open](https://open.ctsu.org/open)

**Protocol Information**

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!
EA3132

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