For Patients with NPNSCC

EA3163 Available Through ECOG-ACRIN Cancer Research Group

Phase II Randomized Trial of Neoadjuvant Chemotherapy Followed by Surgery and Post-operative Radiation versus Surgery and Post-operative Radiation for Organ Preservation of T3 and T4a Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)

### Patient Population

- Age ≥ 18 years, ECOG PS 0-1, adequate lab values
- General physical condition compatible with the proposed chemotherapy and surgery
- Stage T3 or T4a, histologically-confirmed NPNSCC requiring orbital or skull base resection (see protocol for details); measurable disease per protocol
- Must be deemed surgically resectable by the surgical teams at each institution and must have a determination of degree of anticipated structure preservation of orbit and skull base prior to randomization, per protocol
- May not be receiving investigational agents at time of registration, while on study, or during 4 weeks preceding registration
- No history of allergic reactions attributed to compounds of similar chemical/biologic composition to docetaxel and/or both platinum-based chemotherapy agents (must be able to receive 1 chemo regimen)
- No patients with evidence of distant metastases or leptomeningeal disease
- No previous irradiation for head and neck tumor, skull base, or brain tumors
- No patients with uncontrolled inter-current illness which in the opinion of the investigator will interfere with the ability to undergo therapy
- No patients with a history of a different malignancy, unless the disease has not progressed for ≥ 2 years; patients with a prior history of squamous cell/basal carcinoma of the skin or in situ cervical cancer must have been curatively treated
- No current peripheral neuropathy > grade 2 at time of randomization
- No co-existing condition what would preclude full compliance with the study
- No prior history of severe hypersensitivity reaction to Docetaxel/other drugs formulated with polysorbate 80
- Women must not be pregnant or breast-feeding

### Treatment Plan

- Imaging scans will be obtained within 2 weeks prior to registration and within 4 weeks prior to surgical resection
- Following surgery, patients will need to receive post-operative radiation to 60 Gy to the primary tumor and neck nodes; patients with positive margins/extracapsular spread in lymph nodes will receive 66 Gy with weekly cisplatin at 40 mg/m² x 6 weeks concurrent with radiation
  - Carboplatin AUC = 2 x 6 weeks is permitted if patients have contraindications/cannot tolerate cisplatin

#### Arm A:

- Imaging scans will be obtained within 2 weeks prior to registration and within 4 weeks prior to initiation of chemotherapy
- Neoadjuvant chemotherapy with 3 cycles of Docetaxel 75 mg/m² with Cisplatin at 75 mg/m² (or Carboplatin AUC=5); administered every 21 days
- Following completion of chemotherapy, patients will proceed to surgical resection no later than 6 weeks following last dose
- Imaging scans will be obtained within 3 weeks post completion of chemotherapy
- Following surgery, patients will need to receive post-operative radiation to 60 Gy to the primary tumor and neck nodes; patients with positive margins/extracapsular spread in lymph nodes will receive 66 Gy with weekly cisplatin at 40 mg/m² x 6 weeks concurrent with radiation
  - Carboplatin AUC = 2 x 6 weeks is permitted if patients have contraindications/cannot tolerate cisplatin

Note: see protocol for hydration, antiemetics, surgical guidelines, and radiation details

### Patient Enrollment

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

### Protocol Information

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

Please Enroll Your Eligible Patients!
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Schema

Disease Eligibility Requirements
Stage T3 and T4a, N0 or N1-3, requiring resection of BOS, orbit, or both

Accrual Goal: 134

1. Stratify by disease stage (T3 vs. T4a), and disease site involvement (orbit only vs. skull base only vs. both involved).
2. Carboptatin with an AUC=5 for patients who are ineligible to receive cisplatin.
3. Patients with positive margins or positive extracapsular spread in lymph nodes (ECS) will receive postoperative radiation therapy (66 Gy) and weekly concurrent therapy with weekly cisplatin at 40 mg/m². If patients have contraindications or cannot tolerate cisplatin, carboplatin at an AUC=2 on a weekly basis for 6 weeks will be allowed.