Phase II Expansion Trial Evaluating Axitinib in Patients With Unresectable Recurrent or Metastatic Head and Neck Cancer Using Choi Response Criteria

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Condition: Head and neck squamous cell cancer

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Unresectable recurrent or metastatic head and neck squamous cell cancer (R/M HNSCC) has a dismal survival, and development of novel therapeutics has been met with little success. Although immunotherapeutics have shown promise in this devastating disease, most patients do not derive a benefit and a sizable population are not candidates for this therapy. Vascular endothelial growth factor (VEGF) plays a crucial role in tumorigenesis, metastasis, and possibly immune evasion, and therefore VEGF-targeted therapies are of significant interest. A previous trial using the potent VEGFR inhibitor axitinib showed substantial clinical benefit with atypical radiographic responses.

In this prospective, single-arm, phase II study of axitinib in R/M HNSCC of any site, patients must be able to swallow pills and cannot have evidence of lesions encasing major blood vessels (eg, carotid artery). Patients will be started on 5 mg of axitinib twice daily continuously, with subsequent dose escalation to 7 mg and then 10 mg twice daily in the absence of grade 2 or worse toxicities. This will be followed by clinical and/or radiologic response assessment after 8 weeks, and subsequently every 2 months until disease progression (defined per the Choi response criteria) or intolerable toxicity.

Primary Objective:

- Determine 6-month overall survival in patients with unresectable R/M HNSCC treated with axitinib

Secondary Objectives:

- Determine overall survival
- Determine progression-free survival
- Determine disease control rate at 16 weeks and response rate as defined by Choi response criteria
- Determine duration of treatment response
- Assess the toxicities associated with axitinib

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ClinicalTrials.gov Identifier: NCT02762513

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This feature highlights an NCCN study funded through the grant mechanism.

doi: 10.6004/jnccn.2019.0016

For more information on specific trials, including patient selection criteria, use the contact information listed with each study.

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