Highlights of the NCCN Oncology Research Program

The NCCN Oncology Research Program (ORP) strives to improve the quality of life for patients and reduce cancer-related deaths by advancing cancer therapies through research. Since the program's establishment in 1999, the NCCN ORP has brought millions of dollars in research grants to investigators at NCCN Member Institutions. Research grants are provided to NCCN through collaborations with pharmaceutical and biotechnology companies; these grants are in turn used to support scientifically meritorious cancer research efforts.

NCCN ORP studies typically explore new avenues of clinical investigation and seek answers to important cancer-related questions. All studies are approved and funded through a scientific peer-review process and are overseen by the ORP.

An NCCN study funded through the grant mechanism are highlighted below.

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

Principal Investigators: Frances Worden, MD, and Paul L. Swiecicki, MD

Conditions: Head and neck squamous cell carcinoma

Institution: University of Michigan Comprehensive Cancer Center

Unresectable recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) has a dismal survival rate, 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, hence VEGF-targeted therapies are of significant interest. A previous trial using the potent VEGFR inhibitor axitinib demonstrated substantial clinical benefit with atypical radiographic responses.

In this prospective single-arm phase II study of axitinib in patients with unresectable 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 the 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 criteria
- Determine duration of treatment response
- Assess the toxicities associated with axitinib

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ClinicalTrials.gov Identifier: NCT02762513

The goal of the Highlights of the NCCN Oncology Research Program (ORP) is to provide readers with more information on the ORP, including studies currently accruing patients.

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

For more information on the NCCN ORP, including a complete detailing of the clinical studies currently underway at NCCN Member Institutions, please access the NCCN ORP pages at NCCN.org/clinical_trials/clinicians.asp.

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