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.

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

doi: 10.6004/jnccn.2022.0028

For more information on specific trials, including patient selection criteria, 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, go to www.nccn.org/education-research/nccn-oncology-research-program/clinical-trials.

Single-Arm Phase II Trial of Dual Inhibition of EGFR With Afatinib and Cetuximab With Correlative Studies in the Treatment of Advanced Squamous Cell Cancers of the Head and Neck

Principal Investigator: Aarti Bhatia, MD, MPH
Condition: Recurrent or metastatic squamous cell carcinoma of the head and neck
Institution: Yale Cancer Center

This is a single-arm phase II study of patients with recurrent or metastatic squamous cell carcinoma of the head and neck who were previously treated with a platinum-based regimen or an immune checkpoint inhibitor. After a baseline evaluation and biopsy, eligible patients will be treated with weekly intravenous cetuximab and daily oral afatinib. Biopsy will be repeated when feasible after 4 weeks (window of ≥1 week) on therapy and again at disease progression or end of treatment. Treatment will continue until disease progression or development of grade ≥3 drug-related toxicities that fail to resolve to grade 1 despite appropriate supportive care. This trial is particularly timely, as PD-1 inhibition is used in the first-line treatment of recurrent/metastatic head and neck cancer, and more effective strategies are needed to incorporate cetuximab in the management of patients for whom immune checkpoint inhibition failed.

Primary Objective:

- Determine response of advanced squamous cell carcinoma of the head and neck to treatment with combination afatinib + cetuximab

Secondary Objectives:

- Determine impact on long-term efficacy outcomes, safety, and tolerability of the combination
- Determine laboratory correlates for more effective inhibition of EGFR signaling with the combination

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ClinicalTrials.gov Identifier: NCT02979977