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 http://www.nccn.org/clinical_trials/clinicians.asp.

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.

Several NCCN-sponsored studies funded through the grant mechanism are highlighted below.

A Phase I/II Trial of the Combination of Cisplatin, Cetuximab, and Temsirolimus in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

Principal Investigator: Jeffrey Allen, MD

Condition: Squamous cell carcinoma of the head and neck

Institution: University of Tennessee Cancer Institute

This study will accrue in 2 phases. During phase 1, the optimal dose of temsirolimus in combination with cisplatin and cetuximab will be determined. This dose-finding phase is expected to require 9 to 12 patients. After the optimal dose is determined, an additional 41 patients will be enrolled for phase 2. The primary purpose of phase 2 is to learn what effects (good or bad) temsirolimus in combination with cisplatin and cetuximab has on recurrent or metastatic head and neck cancer.

Collection of additional blood and tissue specimens will allow for special tests that will provide information about how tumors respond to the chemotherapy, how the body breaks down and processes the drug, how differences in the genetic makeup of each person affect how the drug may work and is processed in the body, and how the drug affects proteins and cells in the body. The results of these specialized tests will help predict which patients are more likely to benefit from use of the drugs in this study.

Primary Outcome Measure:

- Phase 1: Optimal dose will be determined by whether the subjects experience a dose limiting toxicity.
- Phase 2: Progression-free survival is defined as time from first treatment to documented progression of disease or death, whichever comes first.

Secondary Outcome Measures:

- Overall response rate is defined as a proportion of patients achieving any response (CR + PR) compared with total patient population.
- Disease control rate is defined as proportion of patients who experience CR, PR, or SD (≥ 12 wk) during study treatment compared with total patient population.
- Overall survival is defined as time from first treatment to death, regardless of cause.

Contact: Steve West • 901-722-0581 • swest@utcancer.com

ClinicalTrials.gov Identifier: NCT01015664

Phase II Study of Pralatrexate and Docetaxel in Patients With Advanced Esophageal and Gastroesophageal Carcinoma Who Have Failed Prior Platinum-Based Therapy

Principal Investigator: Jeffrey S. Rose, MD

Condition: Adenocarcinoma of the esophagus, adenocarcinoma of the gastroesophageal junction, recurrent esophageal cancer, squamous cell carcinoma of the esophagus, stage IV esophageal cancer

Institution: The Ohio State University Comprehensive Cancer Center-James Cancer Hospital and Solove Research institute

Pralatrexate is a dihydrofolate reductase inhibitor leading to interference with DNA synthesis and subsequent death of tumor cells. Docetaxel, an established therapy in esophageal carcinoma, binds to microtubules and ultimately inhibits cell division by mitosis. Drugs used in chemotherapy, such as docetaxel and praltarexate, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is proposed that administering pralatrexate together with docetaxel may kill more tumor cells and thus improve survival in patients with esophageal cancers.

This phase II trial is to study the efficacy of pralatrexate with docetaxel in patients with stage IV esophageal or gastroesophageal cancer in whom platinum-based therapy failed.

Primary Outcome Measure:

- Overall response

Secondary Outcome Measures:

- Progression-free survival
- Overall survival
- Correlation of FDG PET response with response rate

Contact: Jeffrey S. Rose, MD • 614-366-8715 • Jeff.Rose@osumc.edu

ClinicalTrials.gov Identifier: NCT01129206