Journal of the National Comprehensive Cancer Network

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.

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.

NCCN studies funded through the grant mechanism are highlighted below.

Phase I Study of Induction Chemotherapy With Afatinib, Ribavirin, and Weekly Carboplatin/Paclitaxel for Stage IVA/IVB Human Papillomavirus–Associated Oropharynx Squamous Cell Cancer

Principal Investigator: Matthew Fury, MD, PhD

Condition: Head and neck cancer

Institution: Memorial Sloan-Kettering Cancer Center

This is a single-institution phase I study with an expansion cohort. Up to 2 dose levels of daily afatinib will be studied: 30 mg/d and 40 mg/d. The doses of ribavirin, carboplatin, and paclitaxel are fixed. A standard 3 + 3 phase I dose escalation design will be used. After completion of the Dose Escalation portion of the study, 10 additional subjects will be enrolled in an Expansion Cohort. The Expansion Cohort run-in is strictly for correlative research purposes.

Primary Objectives:

- Dose Escalation portion of the study: establish the phase II recommended dose of daily afatinib administered with weekly carboplatin/paclitaxel and twice-daily ribavirin for patients with stage IVA/IVB oropharyngeal squamous cell carcinoma
- Expansion Cohort: determine if a 2-week run-in with afatinib and ribavirin results in increased expression of PTPN13, as determined by immunohistochemistry on pretreatment and posttreatment biopsies

Secondary Objectives:

- Establish the safety and tolerability of daily afatinib given with weekly carboplatin/paclitaxel and twice-daily ribavirin
- Tabulate the objective response rate among patients treated with afatinib, carboplatin, paclitaxel, and ribavirin
- Expansion Cohort only: perform immunohistochemistry on pretreatment and posttreatment tumor biopsies to describe the pharmacodynamic effects of afatinib and ribavirin on target proteins of interest (total and phosphorylated epidermal growth factor receptor; total and phosphorylated ErbB2; p16)

Contacts: Matthew Fury, MD, PhD • 646-888-4233
David Pfister, MD • 646-888-4232

ClinicalTrials.gov Identifier: NCT01721525