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 is highlighted below.

Afatinib and Nivolumab as Treatment of Platinum- and Cetuximab-Refractory Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck

Principal Investigator: Michael Gibson, MD, PhD

Conditions: Squamous cell carcinoma of the head and neck

Institution: Vanderbilt-Ingram Cancer Center

This phase I trial will assess the dose, safety, and side effects of the combination of the cancer drugs afatinib (GILOTRIF) and nivolumab (OPDIVO) and assess the anticancer effects of this drug combination when used to treat patients with advanced squamous cell carcinoma of the head and neck (SCCHN) that has not responded to previous treatments.

Primary Objectives:

- Dose escalation: determine dose-limiting toxicities and maximum tolerated dose of combination afatinib and nivolumab as second-line therapy for patients with platinum- and cetuximab-refractory recurrent/metastatic SCCHN
- Dose expansion: determine long-term safety and toxicity of combination afatinib and nivolumab when administered to patients with recurrent/metastatic SCCHN who experienced disease progression during or after platinum- and cetuximab-based chemotherapy

Secondary Objectives:

- Assess progression-free and overall survivals for combination afatinib and nivolumab given as second-line therapy to patients with platinum- and cetuximab-refractory recurrent/metastatic SCCHN
- Estimate the objective response rate as assessed by irRECIST stratified by HPV status in patients with recurrent/metastatic SCCHN who experienced disease progression during or after platinum-based chemotherapy as first-line treatment

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ClinicalTrials.gov Identifier: NCT03652233

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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