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

A Phase I Clinical Trial of Pazopanib in Combination With Escalating Doses of Radioactive ^{131}I in Patients With Well-Differentiated Thyroid Carcinoma Refractory to Radioiodine, Despite Having Some Uptake

Principal Investigator: Laura Q. Chow, MD

Conditions: Recurrent thyroid cancer; stages IVA, IVB, IVC follicular thyroid cancer; and stages IVA, IVB, IVC papillary thyroid cancer

Institution: Fred Hutchinson Cancer Research Center/University of Washington Cancer Consortium

This phase I trial is studying the side effects and best dose of iodine I-131 (^{131}I) when given with pazopanib hydrochloride in treating patients with recurrent and/or metastatic thyroid cancer previously treated with ^{131}I that cannot be removed by surgery. Radioactive drugs, such as ^{131}I, may carry radiation directly to cancer cells and not harm normal cells. Pazopanib hydrochloride may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Giving ^{131}I with pazopanib hydrochloride may be an effective treatment for thyroid cancer.

Primary Objective:

- Determine the safety, tolerability, and feasibility of administrating escalating doses of ^{131}I in combination with concurrent pazopanib (pazopanib hydrochloride) therapy to define the maximum tolerated dose (MTD)/recommended phase II dose in patients with radioiodine (RAI)-refractory disease with minor RAI-uptake

Secondary Objectives:

- Determine the effects of pazopanib in combination with ^{131}I on RAI-avidity, uptake, and tumor response rate (RECIST, version 1.1)
- Determine the time to tumor progression or recurrence (progression determined by RECIST criteria and by increases in suppressed thyroglobulin levels > 50% compared with tumor imaging and suppressed thyroglobulin levels performed within 1 week of the last pazopanib dose)

Contact: Seattle Cancer Care Alliance • 800-804-8824

ClinicalTrials.gov Identifier: NCT01413113

A Phase I Trial of Vorinostat in the Treatment of Advanced Laryngeal, Hypopharyngeal, Nasopharyngeal, and Oropharyngeal Squamous Cell Carcinoma of the Head and Neck

Principal Investigator: Theodoros N. Teknos, MD

Conditions: Advanced laryngeal, hypopharyngeal, nasopharyngeal, and oropharyngeal squamous cell carcinoma of the head and neck

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

Vorinostat may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Drugs used in chemotherapy, such as cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or stopping them from dividing. Radiation therapy uses high-energy x-rays and other types of radiation to kill tumor cells. Giving vorinostat together with chemotherapy and radiation therapy may kill more tumor cells.

This phase I trial is studying the side effects and best dose of vorinostat when given together with cisplatin and radiation therapy in treating patients with advanced laryngeal, hypopharyngeal, nasopharyngeal, and oropharyngeal squamous cell carcinoma (SCC) of the head and neck.

Primary Objective:

- Determine the MTD of vorinostat in combination with concurrent chemoradiotherapy for the treatment of advanced stage laryngeal, hypopharyngeal, nasopharyngeal, and oropharyngeal SCC

Secondary Objective:

- Determine the complete response rate, overall survival, and progression-free survival using the MTD of vorinostat

Tertiary Objectives:

- Assess treatment-related acute and late toxicities when combining vorinostat with chemoradiation, and correlate these toxicities to molecular markers of apoptosis in tumor and normal oral mucosa
- Evaluate the effect of vorinostat on tumor immune surveillance, particularly in HPV-positive patients
- Illustrate that vorinostat alters the methylation status of commonly methylated genes in laryngeal, hypopharyngeal, nasopharyngeal, and oropharyngeal SCC

Contact: Theodoros N. Teknos, MD • 614-293-8074 • Ted.Teknos@osumc.edu

ClinicalTrials.gov Identifier: NCT01064921