Journal of the National Comprehensive Cancer Network

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.

Impact of Temsirolimus Therapy on Circulating Tumor Cell Biology in Men with Castration-Resistant Metastatic Prostate Cancer

Principal Investigator: Andrew Armstrong, MD, ScM

Condition: Prostate cancer

Institutions: Duke University Medical Center, Durham, North Carolina; and Virginia Oncology Associates, Norfolk Virginia

This is a single arm study of 20 men with treatment refractory metastatic castration resistant prostate cancer (CRPC) who will receive temsirolimus IV at a dose of 25 mg weekly until progression. Progression will not include PSA progression; however, on PSA progression, the addition of an antiandrogen will be permitted.

Primary Outcome Measures:

- To evaluate change in circulating tumor cell (CTC) counts over time in men with metastatic treatment-refractory castration-resistant prostate cancer

Secondary Outcome Measures:

- To evaluate the change in CTC counts on addition of an antiandrogen on PSA progression while on temsirolimus therapy
- To evaluate the changes in measures of epithelial plasticity on CTCs in response to mTOR inhibition with temsirolimus, using genomic and protein immunohistochemical methodology
- To evaluate and correlate changes in serum LDH with CTC count changes over time in men with CRPC treated with temsirolimus

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ClinicalTrials.gov Identifier: NCT00887640

Weekly Nanoparticle Albumin-Bound Paclitaxel Plus Weekly Cetuximab Plus Radiation Therapy in Patients With Stage III-IVB Head and Neck Squamous Cell Carcinoma

Principal Investigator: Matthew Fury, MD, PhD

Condition: Head and neck cancer

Institution: Memorial Sloan-Kettering Cancer Center

Paclitaxel is a standard drug in the management of head and neck cancer, and Abraxane (nanoparticle albumin-bound paclitaxel; Abraxis Bioscience; Bridgewater, NJ) is a novel formulation of paclitaxel. The purpose of this study is to establish a safe dose range of nanoparticle albumin-bound paclitaxel given in combination with cetuximab and radiation therapy.

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.

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All patients will receive standard treatment with definitive radiation therapy (intensity-modulated radiation therapy [IMRT]) plus cetuximab (400 mg/m^2 IV loading dose 1 week before radiation therapy, followed by 250 mg/m^2 weekly IV infusions concurrent with radiation therapy). Weekly nanoparticle albumin-bound paclitaxel will also be given by vein concurrently with radiation therapy, according to the dose escalation scheme.

The total number of planned cetuximab infusions is 8 (loading dose, plus 7 weekly infusions concurrent with radiation therapy). The total number of planned nanoparticle albumin-bound paclitaxel infusions is 7 (all concurrent with radiotherapy). Up to 5 dose levels of weekly nanoparticle albumin-bound paclitaxel will be explored.

Primary Outcome Measures:

- To establish the phase II recommended dose of weekly intravenous albumin-bound paclitaxel given concurrently with weekly cetuximab + definitive radiation therapy (IMRT) for patients with head and neck squamous cell carcinoma (HNSCC)

Secondary Outcome Measures:

- To establish the safety and tolerability of weekly albumin-bound paclitaxel plus cetuximab plus RT for patients with HNSCC

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ClinicalTrials.gov Identifier: NCT00736619

Phase I/IIa Study of the Novel Combination of Bendamustine With Irinotecan Followed by Etoposide/Carboplatin in Chemonaive Patients With Extensive-Stage Small Cell Lung Cancer

Principal Investigator: Francisco Robert, MD

Condition: Small cell lung cancer

Institutions: University of Alabama at Birmingham, Birmingham, Alabama; and Georgia Cancer Specialists, Marietta, Georgia

Subjects will be treated with irinotecan (150 mg/m^2) infusion on day 1 followed by infusion of bendamustine on days 1 and 2 at increasing dose levels using a 3+3 design (starting dose of 80 mg/m^2/day with 20 mg/m^2/day incremental increase to max 120 mg/m^2/day; regimen A). This will be repeated every 3 weeks for a total of 3 cycles. Restaging for response will be performed prior to the next regimen.

Currently, cohort 2 of the dose-escalation portion of the study has been completed. All subjects will then be given carboplatin (AUC 6) on day 1 and etoposide (100 mg/m^2) on days 1, 2, and 3 (regimen B). They will receive 3 cycles of this regimen every 3 weeks before restaging.

At the end (3 weeks after) of the sixth total round of chemotherapy, subjects will be reevaluated for response. They will be followed up for recurrent disease every 8 weeks.

Primary Outcome Measures:

- Maximum tolerated dose and safety of the combination bendamustine and irinotecan in chemotherapy-naive patients with extensive small cell lung cancer (SCLC)

Secondary Outcome Measures:

- To investigate the time to progression of bendamustine/irinotecan in sequence with etoposide/carboplatin in chemotherapy-naive patients with extensive stage SCLC

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ClinicalTrials.gov Identifier: NCT00856830