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 Study of Bortezomib (VELCADE) in Combination With Pralatrexate in Relapsed/Refractory Multiple Myeloma

Principal Investigator: Michaela Liedtke, MD
Condition: Multiple myeloma
Institution: Stanford University

This is an open-label, phase I, dose-escalation safety study of bortezomib in combination with pralatrexate in patients with previously treated multiple myeloma. In a standard 3 + 3 dose escalation trial design, escalating doses of pralatrexate in combination with bortezomib will be studied until the maximum tolerated dose (MTD) is determined.

Primary Objectives:
• Determine the MTD for combination pralatrexate and VELCADE in previously treated adult patients with multiple myeloma

Secondary Objectives:
• Clinical evidence of antitumor activity based on response rates
• Time to progression (TTP) assessed after each 4 week cycle (up to 4 cycles) and every 3 months for the first 2 years from protocol registration, every 6 months for years 3 to 5, then annually thereafter
• Duration of response outcome assessed after each 4 week cycle (up to 4 cycles) and every 3 months for the first 2 years from protocol registration, every 6 months for years 3 to 5, then annually thereafter
• Progression-free survival assessed after each 4 week cycle (up to 4 cycles) and every 3 months for the first 2 years from protocol registration, every 6 months for years 3 to 5, then annually thereafter
• Overall survival assessed after each 4 week cycle (up to 4 cycles) and every 3 months for the first 2 years from protocol registration, every 6 months for years 3 to 5, then annually thereafter

Contacts: Vani Jain • 650-725-5459
ClinicalTrials.gov Identifier: NCT01114282

A Phase II Study of Bendamustine in the Treatment of Recurrent High-Grade Gliomas (Anaplastic Gliomas and Glioblastoma)

Principal Investigator: Marc Chamberlain, MD
Condition: Anaplastic glioma (glioblastoma arm closed)
Institution: Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance

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This phase II trial is studying how well bendamustine hydrochloride works in treating patients with recurrent or progressive anaplastic glioma or glioblastoma multiform. (Please note: the glioblastoma arm of this study is closed.)

**Primary Outcome Measures:**
- Six month progression-free survival rate

**Secondary Outcome Measures:**
- Safety
- Efficacy
- Quality of Life
- Best overall response
- Toxicity

**Contact:** Sandra K. Johnston, PhD, RN • 206-288-6365

**ClinicalTrials.gov Identifier:** NCT00823797

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**Phase II Study Evaluating Combination Temsirolimus and Sorafenib in the Treatment of Radioactive Iodine Refractory Thyroid Cancer**

**Principal Investigator:** Eric Sherman, MD

**Condition:** Thyroid cancer

**Institution:** Memorial Sloan-Kettering Cancer Center

A phase II study to evaluate the efficacy of combination sorafenib and temsirolimus in patients with thyroid cancer of follicular cell origin (e.g., papillary, follicular, Hürthle cell, anaplastic).

**Primary Outcome Measures:**
- Determine the objective response rate of combination sorafenib and temsirolimus in I-131 refractory thyroid cancer

**Secondary Outcome Measures:**
- Evaluate if the presence of BRAF mutations, with or without concomitant mutations in the PI3K AKT, mTOR pathway, predicts response to therapy
- Determine progression-free survival of combination sorafenib and temsirolimus in I-131 refractory thyroid cancer
- Evaluate safety and tolerability for combination sorafenib and temsirolimus in I-131 refractory thyroid cancer

**Contacts:**
- Eric Sherman, MD • 212-639-5070
- Matthew Fury, MD, PhD • 212-639-3049

**ClinicalTrials.gov Identifier:** NCT01025453