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.

NCCN studies funded through the grant mechanism are highlighted below.

Phase II Study of Sorafenib Plus Doxorubicin in Patients With Advanced Hepatocellular Carcinoma With Disease Progression on Sorafenib

Principal Investigator: Ghassan Abou-Alfa, MD

Condition: Hepatocellular carcinoma

Institution: Memorial Sloan Kettering Cancer Center

There is an increasing need for the identification of second-line therapies in patients with advanced hepatocellular carcinoma who fail to respond to initial treatment with sorafenib, the current standard of care. A retrospective analysis examining the activity of doxorubicin and sorafenib as second-line treatment suggests that this combination therapy may have activity after sorafenib failure, and was tolerable despite toxicities.

Patients will receive doxorubicin, 60 mg/m^2 intravenously on day 1 of each 3-week cycle until they experience unacceptable toxicity, and sorafenib, 400 mg orally twice daily or the dose used in previous sorafenib-based therapy, until they experience unacceptable toxicity or disease progression, after which sorafenib can be continued as a single agent.

Primary Objective:

- Determine overall survival (OS) at 6 months for patients with advanced hepatocellular carcinomas treated with second-line combination therapy with sorafenib plus doxorubicin

Secondary Objectives:

- Evaluate the median time to progression
- Evaluate the median progression-free survival (PFS)
- Evaluate the median OS
- Evaluate the tolerance to combination therapy with sorafenib and doxorubicin
- Correlate PFS, response rate, time to progression, and OS to previous length of exposure to previous sorafenib therapy
- Assess for ASK-1 and pERK expression in pretreatment and posttreatment tissue samples
- Correlate PFS, response rate, time to progression, and OS to pretreatment and posttreatment biopsied tumor pERK and ASK-1 expression levels

Contacts:

Ghassan Abou-Alfa, MD • 646-888-4184

Leonard Saltz, MD • 646-888-4181

ClinicalTrials.gov Identifier: NCT01840592

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.