Highlights of the NCCN Oncology Research Program

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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A Phase I Trial of Sorafenib and Bavituximab Plus Stereotactic Body Radiation Therapy for First-Line Treatment of Unresectable Hepatocellular Carcinoma

Principal Investigator: Jessica Frakes, MD
Condition: Hepatocellular carcinoma
Institution: H. Lee Moffitt Cancer Center & Research Institute

This is a phase I study with cohort expansion that utilizes a standard 3+3 design for dose escalation. The primary objective of the study is to evaluate the safety and tolerability of bavituximab/sorafenib in combination with stereotactic body radiation therapy (SBRT) in patients with advanced hepatocellular cancer (HCC), and to determine the maximum tolerated dose (MTD) and the recommended dose for cohort expansion of this combination regimen. SBRT will be given first and, after a 1 week break, sorafenib and bavituximab will be started concurrently. The primary study end point is safety and tolerability of the combination of SBRT and bavituximab/sorafenib.

Primary Objective:
• Occurrence of treatment-related adverse events

Secondary Objectives:
• Objective response rate
• Progression-free survival
• Overall survival

Contacts: H. Lee Moffitt Cancer Center & Research Institute
Soha Riad • soha.riad@moffitt.org
Jessica Frakes, MD • jessica.frakes@moffitt.org

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