

TYPE OF CANCER: Refractory or Relapsed Cancer
TYPE OF TRIAL: Phase I
TRIAL SPONSOR: Myriad

PRINCIPAL INVESTIGATOR: Wolfram Samlowski, M.D.
CONTACT PERSON: Annette Johnson
(702) 822-5177

STUDY SUMMARY

Phase 1 Study of MPC-3100 in Patients with Refractory or Relapsed Cancer

TREATMENT OVERVIEW

- MPC-3100 will be dosed orally, daily for 21 days in a 28 day cycle
- Patient should be seen by the physician at least once a week during cycle 1, once every 2 weeks during cycle 2, and every cycle thereafter.
- Patients may continue to participate in the study unless they experience unacceptable toxicity or disease progression or withdrawal from study

PRE-TREATMENT ASSESSMENTS

- Informed consent
- Medical history
- Disease assessment
- Physical exam
- Performance status
- Vital signs
- Electrocardiogram
- Chemistry
- Coagulation
- Hematology
- Urinalysis
- Pregnancy test (if applicable)

ENTRANCE CRITERIA FOR PARTICIPATION IN TRIAL

Inclusion criteria

1. Must have recurrent cancer refractory to available systemic therapy.
2. Must be at least 18 years old.
3. Must have a predicted life expectancy \geq 8 weeks.
4. Must be at least 4 weeks since prior surgical resection.
5. Must be at least 4 weeks post chemotherapy, immunotherapy, or radiation therapy and have recovered from treatment toxicities; must be off

- treatment with other investigational agents or treatments for at least 4 weeks and have recovered from toxicities.
6. Must be at least 1 week post biopsy.
 7. Must sign an informed consent indicating awareness of the investigational nature of this study. Subjects must sign an authorization form for the release of their protected health information.
 8. Must have a Karnofsky performance status of ≥ 60 or ECOG score ≤ 2
 9. Must have adequate organ function before starting therapy defined by: liver function tests < 2.5 times ULN in subjects without liver metastases or liver function tests < 5 times ULN in subjects with liver metastases, total bilirubin < 2 times ULN (total bilirubin < 3 times ULN in patients with Gilbert's Syndrome), neutrophil count $\geq 1500/\mu\text{L}$, hemoglobin > 8 g/dL, platelet count of $\geq 100,000/\mu\text{L}$, and serum creatinine $< 2 \times$ ULN. Target hemoglobin and platelet count may be achieved by transfusions. These tests must be performed within 14 days prior to first dose of study drug.
 10. Both male and female study subjects must use adequate contraceptive methods, or be biologically or surgically sterile.

Exclusion criteria

1. Be pregnant or breast feeding (women of childbearing potential must have a negative pregnancy test within 72 hours prior to first dose of study drug)
2. Have received any other anti-cancer treatment or investigational therapy within 28 days prior to Cycle 1 Day 1
3. Have symptoms of heart failure \geq Class III, according to the New York Heart Association (NYHA) criteria
4. Have any significant medical illnesses that in the investigator's opinion cannot be adequately controlled with appropriate therapy or would compromise the subject's ability to tolerate this therapy
5. Require granulocyte-colony stimulating factor (G-CSF) to maintain neutrophil count at study entry
6. Concurrent treatment with medications that either markedly induce or inhibit CYP3A4