

Protocol No. SWOG S0331

"A Phase II Trial of STI-571/Imatinib (Gleevec[®]) in Neuroendocrine Carcinoma of the Skin (Merkel Cell Carcinoma)"

Objectives

- To assess the feasibility of a Southwest Oncology Group Phase II trial of oral STI-571/imatinib (Gleevec[®]) administered to patients with metastatic or unresectable Merkel cell carcinoma.
- To evaluate the objective response probability (confirmed and unconfirmed complete and partial responses) of oral STI-571/imatinib (Gleevec[®]) administered to patients with metastatic or unresectable Merkel cell carcinoma
- To assess qualitative and quantitative toxicities of oral STI/imatinib (Gleevec[®]) administered to patients with metastatic or unresectable Merkel cell carcinoma.
- To analyze tumor samples for activating mutations of STI-571/imatinib-sensitive kinases (KIT, PDGFRA, PDGFRB) by denaturing HPLC and direct DNA sequencing.

Eligibility Criteria

- Biopsy-proven diagnosis of Merkel Cell Carcinoma (Cutaneous Neuroendocrine Carcinoma) that is distantly metastatic or unresectable. Tumors must meet both of the following criteria:
 - _ Primary must be of skin origin (patients with unknown primary are not eligible).
 - _ Immunohistochemical staining with c-kit (CD117) expression by tumor documented by DAKO antibody staining.
- Slides of tumor tissue must be submitted for pathology review.
- Measurable disease must be present. All measurable lesions must be assessed within 28 days prior to registration, all non-measurable within 42 days.
- Zubrod Performance Status of 0 - 2.
- Age 18 years or older.
- No prior radiotherapy, chemotherapy, biologic therapy or any other investigational drug for any reason within 28 days prior to registration. All toxicities from prior treatment must have been resolved. Patients whose only disease is within a previous

radiation therapy port must demonstrate clearly progressive disease prior to registration. No major surgery within 14 days prior registration.

- Adequate liver, renal, and hematologic function defined by laboratory values specified in protocol.
- Women of reproductive potential must have negative serum pregnancy test within 7 days prior to registration. Postmenopausal who have not had their ovaries removed must be amenorrheic for at least 12 months to be considered of non-childbearing potential. Patients of reproductive potential must employ an effective barrier method of birth control throughout the study and for up to 3 months following discontinuation of study drug.
- Must not be taking therapeutic doses of Coumadin (warfarin) as anticoagulation at time of registration. Those requiring therapeutic anticoagulation may use low molecular weight heparin or other agents, and mini-dose Coumadin as prophylaxis.

Ineligibility Criteria

- Symptomatic, unstable or untreated brain metastases.
- Class 3/4 cardiac problems as defined by the New York Heart Association Criteria (e.g., congestive heart failure, myocardial infarction) within 2 months of study.
- Severe and/or uncontrolled concurrent medical disease (e.g., uncontrolled diabetes, uncontrolled chronic renal or liver disease, or active uncontrolled infection such as HIV).
- Pregnant or nursing women.
- No prior malignancy allowed except for following: adequately treated basal cell or squamous cell skin cancer, *in situ* cervical cancer, adequately treated Stage I or II cancer from which patient is currently in complete remission, or any other cancer from which patient has been disease-free for 5 years.

More Information

This posting is a summary of the basic requirements for participation in this study, and it is not intended to provide all the information needed to decide whether or not to participate.

For additional information on all aspects of cancer, please contact

the [Huntsman Cancer Institute Information Service](#) at phone number listed below.

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