

04-153: A Phase II Study of G3139 (Genasense) in Patients with Merkel Cell Carcinoma

Objective:

To evaluate the overall response rate to G3139 in patients with advanced Merkel cell carcinoma.

Secondary objectives: evaluating the time to progression, evaluating the duration of therapy response, evaluating the safety and tolerance of G3139 in this patient population, and PK effects of G3139 on bcl-2 expression and apoptosis in tumor biopsy specimens.

Eligibility:

Histologically or cytologically confirmed Merkel cell carcinoma which is either metastatic or regionally recurrent. Subjects must have measurable disease.

Subjects with localized disease not amenable to potentially curative intervention (surgery or radiation) will also be eligible.

Prior therapy must have been completed (chemotherapy, radiation or investigational agent) for at least 3 weeks and subjects must have recovered from side effects.

Exclusionary criteria:

No known brain metastases.

No uncontrolled other illnesses such as: Ongoing or active infection, symptomatic or active congestive heart failure, unstable angina pectoris, cardiac arrhythmia, psychiatric illnesses or social situations that would limit compliance with study requirements.

No anticoagulation meds except for 1 mg of Warfarin for Mediport patency. No inability to get satisfactory venous access for continuous infusion of G3139.

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