Doctor's Note — Clinical Trial Summary

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TRIAL

Trametinib With or Without GSK2141795 in Treating Patients With Metastatic Uveal Melanoma

NCT ID: NCT01979523 Phase: PHASE2 Sponsor: National Cancer Institute (NCI) Status: Active Not Recruiting

SUMMARY

This randomized phase II trial studies how well trametinib with or without Akt inhibitor GSK2141795 (GSK2141795) works in treating patients with uveal melanoma that has spread to other parts of the body (metastatic). Trametinib and GSK2141795 may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether trametinib is more effective with or without GSK2141795 in treating patients with metastatic uveal melanoma.

KEY ELIGIBILITY CRITERIA

- * Patients must have metastatic histologically or cytologically confirmed uveal melanoma; if histologic or cytologic confirmation of the primary is not available, confirmation of the primary diagnosis of uveal melanoma by the treating investigator can be clinically obtained, as per standard practice for uveal melanoma; pathologic confirmation of metastatic disease will be performed at Memorial Sloan Kettering (MSK) or at a participating site
- * Patients must have measurable disease, defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded) as \>= 20 mm with conventional techniques or as \>= 10 mm with spiral computed tomography (CT) scan
- * Patients may not have received prior systemic or hepatic directed infusional/embolization therapies for advanced uveal melanoma; local therapies such as radiofrequency ablation or cryotherapy for metastatic disease are permitted but must have been performed at least 21 days prior to initiation of study therapy; lesions treated with local modalities such as radiofrequency ablation or cryotherapy may not be used as target lesions unless they demonstrate growth over a minimum of 3 months on subsequent imaging studies
- * Eastern Cooperative Oncology Group (ECOG) performance status =\< 1 (Karnofsky \>= 70%)
- * Life expectancy of greater than 3 months
- * Able to swallow and retain orally-administered medication and does not have any clinically significant gastrointestinal abnormalities that may alter absorption such as malabsorption syndrome or major resection of the stomach or bowels
- * All prior treatment-related toxicities must be Common Terminology Criteria for Adverse Events (CTCAE) version (v)4 grade =\< 1 (except alopecia) at the time of randomization and crossover
- * Leukocytes \>= 3,000/mcL
- * Absolute neutrophil count \>= 1,500/mcL
- * Platelets \>= 100,000/mcL

Total sites: 7 | 0 currently recruiting

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