

Doctor's Note — Clinical Trial Summary

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TRIAL

Vorinostat in Treating Patients With Metastatic Melanoma of the Eye

NCT ID: NCT01587352 Phase: PHASE2 Sponsor: National Cancer Institute (NCI) Status: Active Not Recruiting

SUMMARY

This phase II trial studies how well vorinostat works in treating patients with melanoma of the eye that has spread to other parts of the body (metastatic). Vorinostat may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth.

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 diagnosis will be performed at Columbia University, Memorial Sloan-Kettering Cancer Center (MSKCC) or Vanderbilt University Medical Center
- * Patients must have measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1
- * Age ≥ 18 years. Because limited dosing or adverse event data are currently available on the use of vorinostat in patients < 18 years of age, children are excluded from this study, but will be eligible for future pediatric single-agent trials, if applicable
- * Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 (Karnofsky $\geq 60\%$)
- * Life expectancy of greater than 3 months
- * Leukocytes $\geq 3,000/\text{mL}$
- * Absolute neutrophil count $\geq 1,500/\text{mL}$
- * Platelets $\geq 100,000/\text{mL}$
- * Hemoglobin ≥ 9.0 g/dL not requiring transfusions within the past 2 weeks
- * Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN); ≤ 3 x institutional ULN if the patient has Gilbert's syndrome

Total sites: 3 | 0 currently recruiting