

Doctor's Note — Clinical Trial Summary

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TRIAL

Adjuvant Quisinostat in High-Risk Uveal Melanoma

NCT ID: NCT06932757 Phase: PHASE2 Sponsor: University of Miami Status: Recruiting

SUMMARY

The purpose of this study is to see if giving participants quisinostat will prevent participants' uveal melanoma tumor from spreading. The researchers want to find out the effects that quisinostat has on participants' condition.

KEY ELIGIBILITY CRITERIA

- 1. Primary diagnosis of uveal melanoma (UM) with a lesion of at least 12 mm in largest basal diameter (LBD) as clinically determined by the treating Investigator. Cytologic determination of diagnosis is not required. Size is based on clinical assessment (e.g., by ultrasound or direct ophthalmoscopy) prior to enucleation or radiation therapy.
- 2. Definitive therapy of the primary UM must have been completed within 183 days of initiating protocol therapy.
- 3. High-risk (class 2) UM as determined by gene expression profiling (GEP; DecisionDx-UM, Castle Biosciences Inc., Friendswood, TX).
- 4. No evidence of metastatic disease.
- 5. Patients aged ≥ 18 years.
- 6. Eastern Cooperative Oncology Group (ECOG) performance status 0-1.
- 7. Life expectancy of greater than 3 months.
- 8. Ability to swallow and retain orally administered medication and no clinically significant gastrointestinal abnormalities that may alter absorption, such as malabsorption syndrome or major resection of the stomach or bowels.
- 9. Adequate organ and marrow function as defined by the local institutional lab and treating physician.
- 10. Women of childbearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation until 6 months after completion of quisinostat administration. Women of childbearing potential must have a negative urine or serum pregnancy test within 14 days prior to study entry.

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting