# Adjuvant Quisinostat in High-Risk Uveal Melanoma

NCT06932757

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| **Status** | RECRUITING |
| **Phase** | Phase 2 |
| **Sponsor** | University of Miami |
| **Enrollment** | 63 participants |

## Plain Language Summary

This trial is studying a drug called quisinostat as an additional (adjuvant) treatment after primary therapy for uveal melanoma — a rare type of eye cancer — in patients considered high-risk for the cancer coming back. Quisinostat works by blocking enzymes that help cancer cells survive.

**You may be eligible if...**
- You have been diagnosed with uveal melanoma (melanoma of the eye)
- Your cancer is considered high-risk — meaning it has features likely to spread
- You have completed your primary eye treatment (such as radiation or surgery)
- You are an adult in adequate overall health

**You may NOT be eligible if...**
- Your cancer has already spread to other parts of the body (distant metastases)
- You have serious heart rhythm abnormalities (QT prolongation)
- You have significant liver or kidney problems
- You are pregnant or breastfeeding
- You have uncontrolled infections or other serious illnesses

Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

### Inclusion (11)

- 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.
- Definitive therapy of the primary UM must have been completed within 183 days of initiating protocol therapy.
- High-risk (class 2) UM as determined by gene expression profiling (GEP; DecisionDx-UM, Castle Biosciences Inc., Friendswood, TX).
- No evidence of metastatic disease.
- Patients aged \>18 years.

... and 6 more (see full listing online)

### Exclusion (14)

- Additional malignancy that is progressing or requires active treatment. Exceptions include the following cancers: basal cell carcinoma or squamous cell carcinoma of the skin that has undergone potentially curative therapy, in situ cervical cancer, ductal carcinoma in situ (DCIS), incidentally discovered asymptomatic thyroid cancer, elevated levels of prostate-specific antigen (PSA) stable on hormonal therapy with no otherwise detectable disease, and a previous diagnosis of malignancy that has shown no evidence of disease progression for 2 years or longer.
- Any major surgery or extensive radiotherapy except that which is required for definitive treatment of primary UM.
- Previous adjuvant treatment for UM after definitive primary tumor therapy.
- History of prior Histone Deacetylase (HDAC) inhibitor use.

• Patients that cannot be taken off medications that are potent inhibitors of cytochrome (CYP) 3a4/A5 (CYP3a4/A5) and CYP2C9. Inclusion of these patients and of patients on warfarin will require discussion and approval by the Sponsor-Investigator prior to enrollment.

... and 9 more (see full listing online)

## Locations (1 total)

University of Miami, Miami, Florida, United States