Doctor's Note — Clinical Trial Summary

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TRIAL

Evaluation of the Safety, Efficacy, and Pharmacokinetics of NBM-BMX in Patients With Metastatic Uveal Melanoma

NCT ID: NCT07136181 Phase: PHASE1 / PHASE2 Sponsor: Novelwise Pharmaceutical Corporation Status: Recruiting

SUMMARY

This study is being done to find the best dose of an investigational drug called NBM-BMX for people with metastatic uveal melanoma, a type of eye cancer that has spread to other parts of the body.

The study will help doctors learn about the side effects of NBM-BMX, how the drug is processed in the body, and whether it may slow down or shrink tumors.

Participants will take NBM-BMX as a capsule by mouth twice daily on an empty stomach with at least six ounces (180 mL) of water. No food or drink (other than water) should be consumed for at least two hours after each dose.

Participants will visit the clinic about once every week or two for exams and blood tests while taking NBM-BMX. After stopping treatment, a follow-up visit will occur about 30 days later.

Treatment may continue as long as the cancer does not get worse and side effects remain manageable.

KEY ELIGIBILITY CRITERIA

- \- Patients must meet the following criteria to be eligible for study entry:
- 1. Signed, written IRB-approved informed consent.
- 2. Men and women age e 18 years
- 3. ECOG Performance status d 2
- 4. Have measurable disease based on RECIST 1.1
- 5. Histologic or cytologic confirmation of metastatic uveal melanoma
- 6. Previous Therapy
- * Surgery: Previous surgery is permitted provided that a minimum of 28 days (4 weeks) has elapsed between any major surgery and date of registration, and that wound healing has occurred.
- * Cytotoxic Chemotherapy: There is no limit to the number of prior regimens received.
- * Other Systemic Therapy: There is no limit to the number of prior therapies received for metastatic uveal melanoma. Prior treatment with tebentafusp is required for HLA-A*02:01-positive patients unless unavailable or clinically inappropriate, as determined by the investigator. Prior HDAC inhibitor treatment is not permitted.

Total sites: 3 | 3 currently recruiting