Doctor's Note — Clinical Trial Summary

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TRIAL

Neoadjuvant/Adjuvant Trial of Darovasertib in Ocular Melanoma

NCT ID: NCT05187884 Phase: PHASE2 Sponsor: St Vincent's Hospital, Sydney Status: Completed

SUMMARY

The purpose of this study is to determine the feasibility and tolerability of neo-adjuvant/adjuvant Darovasertib on uveal melanoma patients.

Who is it for? Patients may be eligible to join this study with high-risk uveal melanoma and planned to undergo enucleation

Study details:

Eligible patients will undergo up to 4 weeks of treatment with Darovasertib (300mg, twice a day as a starting dose) and once determiend safe then up to 6 months after fulfilling inclusion/exclusion criteria and consent. Select patients will undergo adjuvant treatment for 6 months based on their initial response.

It is hoped that this research will provide insight into the safety and tolerability of Darovasertib. Furthermore, it aims to document the pharmacodynamic and pharmacokinectic effects of Darovasertib on uveal melanoma patients.

KEY ELIGIBILITY CRITERIA

- * Patient must be at least 18 years of age.
- * Primary diagnosis of uveal melanoma as clinically determined by the treating investigator planned for enucleation (prior plaque brachytherapy is permitted)
- * Patient is able to provide written, informed consent before initiation of any study related-procedures, and is able, in the opinion of the investigator, to comply with all the requirements of the study.
- * Life expectancy \> 3 months.
- * Able to safely swallow orally administered medication.
- * Patients with a prior history of or clinically stable concurrent malignancy are eligible for enrolment provided the malignancy is clinically insignificant, no treatment is required, and the patient is clinically stable
- * Patients with a history of squamous or basal cell carcinoma of the skin or carcinoma in the situ of the cervix may be enrolled.
- * Patients with prostate cancer with an elevated PSA not requiring treatment may be enrolled
- * Patient has Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1 (Karnofsky = 70%).
- * Patient has adequate organ function at screening:

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