





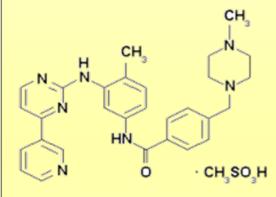
BACKGROUND

- A Phase II, UK based study of Imatinib in the treatment of patients with metastatic uveal melanoma
- Uveal melanoma is the most common primary malignancy involving the eye, but remains rare
- Uveal melanoma is a separate disease distinct from cutaneous melanoma
- Approximately 5% of patients present with metastatic disease
- There is no effective systemic therapy for metastatic uveal melanoma



STUDY OBJECTIVE

To evaluate the 3 month progression free rate of patients with unresectable good performance c-kit positive metastatic uveal melanoma treated with Imatinib



OUTCOMES

Primary Outcome:

Progression free survival at 3 months

Secondary Outcomes:

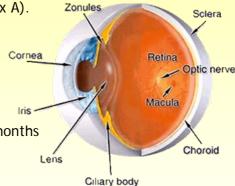
- Safety and toxicity of Imatinib
- Progression free survival (overall)
- Overall survival
- Overall response rate (according to RECIST criteria)
- Biomarker correlation with outcome measures

INCLUSION CRITERIA

- Patients with histologically or cytologically confirmed unresectable, metastatic uveal melanoma
- Any prior therapy for advanced disease excluding agents targeting c-kit.

Normal Eye Anatomy

- Life expectancy > 12 weeks,
- Performance status 0, 1 or 2 (ECOG performance scale : Appendix A).
- Presence of 1 or more measurable lesions, either clinically or radiologically, using RECIST criteria.
- Age ≥ 18 years
- Adequate haematological, renal and liver function
- Written informed consent provided by the patient
- Negative pregnancy test prior to study entry
- Using adequate contraception, which must be continued for 12 months after the study
- Prior radiotherapy is allowed. (measurable lesions not previously irradiated)
- No history of other malignant disease other than adequately treated non-melanomatous skin cancer or in situ carcinoma of the cervix.



FOR FURTHER DETAILS PLEASE CONTACT