Doctor's Note — Clinical Trial Summary

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TRIAL

Adjuvant Tebentafusp in High Risk Ocular Melanoma

NCT ID: NCT06246149 Phase: PHASE3 Sponsor: European Organisation for Research and Treatment of Cancer - EORTC Status: Recruiting

SUMMARY

At least 50% of patients with high-risk primary uveal melanoma will develop a recurrence following treatment of the primary tumour. Observation is currently the standard of care in the non-metastatic setting. Tebentafusp is the first agent proven to improve overall survival in patients with metastatic uveal melanoma in a randomized trial. Based on the results in the advanced setting, it is hypothesized that treatment with tebentafusp may reduce the risk of development of disease recurrence.

KEY ELIGIBILITY CRITERIA

- * Primary non-metastatic UM, except iris melanoma, after definitive treatment either by surgery or radiotherapy
- * Time from primary treatment smaller than 11 weeks (note that the maximum time between primary treatment and randomization is 12 weeks)
- * High-risk according to either 1) clinical criteria: TNM (AJCC8) stage III or 2) genetic criteria: monosomy 3 or GEP class 2. Prior to enrolment of the first patient, each site will declare which of the two genetic criteria it uses. Patients with stage I and stage II are only eligible if they meet the genetic criterion declared by the site.
- * ECOG performance status of 0 or 1
- * 18 years or older
- * HLA-A*02:01 positivity by local assessment
- * No evidence of UM recurrence, as evidenced by the required baseline imaging performed within 4 weeks prior to randomization
- * Adequate organ function
- * Time-interval between the end of primary treatment and the randomization less than or equal to 12 weeks
- * Evidence of post-menopausal status or negative urinary or serum pregnancy test for women of childbearing potential (WOCBP) within 3 days prior to randomization.

ENROLLMENT CONTACT

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Total sites: 14 | 14 currently recruiting