Doctor's Note — Clinical Trial Summary

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TRIAL

Efficacy and Safety of Pembrolizumab in Combination With Lenvatinib in Metastatic Uveal MElanoma Patients (PLUME)

NCT ID: NCT05282901 Phase: PHASE2 Sponsor: Institut Curie Status: Active Not Recruiting

SUMMARY

Because we suspect that the benefit of anti-PD-1 in metastatic UM patients could vary according to previous exposure to Tebentafusp (better efficacy of anti-PD-1 after Tebentafusp), the combination of pembrolizumab and lenvatinib will be assessed in two independent cohorts: cohort 1 with Tebentafusp-naive patients, and cohort 2 with patients previously treated by Tebentafusp.

The study is a monocentric, phase II trial with a single-arm of treatment in each cohort.

Liver MRI and chest-abdomen-pelvis CT will be performed every 9 weeks until progressive disease (PD), followed by a Follow-up visit within 28 days after last treatment intake. Survival status will be registered after patient discontinuation.

KEY ELIGIBILITY CRITERIA

- 1. Male/female participants who are at least 18 years of age on the day of signing informed consent with histologically confirmed diagnosis of metastatic uveal melanoma (UM).
- 2. (i) Not having been treated with Tebentafusp for cohort 1 (Tebentafusp-naive patients) OR (ii) Having been previously treated with Tebentafusp for cohort 2.
- 3. Life expectancy \> 3 months.
- 4. Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. Evaluation of ECOG has to be performed at inclusion.
- 5. Male participants must agree to use contraception
- 6. A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies:
- 1. Not a woman of childbearing potential (WOCBP) OR
- 2. A WOCBP who agrees to follow the contraceptive guidance
- 7. Measurable disease based on RECIST 1.1. lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.
- 8. The participant (or legally acceptable representative if applicable) provides written informed consent for the trial.

Total sites: 1 | 0 currently recruiting