Doctor's Note — Clinical Trial Summary

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TRIAL

PHP in Combination With IPI1/NIVO3 Compared to IPI3/NIVO1 Only in Patients With Uveal Melanoma Liver Metastases

NCT ID: NCT06519266 Phase: PHASE3 Sponsor: Vastra Gotaland Region Status: Recruiting

SUMMARY

Uveal melanoma is the most common primary intraocular malignancy in adults. Despite successful control of the primary tumor, metastatic disease will develop in approximately 35%-50% of the patients within 10 years. The liver is the most common site for metastases, and about 50% of the patients will have isolated liver metastases. These metastases are generally refractory to systemic chemotherapy and the median survival for patients with liver metastases is about 6 months. Regardless of treatment, the mortality rate is approximately 90% at 2 years with only about 1% of the patients surviving more than 5 years.

The primary objective with this study is to evaluate progression-free survival in patients with uveal melanoma liver metastases randomized to either percutaneous hepatic perfusion (PHP) in combination with ipilimumab and nivolumab or ipilimumab and nivolumab only. Secondary objectives include further efficacy and safety analysis, as well as biomarker discovery.

KEY ELIGIBILITY CRITERIA

- 1. Patient is e18 years.
- 2. Signed informed consent.
- 3. ECOG performance status of 0 or 1.
- 4. Histologically or cytologically confirmed liver metastasis of uveal melanoma.
- 5. Measurable disease by computed tomography (CT) per RECIST 1.1 criteria with at least one target lesion identified in the liver.
- 6. No previous treatment for uveal melanoma metastases, except patients that have confirmed progression on tebentafusp, or after surgical resection or ablative treatments (e.g., radiofrequency ablation or stereotactic body radiation therapy).
- 7. Patient deemed suitable for percutaneous hepatic perfusion.
- 8. Female patient of childbearing potential should have a negative urine or serum pregnancy test within 72 hours prior to receiving the first treatment. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.
- 9. Female patients of childbearing potential must be willing to use an adequate method of contraception, for the course of the study through 150 days after the last dose of study medication. Note: Abstinence is acceptable if this is the usual lifestyle and preferred contraception for the subject.
- 10. Male patients of childbearing potential must agree to use an adequate method of contraception, starting with the first dose of study therapy through 150 days after the last dose of study therapy. Abstinence is acceptable if this is the usual lifestyle and preferred contraception for the subject.

ENROLLMENT CONTACT

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Total sites: 6 | 3 currently recruiting