Doctor's Note — Clinical Trial Summary

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TRIAL

Locoregional or Systemic Administration of Autologous Tumor Infiltrating Lymphocytes in Patients With Metastatic Melanoma

NCT ID: NCT07183852 Phase: PHASE1 Sponsor: Vastra Gotaland Region Status: Not Yet Recruiting

SUMMARY

The purpose of this study is to evaluate the feasibility, safety and tolerability of locoregional or systemic administration of autologous tumor infiltrating lymphocytes in patients with metastatic melanoma

KEY ELIGIBILITY CRITERIA

- 1. Participants must be at least 18 years of age.
- 2. Can provide a signed informed consent as described in the protocol, including compliance with the requirements and restrictions listed in the ICF and in this protocol.
- 3. World Health Organization (WHO) Performance Status 0 or 1.
- 4. Patient must have a histologically/cytologically confirmed diagnosis of:
- * stage IV uveal melanoma with confirmed progression following prior systemic therapy with tebentafusp (if HLA A2:01 positive) OR
- * stage IV cutaneous melanoma with confirmed progression following prior systemic therapy with a programmed cell death protein-1 (PD-1) inhibitor with or without a CTLA-4 inhibitor
- 5. At least one resectable lesion in the liver (or aggregate of lesions resected) of a minimum size of 0.5 cm in diameter to generate TILs.
- 6. Measurable disease by computed tomography (CT) per RECIST 1.1 criteria after resection of lesion for TILs production
- 7. No other malignancies, except if treated with curative intent and with a cancer-related life expectancy of more than 5 years.
- 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.

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