Doctor's Note — Clinical Trial Summary

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TRIAL

Locoregional Administration of TIL and Lymphodepletion in Patients With Melanoma and Liver Metastases

NCT ID: NCT05903937 Phase: PHASE1 Sponsor: Vastra Gotaland Region Status: Not Yet Recruiting

SUMMARY

Evaluate the safety and tolerability of treatment with autologous tumor infiltrating lymphocytes (TIL) administered via hepatic arterial infusion and preconditioning with percutaneous hepatic perfusion in patients with liver metastases (but not restricted to) of malignant melanoma

KEY ELIGIBILITY CRITERIA

- * Patient is willing and able to provide written informed consent and comply with study procedures. Written informed consent must be signed and dated before the start of specific protocol procedures.
- * Patient must have a histologically/cytologically confirmed diagnosis of:
- * stage IV uveal melanoma with or without any previous systemic therapy OR
- * stage IV cutaneous melanoma with confirmed progression following at least one or two prior systemic therapies including a programmed cell death protein-1 (PD-1) inhibitor with or without a CTLA-4 inhibitor; and if BRAF V600 mutation-positive, also a BRAF inhibitor or a BRAF inhibitor in combination with a MEK inhibitor.
- * Measurable disease by computed tomography (CT) per RECIST 1.1 criteria with at least one target lesion identified in the liver and where the distribution pattern of metastasis is predominantly engaging the liver as judged by the investigator.
- * At least one resectable lesion in the liver (or aggregate of lesions resected) of a minimum size of 0.5 cm in diameter post- resection to generate TILs.
- * ECOG performance status of 0 - 1.
- * Life expectancy of less than 3 months.
- * Reduced renal function defined as S-Creatinine \>=1.5xULN or Creatinine Clearance \< 40 mL/min, calculated using the Cockroft and Gault formula.
- * Reduced hepatic function (defined as ASAT, ALAT, bilirubin \> 3*ULN and PK- INR \> 1.5) or medical history of liver cirrhosis or portal hypertension.

Total sites: 0 | 0 currently recruiting

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