Doctor's Note — Clinical Trial Summary

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TRIAL

Safety and Preliminary Efficacy of MBS8(1V270) in Cancer Patients With Advanced Solid Tumours

NCT ID: NCT04855435 Phase: PHASE1 Sponsor: MonTa Biosciences ApS Status: Recruiting

SUMMARY

The Phase I trial is evaluating safety, tolerability, pharmacokinetics and preliminary efficacy of MBS8(1V270) in subjects with advanced solid tumours. The trial is designed to provide data for further clinical development of MBS8(1V270)

KEY ELIGIBILITY CRITERIA

- Stage I Inclusion Criteria
- 1. Male or female aged e18 years.
- 2. Diagnosis of a histologically or cytologically confirmed solid tumour that was advanced and with progression. No standard treatment existed, or the participant refused standard treatment. Experimental immunotherapy appeared as a feasible exploratory treatment option as per Investigator's assessment.
- 3. Tumour lesion(s) accessible to serial biopsies.
- 4. Was willing and able to comply with scheduled visits, treatment schedule, laboratory tests, and tumour biopsies. Mandatory Baseline and on-treatment tumour biopsies were required. However, a biopsy may have been omitted if the procedure was deemed medically unsafe or not feasible, based on the Investigator's clinical judgment and after discussion with the Medical Monitor (or Sponsor's designee).
- 5. Measurable disease according to RECIST v1.1. Previously irradiated lesions were measurable if subsequent progression was documented.
- 6. Eastern Cooperative Oncology Group (ECOG) performance status 0 to 1.
- 7. Life expectancy \>3 months as assessed by the Investigator.
- 8. Adequate bone marrow, cardiopulmonary, renal and hepatic functions:
- • Haemoglobin e5.6 mmol/L (e90 g/dL) (without transfusion or erythropoietin therapy within 4 weeks prior to therapy)

ENROLLMENT CONTACT

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Total sites: 5 | 5 currently recruiting

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