TX 200 – KT03

Status ongoing: active inclusion

S-nummer: S67301 Long-term follow-up study
Principal Investigator: prof. dr. Dirk Kuypers

Title: Long-term follow-up of patients who have received an autologous antigen-specific chimeric antigen receptor T regulatory cell therapy (CAR-Treg therapy, TX200-TR101) in a prior clinical study.

Purpose and rationale: This long term follow up study (TX200-KT03) is being conducted to collect long-term (up to 15 years post-infusion) safety and tolerability data from subjects enrolled in studies evaluating TX200-TR101.

Primary endpoint: From the day of TX200-TR101 infusion through to 15 years post-TX200-TR101 infusion/baseline: overall survival and incidence and grade of Serious Adverse Events (SAEs).

Medication/treatment: Not applicable (no investigational medicinal product will be administered).

Duration of study: an additional 13.5 years of follow-up after completion of the end of the TX200-KT02 study with administration of TX200-TR101. The visit schedule is every 6 months for years 2-5 after treatment with TX200-TR101 followed by once a year for years 6-15 after treatment with TX200-TR101.

Key inclusion criteria:
- Subjects who enrolled in the Phase 1/2a study TX200-KT02, received a transplanted kidney and have either completed or withdrawn post-dosing of TX200-TR101 from that study.

Key exclusion criteria:
- None