Paes

Status ongoing: active inclusion

S-nummer: S66199 Phase III study
Principal Investigator: prof. dr. Dirk Kuypers

Title: A controlled, open-label post-authorisation efficacy and safety study in imlifidase desensitised kidney transplant patients with positive crossmatch against a deceased donor prior to imlifidase treatment, including non-comparative registry and concurrent reference cohorts.

Purpose and rationale: This controlled, non-randomised, open-label post-authorisation trial is designed to provide comprehensive efficacy and safety data to support a full marketing authorisation of imlifidase in EU. The trial will include highly sensitised patients who will receive and accept crossmatch positive kidney offers in line with the mode-of-action of imlifidase, i.e. conversion of a positive crossmatch to a negative crossmatch.

Primary endpoint: 1-year graft failure-free survival in patients who have been kidney transplanted after imlifidase treatment.

Medication/treatment: 0.25 mg/kg imlifidase (cysteine protease) IV over a period of 15 minutes. Following transplantation, patients will receive induction therapies (corticosteroids, ATG), rejection prophylaxis (high-dose IVIg, rituximab) and maintenance immunosuppressive therapies.

Duration of study: approximately 12 until 15 months, consisting of 13 visits.

Key inclusion criteria:

- Male and female patients aged 18-75 years
- ABO-compatible deceased donor aged 10-70 years
- ESRD active on the renal transplant waiting list of a kidney allocation system at the time of screening
- Highly sensitized patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients
- Known DSA against an available deceased donor
- Positive B-cell crossmatch test determined by Complement-Dependent Cytotoxicity crossmatch (CDCXM) and/or Flow Cytometry Crossmatch (FCXM) against an available deceased donor

Key exclusion criteria:

- Previous treatment with imlifidase
- Previous high dose IVIg treatment (2 g/kg) within 28 days prior to imlifidase treatment
- Use of investigational agents within 5 terminal elimination half-lives prior to the transplantation
- Malignancy within 5 years prior to transplantation
- Positive for HIV or active infections (HBV, HCV, CMV, EBV, tuberculosis)