IgA Applause

Status ongoing: stop inclusion

S-nummer: S64734 Phase III study
Principal Investigator: prof. dr. Kathleen Claes

Title: A multi-center, randomized, double-blind, placebo-controlled, parallel group, phase III study to evaluate the efficacy and safety of LNP023 (Iptacopan) in primary IgA nephropathy patients.

Purpose and rationale: The study is designed to demonstrate the superiority of LNP023 at a dose of 200 mg b.i.d. compared to placebo on top of maximally tolerated or maximal locally approved ACEi or ARB on reduction of proteinuria and slowing disease progression in primary IgAN patients.

Primary endpoint: Log-transformed ratio to baseline in UPCR (sampled from 24h urine collection) at 9 months.

Medication/treatment: 200 mg LNP023 (Iptacopan, Factor B inhibitor) or matching placebo, taken orally twice daily.

Duration of study: Approximately 24 to 27 months, consisting of approximately 13 visits.

Key inclusion criteria:
- Male and female patients ≥ 18 years of age
    - eGFR ≥45mL/min/1.73m²: qualifying biopsy within the last 5 years
    - eGFR 30 to <45mL/min/1.73m²: qualifying biopsy within 2 years with < 50% TIF
    - eGFR 20 to <30mL/min/1.73m²: qualifying biopsy at any time
- Proteinuria due to primary diagnosis of IgAN: UPCR ≥1 g/g
- On supportive care of ACEi of ARB: 90 days before 1st dose.

Key exclusion criteria:
- Any secondary IgAN
- Severe urinary obstruction or difficulty in voiding
- Within 4 weeks of study drug admin.: acute kidney injury
- Rapidly progressive glomerulonephritis (50% loss of GFR within the last 3 months)
- SBP >140 mmHg or DBP >90 mmHg
- Patients treated with IM within 90 days prior to first dose (180 days for RTX)
- All transplant patients
- History of recurrent invasive infections by encapsulated organisms
- HIV infection
- Abnormal LFT at screening and baseline (ALT, AST, GGT, alk. Ph., bilir.)
- History of malignancy within 5 past years