IgA Roll Over

Status ongoing: active inclusion

S-nummer: S65669 Phase IIIb study
Principal Investigator: prof. dr. Kathleen Claes

Title: A multicenter rollover extension programme (REP) to evaluate the long-term safety and tolerability of open label Iptacopan in adult participants with primary IgA nephropathy who have completed study CLNPO23X2203 and CLNPO23A2301 (IgA Applause)

Purpose and rationale: The purpose of this study is to evaluate the long-term safety and tolerability, of open label iptacopan in primary IgA nephropathy adult participants who have completed either the CLNP023X2203 or CLNP023A2301 (IgA Applause) clinical trials. The open label design of the current study is appropriate to provide study participants the opportunity to receive treatment with iptacopan until marketing authorizations are received and the drug product becomes commercially available while enabling collection of long-term safety and tolerability data for the investigational drug.

Primary endpoint: Safety and tolerability endpoints (including but not limited to AEs/SAEs, safety laboratory parameters, vital signs)

Medication/treatment: Open label Iptacopan (Factor B inhibitor). Capsule 200 mg taken orally twice daily.

Duration of study: Until 3 years after last patient first visit

Key inclusion criteria:
- Patients must have completed the trial of CLNPO23X2203 or CLNPO23A2301 (IgA Applause)
- eGFR ≥20 ml/min:1.73m²
- Prior vaccination: Neisseria menigitidis A,C,Y,W135, N.menigitidis B: up-to-date
- On supportive care of ACEi of ARB: 90 days before 1st dose.

Key exclusion criteria:
- Screen-/ baseline failed or early withdrawal in CLNPO23X2203 or CLNPO23A2301 (IgA Applause)
- 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)
- 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