Iris

Status ongoing: active inclusion

S-nummer: S66114 Phase III study
Principal Investigator: prof. dr. Katrien De Vusser

Title: A multicenter randomized double-blind placebo-controlled phase 3 study to evaluate the efficacy and safety of anifrolumab in adult patients with active proliferative lupus nephritis (LN).

Purpose and rationale: This is a placebo-controlled study with open-label extension (OLE) to evaluate the efficacy and safety of anifrolumab as compared with placebo in adults with active, proliferative lupus nephritis while taking standard of care treatment with MMF and glucocorticoids.

Primary endpoint: Complete renal response at Week 52, ie, meeting all of the following: 1) UPCR ≤0.5 mg/mg 2) eGFR ≥60 mL/min/1.73 m² or no decrease from baseline of ≥ 20%.

Medication/treatment: Anifrolumab (type I interferon inhibitor) 900 mg IV Q4W for the first 6 doses, followed by 300 mg IV Q4W (Weeks 24 to 72) or matching placebo (Week 0 to Week 72). This will be followed by an open label extension with 300 mg anifrolumab IV Q4W for all eligible participants who completed the double-blind treatment period.

Duration of study: Approximately 142 weeks (2 years and 7 months). The trial includes a screening period (up to 6 weeks, consisting of 1 visit), a treatment period (up to 76 weeks, consisting of 20 visits), an open-label period (up to 52 weeks, consisting of 13 visits) and a follow-up period (up to 8 weeks, consisting of 2 visits).

Key inclusion criteria:
- Males and females aged 18 to 70 years ≥ 40.0 kg
- Fulfills updated 2019 SLE criteria
- Positive ANA, anti-dsDNA, or anti-Sm test result
- UPCR > 1 mg/mg
- Active proliferative LN Class III or IV either with or without the presence of Class V (excluding pure Class III[C], IV-S[C], or IV-G[C]). Based on renal biopsy within 6 months prior to signing ICF
- eGFR ≥ 35 mL/min/1.73 m²
- Chest radiograph: No evidence of current active infection or active/previous TB, malignancy and pulmonary nodules suspicious for lung cancer

Key exclusion criteria:
- Pure Class V LN
- History of dialysis within 12 months prior to signing the ICF
- History of recurrent infection requiring hospitalization and/or IV antibiotics
- History of a primary immunodeficiency, splenectomy, or any underlying condition that predisposes the participant to infection
- Diagnosis of HIV, hepatitis B, or hepatitis C infection
- History of cancer, apart from: 1) Squamous or basal cell carcinoma of the skin treated with documented success of curative therapy 2) Cervical cancer in situ treated with apparent success with curative therapy
- AST/ALT > 2.5xULN; TBL > ULN; Glycosylated Hb >8%; Neutrophil count <1.0 x10^9/L; Platelet count <25 ×10^9/L; Hb <8 g/dL