Artemis

completed: no inclusion

S-nummer: S61468 Phase III study
Principal Investigator: prof. dr. Kathleen Claes

Title: A randomized, double-blind, placebo-controlled, phase 3 study of the safety and efficacy of OMS721 in patients with immunoglobulin A (IgA) nephropathy (artemis – IgAN).

Purpose and rationale: The study is designed to evaluate whether OMS721 reduces proteinuria in patients with IgAN, assessed by 24-hour urine protein excretion (UPE) in g/day at 36 weeks from baseline.

Primary endpoint: The change from baseline in log-transformed 24-hour UPE in g/day at 36 weeks from baseline

Medication/treatment: 370 mg OMS721 (human IgG4 mAb directed against MASP-2.) in 50 mL of 5% dextrose or a placebo infused IV over approximately 30 minutes.

Duration of study: Approximately 160 weeks, comprising a 1-year study with a 2-year follow up. The study consists of five periods: Screening, Run-In, Initial Treatment (Weeks 1-12), Response Evaluation (Weeks 13-36), and Follow-Up (Weeks 37 to Week 144/end-of-study [EOS]).

Results: The results are currently under investigation. As soon as these are available, they will be shared.