Pediatric Rheumatology



Oral presentation



# 2.2 A phase II trial with canakinumab, a new IL-1beta blocking monoclonal antibody (ACZ885), to evaluate preliminary dosing, safety and efficacy profile in children with systemic Juvenile Idiopathic arthritis (sJIA)

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## Objectives

Phase II trial to evaluate dosing and interval range, preliminary efficacy, safety, immunogenicity, and pharmacokinetics of subcutaneous (s.c.) canakinumab in patients with active sJIA.

## Methods

19 children 4–19 years old, with fever, at least 2 active joints, CRP > 50 mg/L and steroids ≤0.4 mg/kg, were enrolled in an open label, staggered dose escalation study. Patients received a single sc injection of canakinumab in the dose range 0.5–9 mg/kg, followed by an observation period and re-dosing upon relapse. Dose escalation was based on safety and efficacy review of each cohort. Response was measured according to modified ACR pediatric criteria, (at least 3/6 variables improved by ≥30% with no more than one variable worsening by >30% and no fever). Relapse was defined as reappearance of fever and CRP > 30 mg/L, and/or ACR pediatric flare criteria.

## Results

11/19 patients responded to canakinumab. At Day 15 post first dose all the 11 responders achieved at least an ACR pediatric 50. In 4 cases inactive disease status was reached (no joints with active arthritis, no fever, normal CRP and no disease activity according to physician's assessment). Time to relapse after first dose ranged from 23 days to >200 days. The injections were well tolerated and no immunogenicity developed. One serious adverse event (gastritis with ulcer bleeding) was reported.

## Conclusion

In this dose-escalation trial canakinumab was efficacious and provided improvement in sign and symptoms of sJIA with an acceptable safety profile.