



ORAL PRESENTATION

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# Pharmacokinetics of Canakinumab in children younger than 2 years old with CAPS

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## Background

Canakinumab (CAN) is indicated for the treatment of cryopyrin-associated periodic syndrome (CAPS) in patients  $\geq 2$  years of age [1]. However, information on the pharmacokinetics (PK) of CAN in patients  $< 2$  years of age is not available. Here, we present preliminary PK data from a phase III study in CAPS patients.

## Objectives

To assess the efficacy of CAN with respect to the treatment response in CAPS patients  $\leq 4$  years of age and to evaluate PK and pharmacodynamics (PD) profiling of CAN.

## Methods

CAN-naïve patients with confirmed CAPS aged 44 days to 4 years received open-label CAN 2 mg/kg every 8 weeks for 56 weeks. For NOMID patients, an initial dose of 4 mg/kg was administered. Patients who did not achieve complete response following CAN injection, or experienced a flare before the next planned administration, were eligible for dose up-titration with possible maintenance and step wise up-titration regimens of 4, 6, or 8 mg/kg s.c.

## Results

Seventeen patients, 6 patients  $< 24$  months old (44 days to 14 months; mean age = 7 months), were enrolled and administered body weight-based (2 mg/kg up to 12 mg/kg) doses of CAN s.c. every 8 weeks, with the exception of one patient who received doses of 4-6 mg/kg once weekly. Of the 6 patients  $< 24$  months old, 5 were dosed with 2 mg/kg at each dose while 1 NOMID patient started with 4 mg/kg and up-titrated to 8 mg/kg at last dose. Sixteen patients achieved a complete response, with 7 patients requiring

dose escalation to achieve and/or maintain their responses. Mean dose-normalized CAN trough concentrations at steady-state in the patients  $< 24$  months old were similar across the 6 patients from 44 days to 15 months, while the range of exposures as represented by the dose normalized trough levels overlapped with the remaining 11 study patients  $> 2$  years old who received CAN doses ranging from 2 mg/kg up to 12 mg/kg.

## Conclusions

Canakinumab is an effective treatment for patients with CAPS aged as young as 44 days old. The preliminary PK results demonstrated that dose-normalized canakinumab exposure in patients  $< 2$  years old was similar to patients  $> 2$  years supporting the utilization of weight-based dosing in the CAPS infantile population.

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