



ORAL PRESENTATION

Open Access

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

J Kalabus¹, P Brogan^{2*}, M Hofer³, J Kuemmerle-Deschner⁴, B Lauwerys⁵, A Speziale⁶, R Laxer⁷, H Sun⁸, K Abrams⁸, K Leon⁸, G Junge⁶

From 8th International Congress of Familial Mediterranean Fever and Systemic Autoinflammatory Diseases Dresden, Germany. 30 September - 3 October 2015

Background

Canakinumab (CAN) is indicated for the treatment of cryopyrin-associated periodic syndrome (CAPS) in patients ≥ 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 ≤ 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.

Authors' details

¹Novartis Institutes for Biomedical Research, New Jersey, USA. ²UCL Institute of Child Health, and Great Ormond Street Hospital NHS Foundation Trust, Department of Paediatric Rheumatology, London, UK. ³Unité romande de rhumatologie pédiatrique, Hôpitalier Universitaire Vaudois, Lausanne, Switzerland. ⁴University Hospital Tuebingen, Tuebingen, Germany. ⁵Cliniques Universitaires Saint-Luc and Université Catholique de Louvain, Brussels, Belgium. ⁶Novartis Pharma AG, Basel, Switzerland. ⁷University of Toronto, Staff Rheumatologist, The Hospital for Sick Children, Toronto, Ontario, Canada. ⁸Novartis Pharmaceuticals Corporation, New Jersey, USA.

Published: 28 September 2015

Reference

1. ILARIS [summary of product characteristics]: Novartis Europharm Limited; 2014.

doi:10.1186/1546-0096-13-S1-O38

Cite this article as: Kalabus *et al.*: Pharmacokinetics of Canakinumab in children younger than 2 years old with CAPS. *Pediatric Rheumatology* 2015 **13**(Suppl 1):O38.

²UCL Institute of Child Health, and Great Ormond Street Hospital NHS Foundation Trust, Department of Paediatric Rheumatology, London, UK
Full list of author information is available at the end of the article