



ORAL PRESENTATION

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Predictors of response in patients with active systemic JIA (SJIA) receiving canakinumab: an exploratory analysis of pooled 12-week data

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Introduction

Canakinumab (CAN), a selective, human, anti-interleukin-1 β monoclonal antibody, has been shown to be efficacious in the treatment of SJIA (Ruperto et al. *N Engl J Med* 2012).

Objectives

To explore baseline demographics and clinical characteristics that are most predictive of response to CAN in CAN-naïve SJIA patients during the initial 12 weeks of therapy.

Methods

Data from 3 trials were pooled for this analysis. CAN-naïve patients (pts; n=178) aged 2–19 years with active SJIA were enrolled and received sc CAN 4 mg/kg/month; Predictors of response (according to aACR* 30, 70, and Inactive Disease [ID]) at Days (D) 15, 29, 57 and 85 were explored using univariate and multivariate logistic regression analyses. The candidate predictors (categorical variables) of CAN-response considered were: Age group, Gender, Prior NSAIDs (no/yes), Prior MTX(no/yes), Steroids (0, >0 – ≤ 0.4 ; > 0.4), Number of Active Joints (≤ 10 , 11– ≤ 20 , >20) and Joints with Limitation of Motion (≤ 10 , 11– ≤ 20 , >20), CRP (elevated/normal) at baseline and at D15. All candidate predictors with $p < 0.1$ in univariate analyses were included in the multivariate analysis. *ACR response plus absence of fever.

Results

By week 2 there was substantial clinical benefit with 102 pts (57%) and 36 pts (20%) achieving aACR70 and

ID, respectively; by week 12, 108 pts (61%) had aACR70 and 50 pts (28%) ID. The multivariate analysis indicated that normal CRP at D15 is the only predictor significant (all $p < 0.05$) for ID at all time-points (Table 1).

Conclusion

This exploratory analysis suggests that CAN-naïve patients with normal CRP (i.e. ≤ 10 mg/l) at Day 15, lower baseline steroid doses, low number of active joints, no prior anti-TNF or prior NSAID use are those most likely to achieve inactive disease up to 12 weeks.

Disclosure of interest

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Table Inactive Disease - Multivariate logistic regression analysis on 12-week data

Variable*, Odds Ratio (95% CI)	Day 15	Day 29	Day 57	Day 85
CRP at Day 15 (elevated vs normal)	0.20 (0.07, 0.55)	0.14 (0.04, 0.41)	0.26 (0.10, 0.66)	0.31 (0.12, 0.82)
Number of active joints (11-≤20 vs. ≤10)	0.22 (0.03, 1.66)	0.55 (0.09, 3.41)	0.17 (0.031, 0.97)	0.37 (0.06, 2.10)
Number of active joints (≤10 vs. >20)	2.56 (0.12, 55.39)	1.53 (0.06, 37.44)	16.10 (1.00, 258.12)	25.41 (1.60, 404.61)
Prior NSAID treatment (no vs. yes)	2.01 (0.71, 5.71)	9.33 (2.44, 35.68)	3.10 (1.03, 9.31)	5.31 (1.66, 17.05)
Steroid Level (0 vs. >0.4 mg/kg/day)	5.48 (0.97, 31.01)	8.89 (1.26, 62.64)	2.98 (0.51, 17.46)	11.16 (1.72, 72.34)
Steroid Level (>0.4 vs. >0-≤0.4 mg/kg/day)	0.32 (0.08, 1.29)	0.41 (0.09, 1.82)	0.81 (0.25, 2.60)	0.13 (0.03, 0.57)
Prior MTX treatment (no vs. yes)	1.94 (0.75, 5.00)	2.78 (0.93, 8.33)	2.79 (1.04, 7.51)	1.77 (0.65, 4.83)
Prior anti-TNFs treatment (no vs. yes)	1.83 (0.52, 6.49)	3.62 (0.77, 17.00)	2.01 (0.63, 6.38)	3.64 (1.04, 12.77)

Values in bold are significant; *Significant in at least one time point

Novartis, F. Corona: None declared., K. Lheritier Shareholder of: Novartis, Employee of: Novartis Pharma AG, C. Gaillez Employee of: Novartis Pharma AG, A. Martini Grant / Research Support from: Bristol Myers and Squibb, Centocor Research & Development, Glaxo Smith & Kline, Novartis, Pfizer Inc, Roche, Sanofi Aventis, Schwarz Biosciences GmbH, I declare that the Gaslini Hospital which is the public Hospital where I work as full time employee has received contributions to support the PRINTO research activities from the industries above mentioned. OLD: Francesco Angelini S.P.A., Janssen Biotech Inc, Abbott. , Consultant for: Bristol Myers and Squibb, Centocor Research & Development, Glaxo Smith & Kline, Novartis, Pfizer Inc, Roche, Sanofi Aventis, Schwarz Biosciences GmbH, I declare that the Gaslini Hospital which is the public Hospital where I work as full time employee has received contributions to support the PRINTO research activities from the industries above mentioned. , Speaker Bureau of: Abbott, Bristol Myers Squibb, Astellas, Boehringer, Italfarmaco, MedImmune, Novartis, NovoNordisk, Pfizer, Sanofi, Roche, Servier, D. Lovell Grant / Research Support from: National Institutes of Health- NIAMS , Consultant for: Astra-Zeneca, Centocor, Amgen, Bristol Meyers Squibb, Abbott, Pfizer, Regeneron, Roche, Novartis, UBC, Forest Research Institute, Horizon, Johnson & Johnson, Speaker Bureau of: Novartis, Roche.

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