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POSTER PRESENTATION Open Access

PReS-FINAL-2158: Effect of canakinumab on functional ability and health-related quality of life in systemic juvenile idiopathic arthritis (SJIA) patients

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Introduction

Canakinumab (CAN), a selective, fully human, anti-interleukin-1β monoclonal antibody, has been shown to be efficacious in SJIA patients (pts) in 2 phase 3 trials: Trial 1 (4-wk, randomized placebo [PBO]-controlled) and Trial 2 (open-label CAN treatment [Part 1] followed by a randomized PBO-controlled withdrawal phase [Part 2]). In Trial 1, statistically significantly more CAN than PBO group pts achieved an adapted pediatric ACR 30 response and in Trial 2, CAN allowed successful reduction/discontinuation of steroids and significantly reduced risk of flare. Safety profile of CAN was in line with expectations for a biologic agent in active SJIA. The persistent disabling features of SJIA and chronic pain can have a negative impact on health-related quality of life (hrqol). These outcomes were evaluated in the CAN phase 3 program.

Objectives

To report pt-reported functional ability and hrqol outcomes from the CAN phase 3 program.

Methods

The phase 3 analysis included 84 pts (CAN, 43; PBO, 41) in Trial 1 and 177 pts in Trial 2 (71 from Trial 1 entered) in Part 1, and 100 rolled into Part 2 (CAN, 50; PBO, 50). Pt-reported assessments included functional ability (as measured by the Childhood Health Assessment Questionnaire [CHAQ©]), pain (measured on a visual analog scale [VAS] of 0-100 mm as part of the CHAQ©), and physical (phs) and psychosocial (pss) health status in 5-18 year old pts., according to the Child Health Questionnaire-Parent Form (CHQ-PF50).

Results

In Trial 1, CAN treatment was associated with a significant improvement in CHAQ disability score (estimated difference [ED] of -0.69 over time vs PBO in the least square mean [LSM] change from baseline [BL] [p = 0.0002]), which was ~3.6 × the minimal clinically important difference of -0.19. The LSM in overall pain intensity were significantly lower (both p < 0.0001) in the CAN group vs

Table 1 Patient- or Parent-reported functional ability and hrqol parameters in Trial 2

Outcome measure, mean (SD)	Baseline CAN, N = 177	End of Part 1 CAN, N = 177	End of Part 2 CAN, N = 50	End of Part 2 PBO, N = 50
CHAQ disability score	1.7 (0.8)	0.74 (0.9)	0.5 (0.9)	0.6 (0.8)
Pain (VAS, 0-100 mm)	66.6 (23.3)	20.2 (25.8)	13.6 (26.9)	17.0 (24.2)
CHQ-PF50 phs score	16.1 (14.3)	37.7 (17.2)	43.6 (17.4)	39.0 (18.1)
CHQ-PF50 pss score	41.6 (11.1)	50.7 (11.1)	53.6 (11.3)	52.7 (9.8)

Results are based on patients with both baseline and post-baseline values. N18 years old.

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PBO both at Day 15 (ED, -46.42) and Day 29 (ED, -41.86). CHQ-PF50 phs and pss scores also showed significant improvements over time (ED CAN vs PBO in LSM change from BL, 12.07 and 7.28; $p < 0.005$ for both). Improvements in CHAQ disability, CHQ-PF50 phs and pss, and VAS pain scores were also observed in Trial 2 (Table 1).

Conclusion

Treatment with CAN demonstrated rapid, marked and continued improvement in patient-reported functional ability and hrqol of SJIA patients.

Disclosure of interest

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