Spondyloarthritis – treatment

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EFFECT OF TOFACITINIB ON PATIENT-REPORTED OUTCOMES IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: RESULTS FROM A PHASE 3 TRIAL

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Background: Ankylosing spondylitis (AS) can significantly impact quality of life. Tofacitinib is an oral Janus kinase inhibitor under investigation for the treatment of adult patients (pts) with AS. The safety/efficacy (including pt-reported outcomes [PROs]) of tofacitinib in pts with AS was assessed in a Phase 3 trial (NCT03502616).¹

Objectives: To evaluate the effect of tofacitinib on pt-reported pain, fatigue, overall health and work productivity in pts with active AS enrolled in the Phase 3 trial.

Methods: Pts with an inadequate clinical response or intolerance to ≥ 2 oral NSAIDs were randomised in a double-blind fashion to tofacitinib 5 mg twice daily (BID) or placebo (PBO) for 16 weeks. At Week (W)16, all pts received open-label tofacitinib 5 mg BID up to W48. Least squares (LS) mean changes from baseline (Δ) up to W48 are reported for the following outcomes: pt assessment of nocturnal spinal pain, Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Short Form-36 Health Survey version 2 (SF-36v2; W16 and W48 only), and Work Productivity and Activity Impairment Questionnaire (WPAI; W16 and W48 only).

Results: At W16, there were greater improvements from baseline in pain (total back pain [previously published¹] and nocturnal spinal pain) and fatigue (FACIT-F total score; experience and impact domain scores) with tofacitinib vs PBO ($p \leq 0.05$; Table 1); improvements were observed as early as W2. Also, improvements in SF-36v2 physical component summary (PCS) (Table 1), and physical functioning, role-physical, bodily pain, general health and social functioning domains (Figure 1) were greater with tofacitinib vs PBO at W16 ($p \leq 0.05$). Similarly, improvements in WPAI scores at W16 were greater with tofacitinib vs PBO ($p \leq 0.05$), except for % work time missed (Table 1). Improvements with tofacitinib

continued up to W48 (Table 1/Figure 1). Generally, pts receiving PBO who advanced to tofacitinib at W16 reported similar improvements after switching to tofacitinib (Table 1/Figure 1).

Figure. LS mean Δ SF-36v2 domain scores (norm-based) at W16 and W48

** $p < 0.01$, *** $p < 0.001$ for tofacitinib 5 mg BID vs PBO (analysis of covariance model)

Conclusion: In pts with active AS, improvements in spinal pain, fatigue, overall health and work productivity were greater with tofacitinib vs PBO at W16; improvements continued up to W48. These PRO findings support the primary efficacy results of this Phase 3 trial,¹ and add to the overall understanding of the benefit/risk profile of tofacitinib in patients with AS.

REFERENCES:

[1] Deodhar et al. Arthritis Rheumatol 2020; 72 (S10): Abs L11.

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Table 1. PROs at baseline and Δ at W16 and W48

	Baseline, mean (SD) [N1]		Δ , W16, LS mean (SE)		p value	Δ , W48, LS mean (SE)	
	Tofacitinib 5 mg BID (N=133)	PBO (N=136)	Tofacitinib 5 mg BID	PBO		Tofacitinib 5 mg BID	PBO→tofacitinib 5 mg BID
Nocturnal spinal pain ^a	6.8 (1.9)	6.8 (1.9)	-2.67 (0.20)	-0.84 (0.20)	<0.0001	-3.52 (0.23)	-3.01 (0.23)
FACIT-F	27.2 (10.7)	27.4 (9.3)	6.54 (0.80)	3.12 (0.79)	0.0008	9.54 (0.90)	7.35 (0.89)
total score ^{a,b}	8.9 (4.3)	8.7 (4.0)	2.85 (0.36)	1.29 (0.36)	0.0007	4.22 (0.40)	3.40 (0.40)
FACIT-F experience domain ^a	18.3 (6.9)	18.8 (5.9)	3.68 (0.49)	1.81 (0.49)	0.0028	5.32 (0.54)	3.95 (0.54)
FACIT-F impact domain ^a	33.5 (7.3)	33.1 (7.0)	6.69 (0.59)	3.14 (0.59)	<0.0001	8.81 (0.720)	7.39 (0.71)
SF-36v2 PCS ^{b,c}	39.4 (11.1)	39.8 (12.7)	3.45 (0.91)	2.13 (0.92)	0.2529	7.07 (0.93)	6.35 (0.92)
SF-36v2 MCS ^c	56.5 (23.4)	56.0 (21.4)	-19.03 (1.97)	-5.63 (1.97)	<0.0001	-27.37 (2.34)	-19.77 (2.31)
WPAI ^e	9.9 (22.4)	11.5 (24.6)	-3.65 (2.66)	0.88 (2.62)	0.1784	-8.10 (2.14)	-5.79 (2.05)
% activity impairment	48.4 (26.3)	49.6 (22.2)	-19.83 (2.27)	-6.94 (2.30)	<0.0001	-25.35 (2.77)	-23.00 (2.66)
% work time missed	50.8 (27.4)	53.5 (23.1)	-21.49 (2.51)	-7.64 (2.56)	<0.0001	-27.63 (3.01)	-23.22 (2.90)
% impairment while working							
% overall work impairment							

^aMMRM^bGlobal type I error-controlled endpoint^cAnalysis of covariance model for W16 and MMRM for W48MCS, mental component summary; MMRM, Mixed Model for Repeated Measures; N, number of pts in full analysis set; N1, number of pts included in the analysis (if different from N); SD, standard deviation; SE, standard error

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PREDICTORS OF RESPONSE IN PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS RECEIVING CERTOLIZUMAB PEGOL IN THE C-AXSPAND STUDY

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Background: Identification of predictive clinical factors of long-term treatment response in non-radiographic axial spondyloarthritis (nr-axSpA) may contribute to improved management of patients with this chronic disease. Certolizumab pegol (CZP) is currently the only FDA-approved tumour necrosis factor inhibitor (TNFi) for treatment of nr-axSpA.¹

Objectives: To identify whether any demographic or baseline characteristics of nr-axSpA patients from the C-axSpAnd study² are predictive of achieving a clinical response after 1 year of CZP treatment.

Methods: C-axSpAnd (NCT02552212) was a phase 3, interventional multi-centre study including a 52-week double-blind, placebo-controlled period. Full