adalimumab tapering at 6 months' remission and 2 cases initiated adalimumab tapering at 9–12 months' remission. No patients had recurrent uveitis at 12 months' remission or longer in both groups. Adalimumab plus MTX were well tolerated in all patients.

Conclusions: For maintaining remission of SpA-related uveitis, adalimumab tapering can be effective when combined with MTX. Initiation of the tapering after 12 months' remission largely lower the rate of recurrence.

References:

[1] Jaffe GJ, Dick AD, Brézin AP, et al. Adalimumab in Patients with Active Noninfectious Uveitis. *N Engl J Med*. 2016 Sep 8; 375(10):932–43.

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THU0352 TOFACITINIB TREATMENT IS ASSOCIATED WITH ATTAINMENT OF THE MINIMALLY IMPORTANT REDUCTION IN AXIAL MRI INFLAMMATION IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Tofacitinib is an oral Janus kinase inhibitor. The minimally important changes (MICs) for the SPondyloArthritis Research Consortium of Canada (SPARCC) MRI sacroiliac joint (SIJ) and spine scores based on agreement with global change scores by readers are ≥ 2.5 and ≥ 5 , respectively.¹

Objectives: To assess whether MIC in SIJ and spine can discriminate between tofacitinib and placebo (PBO) in patients (pts) with ankylosing spondylitis (AS) and if this is concordant with clinical responses.

Methods: In this 16-week (wk), Phase 2, double-blind, dose-ranging study (NCT01786668),² 207 adult pts meeting modified New York AS criteria were randomised 1:1:1 to PBO or tofacitinib 2, 5 or 10 mg twice daily (BID) for 12 wks. Clinical endpoints included in this post-hoc analysis were: Assessment of SpondyloArthritis International Society 20% improvement (ASAS20) and ASAS 40% improvement (ASAS40) response rates, AS disease activity score major improvement (ASDAS MI; change ≥ 2.0 from baseline), ASDAS inactive disease (ASDAS ID; < 1.3), Bath AS disease activity index (BASDAI), Bath AS functional index (BASFI) and back pain. Pts (%) achieving MIC in SIJ, spine and both SIJ and spine, in tofacitinib and PBO groups, were summarised based on observed data, and pooled tofacitinib (5 and 10 mg BID) vs PBO data were compared using Fisher's exact test. Concordance between achieving MIC and Wk 12 clinical responses was assessed. Wk 12 clinical responses were compared between pts achieving/not achieving MIC.

Results: MRI data for 164 pts were evaluated. Baseline demographics were generally balanced between treatment groups and typical of AS populations.² Tofacitinib 2, 5 and 10 mg BID improved mean (range) SPARCC scores vs PBO (SIJ: -2.2 [-22.0, 10.5], -3.5 [-34.5, 11.0], -3.6 [-29.0, 0.5] vs -0.7 [-9.5, 6.5]; spine: -3.2 [-34.5, 20.5], -5.5 [-36.5, 8.0], -6.7 [-32.5, 7.5] vs -0.8 [-8.0, 14.0]). Approximately 3 times more pts achieved MIC in SIJ or spine in the pooled tofacitinib group vs PBO (SIJ: 34.1% vs 11.8%, $p < 0.05$; spine: 38.6% vs 11.8%, $p < 0.01$). Achieving MIC in SIJ and spine correlated with clinical response. In pts on tofacitinib, ASAS20, ASAS40 and ASDAS MI responses were more likely in pts achieving MIC in SIJ or spine (Table) vs not achieving MIC. Compared with not achieving MIC, pts on tofacitinib achieving MIC in SIJ had larger improvements in BASDAI, BASFI and back pain.

Conclusions: Pts who received tofacitinib who had AS experienced clinically meaningful reductions in axial MRI inflammation. Pts achieving MIC for MRI inflammation had increased clinical response rates.

References:

[1] Maksymowych WP et al. *J Rheumatol* 2012; 39: 1666–1674.

[2] van der Heijde D et al. *Ann Rheum Dis* 2016; In press.

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Table. Relationship between Wk 12 clinical response rates and achievement of MIC

	ASAS20 n/N (%)	ASAS40 n/N (%)	ASDAS MI n/N (%)	ASDAS ID n/N (%)
Placebo				
SIJ $\geq$ MIC (2.5)	3/4 (75.0)	1/4 (25.0)	0/4	0/4
SIJ $<$ MIC (2.5)	14/29 (48.3)	6/29 (20.7)	3/28 (10.7)	3/28 (10.7)
Spine $\geq$ MIC (5)	3/4 (75.0)	2/4 (50.0)	2/4 (50.0)	1/4 (25.0)
Spine $<$ MIC (5)	14/29 (48.3)	5/29 (17.2)	1/28 (3.6)	2/28 (7.1)
Tofacitinib 2 mg BID				
SIJ $\geq$ MIC (2.5)	9/12 (75.0)	7/12 (58.3)	5/12 (41.7)	2/12 (16.7)
SIJ $<$ MIC (2.5)	15/29 (51.7)	12/29 (41.4)	3/30 (10.0)	4/30 (13.3)
Spine $\geq$ MIC (5)	11/12 (91.7)	8/12 (66.7)	4/12 (33.3)	3/12 (25.0)
Spine $<$ MIC (5)	13/28 (46.4)	11/28 (39.3)	4/29 (13.8)	3/29 (10.3)
Tofacitinib 5 mg BID				
SIJ $\geq$ MIC (2.5)	15/17 (88.2)	10/17 (58.8)	6/17 (35.3)	2/17 (11.8)
SIJ $<$ MIC (2.5)	21/25 (84.0)	12/25 (48.0)	5/26 (19.2)	5/26 (19.2)
Spine $\geq$ MIC (5)	12/14 (85.7)	8/14 (57.1)	5/15 (33.3)	3/15 (20.0)
Spine $<$ MIC (5)	24/28 (85.7)	14/28 (50.0)	6/28 (21.4)	4/28 (14.3)
Tofacitinib 10 mg BID				
SIJ $\geq$ MIC (2.5)	9/13 (69.2)	8/13 (61.5)	4/13 (30.8)	4/13 (30.8)
SIJ $<$ MIC (2.5)	18/31 (58.1)	12/31 (38.7)	9/31 (29.0)	4/31 (12.9)
Spine $\geq$ MIC (5)	13/18 (72.2)	10/18 (55.6)	7/18 (38.9)	2/18 (11.1)
Spine $<$ MIC (5)	14/26 (53.9)	10/26 (38.5)	6/26 (23.1)	6/26 (23.1)
Pooled tofacitinib 5 and 10 mg BID				
SIJ $\geq$ MIC (2.5)	24/30 (80.0)	18/30 (60.0)	10/30 (33.3)	6/30 (20.0)
SIJ $<$ MIC (2.5)	39/56 (69.6)	24/56 (42.9)	14/57 (24.6)	9/57 (15.8)
Spine $\geq$ MIC (5)	25/32 (78.1)	18/32 (56.3)	12/33 (36.4)	5/33 (15.2)
Spine $<$ MIC (5)	38/54 (70.4)	24/54 (44.4)	12/54 (22.2)	10/54 (18.5)

ASAS, Assessment of SpondyloArthritis International Society; ASDAS, ankylosing spondylitis disease activity score; BID, twice daily; ID, inactive disease; MI, major improvement; MIC, minimally important change; SIJ, sacroiliac joints; Wk, week

Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, K. Kanik Shareholder of: Pfizer Inc, Employee of: Pfizer Inc

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THU0353 CHANGE IN MRI STRUCTURAL LESIONS IN THE SACROILIAC JOINT AFTER TWO YEARS OF ETANERCEPT THERAPY IN COMPARISON TO A CONTEMPORARY CONTROL COHORT IN NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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Background: Demonstrating a structural effect of TNF inhibitors in axial SpA (axSpA) is challenging.

Objectives: To compare 2 yrs of structural lesion changes on T1W MRI in the sacroiliac joints (SIJ) of pts receiving etanercept (ETN) in a clinical trial to similar pts not receiving biologics in a cohort study.

Methods: Pts had recent onset non-radiographic (nr)-axSpA fulfilling ASAS criteria. Study group: pts receiving ETN 50 mg once weekly for 2 yrs in EMBARK (NCT01258738). Control group: pts in a longitudinal cohort study not receiving biologics for 2 yrs (DESIR, NCT01648907). Outcome measure: change in structural lesions of erosion, backfill, fat metaplasia, and ankylosis. MRI images were read by 3 experienced readers unaware of image chronology and pt group, using the SpondyloArthritis Research Consortium of Canada SIJ Structural Score (SSS).¹ For each group, differences were calculated between percentages of patients experiencing increases and decreases in structural lesion scores over 2

Figure 1. Cumulative Probability of Change in MRI SIJ Erosion, BL to Week 104.

Abstract THU0353 – Table 1. Observed Change in MRI SIJ Structural Lesions, BL to Week 104

Structural lesion	Cohort	Decreased n/N (%)	Increased n/N (%)	Mean Difference* (95% CI) [†]	Mean differences (Control – ETN) (95% CI)
Erosion	Control	14/76 (18.4)	10/76 (13.2)	-5.3% (-18.1, 7.6)	18.8% (3.5, 34.1) ^{†‡}
	ETN	46/162 (28.4)	7/162 (4.3)	-24.1 (-32.1, -16.0)	17.8% (2.1, 33.6) ^{†‡}
Backfill	Control	2/76 (2.6)	10/76 (13.2)	10.5% (1.7, 19.3)	-5.5% (-16.6, 5.5) [‡]
	ETN	1/162 (0.6)	27/162 (16.7)	16.0% (10.1, 22.0)	-3.7% (-15.2, 7.8) [‡]
Fat metaplasia	Control	0/76 (0)	7/76 (9.2)	9.2% (2.6, 15.9)	1.8% (-6.6, 10.2) [‡]
	ETN	2/162 (1.2)	14/162 (8.6)	7.4% (2.7, 12.2)	-2.4% (-11.2, 6.4) [‡]
Ankylosis	Control	0/76 (0)	1/76 (1.3)	1.3% (-1.3, 3.9)	1.3% (-2.2, 4.9) [‡]
	ETN	2/162 (1.2)	2/162 (1.2)	0% (-2.4, 2.4)	1.5% (-3.1, 6.2) [‡]

Based on 2 of 3 readers assigning same category; otherwise considered no change. Some pts started with the lowest possible score and could not decrease. *Percent pts with increase – percent pts with decrease. [†]One-way ANOVA. [‡]Adjusted for covariates listed in Methods. [§]P<0.05.

Yrs. Treatment effect was analyzed without and with adjustment for the baseline (BL) covariates of sex, symptom duration, smoking status, HLA-B27 status, ASDAS-CRP, SPARCC MRI SIJ score, and SIJ radiography score.

Results: At BL, pts with MRI images in the control (DESIR, N=76) and ETN (EMBARK, N=162) cohorts differed significantly in symptom duration, smoking status, ASDAS-CRP and SPARCC MRI SIJ score. The table presents structural lesion changes on MRI. The mean difference between control and ETN was significant for erosion (table). Figure shows cumulative probability plot.

Conclusions: This analysis confirms the slow rate of structural lesion progression in the SIJ over 2 yrs in nr-axSpA and suggests a lower rate of progression with ETN than without a TNF inhibitor.

References:

[1] Maksymowych WP, et al. J Rheumatol. 2015;42:79–86.

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THU0354 DISEASE WORSENING AND SAFETY IN PATIENTS SWITCHING FROM ORIGINATOR INFLIXIMAB TO BIOSIMILAR INFLIXIMAB (CT-P13) IN THE RANDOMIZED NOR-SWITCH-STUDY: EXPLORATIVE ANALYSIS IN SPA PATIENTS

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Abstract THU0354 – Table 1. Demographics, baseline characteristics (FAS), percentage of patients with disease worsening, change in disease measures during 52 weeks follow-up (PPS)

Demographics, baseline characteristics	INX	CT-P13	
Total number of SpA patients PPS/FAS	43/45	42/46	
Age (years) mean (SD)	50.0 (10.3)	52.8 (10.8)	
Females	7 (16%)	8 (17%)	
Duration of ongoing INX treatment (years) mean (SD)	8.6 (3.1)	8.7 (3.2)	
Immunosuppressive co-medication	15 (33%)	10 (22%)	
HLA B27 pos	31 (94%)	33 (87%)	
Disease worsening			95% CI of group difference after 52 weeks
All study patients	53 (26.2%)	61 (29.6%)	-12.7–3.9%
SpA	17 (39.5%)	14 (33.3%)	-14.5–27.2%
Change in disease measures from baseline			
Physician Global Assessment of Disease Activity (0–10)	-0.1 (1.4)	-0.5 (1.3)	0.53–0.53
Patient Global Assessment of Disease Activity (0–10)	0.1 (2.2)	-0.4 (1.8)	-0.08–0.62
Log ₁₀ erythrocyte sedimentation rate (mm/h)	0.0 (0.3)	-0.0 (0.3)	-0.14–0.06
Log ₁₀ C-reactive protein (mg/L)	-0.0 (0.4)	-0.1 (0.4)	-0.11–0.15
ASDAS	0.1 (0.6)	-0.2 (0.7)	-0.27–0.24
BASDAI	0.3 (1.0)	-0.2 (1.4)	-0.50–0.47
TEAE (FAS)	116	102	

Data are n (%), mean (SD) or median (25–75 percentiles). 95% CI, 95% confidence interval of the adjusted treatment difference. BASDAI, Bath Ankylosing Spondylitis Disease Activity Index. ASDAS, Ankylosing Spondylitis Disease Activity Score. FAS, Full Analysis Set. PPS, Per Protocol Set. TEAE, treatment emergent adverse events.

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Background: The NOR-SWITCH study is a 52-week randomized, double-blind, non-inferiority, phase IV switch trial in patients with Crohn's disease (CD), ulcerative colitis (UC), spondyloarthritis (SpA), rheumatoid arthritis (RA), psoriatic arthritis (PsA) and plaque psoriasis (Ps) on stable treatment with originator infliximab (Remicade®, INX), funded by the Norwegian government. Previously, primary analyses of the pooled indications have been published¹.

Objectives: To investigate efficacy, safety and immunogenicity in SpA patients treated with continuous INX vs patients switched to CT-P13 (biosimilar infliximab, Remsima®) in the NOR-SWITCH study (explorative analyses).

Methods: Patients were randomized 1:1 to continued INX or switch to CT-P13. Serum drug levels were analyzed by automated in-house assay. The primary endpoint was disease worsening according to disease-specific composite measures and/or consensus between investigator/patient. Exploratory subgroup analyses examined disease worsening and safety in SpA. The primary endpoint was analysed by logistic regression, adjusted for diagnosis and disease duration.

Results: Demographics, occurrence of disease worsening, change in disease measures and treatment-emergent adverse events (TEAE) were similar (Table), as were serum drug levels for INX and CT-P13 (Figure).

Conclusions: Explorative analyses in the NOR-SWITCH study showed similar efficacy, drug levels and safety in SpA patients switched to CT-P13 as those on continuous INX. The study was not powered to show non-inferiority within each diagnosis.

References:

[1] Jørgensen KK et al. Switching from originator infliximab to biosimilar CT-P13 compared to maintained treatment with originator infliximab (NOR-SWITCH): a 52-week randomised double-blind non-inferiority trial. The Lancet, in press.

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