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OP0141

EFFECTS OF FILGOTINIB ON SPINAL LESIONS IN ANKYLOSING SPONDYLITIS: MAGNETIC RESONANCE IMAGING DATA FROM THE TORTUGA TRIAL

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Background: The oral Janus kinase 1 preferential inhibitor filgotinib (FIL) significantly improved Spondyloarthritis Research Consortium of Canada (SPARCC) magnetic resonance imaging (MRI) inflammation scores (bone marrow oedema) in the spine and sacroiliac joints vs placebo (PBO) in the Phase 2 TORTUGA trial (NCT03117270) in patients with active ankylosing spondylitis (AS).¹

Objectives: This post-hoc analysis evaluated the effects of FIL on Canada-Denmark (CANDEN) MRI measures of spinal inflammation and structural lesions in patients from the TORTUGA trial.

Methods: TORTUGA was a PBO-controlled, multicentre, double-blind, randomised trial. Patients with active AS (as per modified New York classification criteria, with sacroiliitis confirmed by central reading) were treated with FIL 200 mg (n=58) or PBO (n=58) once daily for 12 weeks. MRI of the total spine was conducted at baseline and at treatment end. Scans were re-evaluated post-hoc by 2 independent experts (blinded to time point and assigned treatment) using the CANDEN method;² inter-reader discrepancies were resolved by an independent adjudicator. Observed changes from baseline were evaluated using analysis of covariance, with factors for treatment, baseline value, and randomisation stratification by prior tumour necrosis factor inhibitor use. Least-squares (LS) mean changes from baseline and between-group differences with 95% confidence intervals (CI) were calculated; P values are nominal.

Results: MRI scans from 88 patients (47 FIL, 41 PBO) with an evaluable scan at baseline and Week 12 (or early termination) were re-evaluated. Baseline characteristics were generally similar between patients with/without an MRI scan. Of those with MRI scans, mean total spine inflammation score (which ranges from 0–614) was higher, and mean ankylosis score (which ranges from 0–460) was lower, in the FIL vs PBO group at baseline. Total spine inflammation scores decreased from baseline with FIL but not with PBO (Figure and Table; P=0.0003 for between-group difference). Cumulative probability plots favoured FIL over PBO for change from baseline in subregion inflammation scores, including posterolateral elements (i.e. sum of lesions in ribs, transverse processes, spinous processes, soft tissue inflammation, and postero-lateral vertebral body), facet joint, and vertebral body. Total spine fat lesion scores numerically increased from baseline in the FIL but not PBO group (P=0.0878 for between-group difference; Table). There were no significant differences between groups for changes in erosion (P=0.1956) or ankylosis (P=0.3888) scores (Table).

Table 1. Change from baseline at Week 12 in CANDEN total spine inflammation, total spine fat, total spine bone erosion, and ankylosis scores

Treatment group	Sample mean (SE)	LS mean (SE)	95% CI of treatment mean	LS mean of group difference (SE)	95% CI of group difference	Between-group P value
Total spine inflammation score						
Filgotinib	47	−4.98 (0.96)	−6.65, −2.15	−4.49 (1.21)	−6.85, −2.12	0.0003
Placebo	41	0.29 (0.78)	−2.17, 2.34			
Total spine fat score						
Filgotinib	47	1.01 (0.62)	−0.22, 2.40	1.18 (0.69)	−0.18, 2.55	0.0878
Placebo	41	−0.25 (0.19)	−1.40, 1.21			
Total spine bone erosion score						
Filgotinib	47	0.01 (0.02)	−0.04, 0.09	0.05 (0.04)	−0.02, 0.12	0.1956
Placebo	41	0.30 (0.03)	−0.04, 0.09			
Total ankylosis score						
Filgotinib	47	−0.01 (0.29)	−0.40, 0.85	0.28 (0.34)	−0.37, 0.94	0.3888
Placebo	41	−0.06 (0.08)	−0.68, 0.56			

SE, standard error

Conclusion: This is the first PBO-controlled trial to demonstrate a decrease in inflammatory activity with FIL, not only in the spinal vertebrae but also in the postero-lateral elements of the spine and facet joints. As expected in a 12-week study period, no changes in erosion or ankylosis were seen, while fat lesions showed a tendency to increase with FIL. Larger trials are needed to confirm these results.

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Figure. Change from baseline in total CANDEN spine inflammation score

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OP0142

NETAKIMAB REDUCES ANKYLOSING SPONDYLITIS ACTIVITY IN PATIENTS WITH OR WITHOUT SACROILIITIS ON MRI: RESULTS OF SUBANALYSIS OF PHASE 3 ASTERA TRIAL

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Background: The presence of sacroiliitis in patients (pts) with ankylosing spondylitis (AS) on imaging can be established both by sacroiliac joint (SIJ) X-ray or MRI. Active sacroiliitis on MRI as defined by ASAS is predictor of good treatment response to biological disease modifying anti-rheumatic drugs [1, 2]. Netakimab (NTK) is a humanized anti-interleukin-17A antibody approved for the treatment of AS, psoriatic arthritis, moderate-to-severe plaque psoriasis in Russia and Belarus. The difference in treatment response to NTK in AS pts with and without active sacroiliitis on MRI (MRI+/MRI-) is unclear.

Objectives: To report the changes in AS activity in pts with and without sacroiliitis on MRI at week 16 of NTK treatment.

Methods: ASTERA (NCT03447704) is an ongoing phase 3 placebo (PBO)-controlled clinical study, aimed at evaluating NTK efficacy in AS. All pts fulfilled modified New York criteria. Evaluation of acute inflammation on SIJ MRI was performed at the baseline but was not an inclusion criterion. This analysis includes pts received subcutaneous NTK 120mg every 2 wks with available baseline SIJ MRI. The presence of sacroiliitis on MRI was defined as SPARCC>2. Efficacy endpoints included ASAS20/40, ASAS partial remission (PR), changes from baseline in BASDAI (Bath Ankylosing Spondylitis Disease Activity Index), ASDAS-CRP (Ankylosing Spondylitis Disease Activity Score).

Results: 67 MRI+ and 46 MRI- pts were included into analysis. Baseline characteristics were balanced across both arms. 42.4% of MRI+ pts and 38.3% of MRI- pts achieved ASAS40 at week 16 ($p \geq 0.05$), ASAS20 was observed in 65.2%/55.3% pts in the same arms respectively ($p \geq 0.05$). ASAS PR was reported for 15.2% MRI+ and 17.0% MRI- pts ($p \geq 0.05$). Improvements in BASDAI and ASDAS-CRP were similar across both arms. At wk 16, mean change from baseline in BASDAI was -2.7 vs -3.0 for MRI+ and MRI- pts respectively, mean change in ASDAS-CRP was -1.7 vs -1.4 in the same arms ($p \geq 0.05$ for all), (figure 1).

Figure 1. Clinical improvements in AS disease activity. Mean change from baseline is shown for (A) ASDAS-CRP, and (B) BASDAI

Conclusion: NTK leads to decline of disease activity in AS pts irrespectively of sacroiliitis on MRI.

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OP0143

IMPACT OF ADALIMUMAB VERSUS NON-BIOLOGIC THERAPY ON DISEASE ACTIVITY AND PATIENT-REPORTED OUTCOMES IN ANKYLOSING SPONDYLITIS OVER 24 MONTHS – RESULTS OF THE COMPLETE-AS CANADIAN OBSERVATIONAL STUDY

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Background: COMPLETE-AS was an observational study among Canadian biologic-naïve adults with active ankylosing spondylitis (AS) treated with either adalimumab or subsequent non-biologic disease-modifying anti-rheumatic drugs and/or non-steroidal anti-inflammatory drugs (nbDMARD/NSAID) after having switched from initial treatment with a preceding nbDMARD and/or NSAID due to lack of response or intolerance, as per treating physician judgement.