Results: The mean age at baseline was 39.14±9.9 years, the mean symptoms duration was 4.3±4.5 years. 76.8% of pts were naïve to biological treatment. At Wk 16 ASAS40 rate was higher in NTK arm compared to PBO: 40.35% versus (vs.) 2.63% pts (95% CI for the difference in ASAS40 rate was [27.37%; 48.07%] ($p<0.0001$, Figure 1). Efficacy of NTK was also proved by comparison of secondary endpoints (Figure 2); improvement in BASDAI, MASES, BASFI became significant from Wk 4 and remained during the study (no data presented). Most reported adverse events (AE) and treatment-related AEs (TRAE) were mild/moderate (Table 1). The most frequent AEs were anemia, neutropenia, ALT increase. One serious AE (SAE), not related to the treatment (bone fracture), was reported in NTK arm.

Conclusion: NTK at a dose 120 mg is well-tolerated drug with favorable safety profile that leads to decline in r-axSpA activity, function improvement and axial mobility in 16 Wks.

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Table 1. Safety data

% of patients with	NTK (n = 114)	PBO (n = 114)	p-value
AE/SAE	33.3% (38)	25.4% (29)	0.245
TRAE	17.5% (20)	14.0% (16)	0.586
SAE	0.9% (1)	0	1.0
Grade 3-4 AEs	2.6% (3)	3.5% (4)	1.0
Grade 3-4 TRAEs	1.8% (2)	1.8% (2)	1.0
Local reactions	1.8% (2)	0.9% (1)	1.0

Figure 1

Figure 2

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OP0233

THE IMPACT OF EXTRA-ARTICULAR MANIFESTATIONS ON THE CHOICE OF TNF INHIBITOR IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS IN THE BSRBR-AS REGISTER

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Background: Axial spondyloarthritis (axSpA) is associated with important extra-articular manifestations (EAMS), most notably acute anterior uveitis (AAU), inflammatory bowel disease (IBD) and psoriasis, which may influence the choice of biologic agent used to treat axSpA.

Objectives: To examine the factors associated with choice of 1st TNF inhibitor (TNFi) for the treatment of axSpA.

Methods: Clinical and patients-reported outcomes of 2420 patients with axSpA from 83 rheumatology centres in the United Kingdom were collected as part of the British Society for Rheumatology Biologics Register in Ankylosing Spondylitis (BSRBR-AS). History of pre-treatment AAU, IBD and psoriasis were analysed to explore their association with the choice of 1st TNFi. This preference was also examined in relation to other demographic and background factors. These associations were analysed using univariable and multivariable logistic regression models, considering necessary interaction terms.

Results: First-line biologic data was available for 441 patients, comprising of 284 (64.4%) adalimumab (ADA), 109 (24.7%) etanercept (ETA) and 48 (10.9%) certolizumab (CZP). Pre-treatment EAMS in the entire cohort were 568 cases of AAU, 247 IBD and 264 psoriasis.

Prior diagnosis of AAU was associated with a choice of ADA over the other TNFi (ETA and CZP) [OR=3.13, 95% CI: 1.78 – 5.52]. Conversely, a diagnosis of AAU was associated with less preference for ETA (OR=0.16, 95% CI: 0.07 – 0.37) compared with ADA and CZP.

The choice of a particular TNFi was not associated with HLA-B27, age, gender, axSpA disease duration, BASDAI or BASFI scores.

When IBD and psoriasis, and interactions with AAU, were considered in multivariable models (Table), a diagnosis of either AAU or IBD was associated with more preference of ADA versus other TNFi. In contrast, diagnosis of either AAU or IBD was associated with significantly less preference of ETA over other TNFi. The preference of CZP was not associated with presence any pre-treatment extra-articular manifestations.

Table 1. Pre-treatment extra-articular manifestations and the choice of 1st TNFi

		Wald	p value	OR	95% CI for OR
ADA vs. others	Acute Anterior Uveitis (AAU)	19.91	<0.001	3.79	2.11 - 6.80
	Inflammatory Bowel Diseases (IBD)	11.93	0.001	5.50	2.09 - 14.46
	Psoriasis	0.17	0.684	1.15	0.58 - 2.28
	Constant	3.08	0.079	1.23	
ETA vs. others	AAU	20.41	<0.001	0.14	0.06 - 0.33
	IBD	8.34	0.004	0.17	0.05 - 0.57
	Psoriasis	1.02	0.313	0.67	0.30 - 1.47
	Constant	27.38	<0.001	0.52	
CZP vs. others	AAU	0.01	0.959	1.02	0.48 - 2.16
	IBD	1.50	0.221	0.40	0.09 - 1.74
	Psoriasis	0.65	0.420	1.47	0.58 - 3.73
	Constant	126.09	<0.001	0.12	

Conclusion: EAMS appear to play an important role in the choice of TNFi in axSpA. Patients with previous AAU and IBD are more likely to be prescribed ADA

and less likely to receive ETA, consistent with the superior efficacy of monoclonal TNFi for these conditions. The presence or absence of EAMS did not influence the use of CZP, although small sample size might explain the lack of associations. Future work will determine whether EAMS influence TNFi survival, or effectiveness, and whether this varies between agents.

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OP0234

EFFICACY AND SAFETY OF BRODALUMAB, AN ANTI-INTERLEUKIN-17 RECEPTOR A MONOCLONAL ANTIBODY, IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: A 16 WEEK RESULTS OF A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

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Background: It is known that clinical features and pathophysiological pathways of ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) have similarities. Recent reports suggest that IL-17 signaling pathway may be involved in development of axial spondyloarthritis (axSpA). Here we reported the confirmatory phase 3 trial of brodalumab, a human anti-interleukin-17 receptor A monoclonal antibody, in patients with axSpA (4827-006 Study, NCT02985983).

Objectives: To evaluate the efficacy and safety of brodalumab in axSpA (including AS and nr-axSpA) patients at week 16.

Methods: In this phase 3, multicenter, randomized, double-blind, placebo-controlled study conducted in Japan, South Korea and Taiwan, eligible axSpA patients were randomized 1:1 to brodalumab subcutaneously (s.c.) 210 mg or placebo at baseline, weeks 1 and 2, every 2 weeks thereafter. At week 16, all subjects entered an open label extension phase and received brodalumab 210 mg s.c. Q2W. ASAS 40 (Assessment of SpondyloArthritis international Society) response rate at week 16 was the primary endpoint. Secondary outcomes and safety profiles were also assessed.

Results: A total of 159 patients were randomized, and 77/80 patients in brodalumab arm and 69/79 patients in placebo arm were completed the 16 weeks' double-blind phase study. The ASAS 40 response rate at week 16 was significantly higher in brodalumab group (35/80, 43.8%, p=0.018) compared to placebo group (19/79, 24.1%). Other disease activity parameters demonstrated trend to improvement in therapeutic arm (Table). Brodalumab 210 mg had good safety profile. Most commonly reported adverse event was nasopharyngitis observed in both brodalumab (11.1%) and placebo (10.3%) arms. AE rates including SAE rates were comparable between groups. No suicidal ideation or behavior were observed.

Conclusion: Brodalumab s.c. 210 mg Q2W treatment was effective and tolerable in axSpA patients in this 16 week phase 3 clinical trial. Based on the ongoing trial results, brodalumab could be considered as a future therapeutic option for patients with axSpA.

Table 1. Summary of efficacy result at Week 16 (FAS)

Efficacy End Points	axSpA (N=159)	
	Placebo (N=79)	210 mg Brodalumab (N=80)
ASAS 40 Response at Week 16 (NRI), n (%)	19 (24.1)	35 (43.8, p=0.018)
ASAS 20 Response at Week 16 (NRI), n (%)	33 (41.8)	54 (67.5)
ASDAS-CRP change from baseline at Week 16 (BOCF), LS mean	-0.672	-1.127
BASDAI change from baseline at Week 16, Mean	-2.4	-2.9
BASFI change from baseline at Week 16, Mean	-0.7	-1.1

FAS, Full Analysis Set; NRI, Non responder input; BOCF, Baseline Observation Carried Forward; LS mean is based on ANCOVA model adjusted with the baseline, treatment group, strata of CRP level at screening ($\geq$ ULN and $<$ ULN), region (Japan, Korea, Taiwan), and disease subpopulations (AS, nr-axSpA).

Figure. ASAS 20/40 response rate

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OP0235

SECUKINUMAB IMPROVES AXIAL MANIFESTATIONS IN PATIENTS WITH PSORIATIC ARTHRITIS AND INADEQUATE RESPONSE TO NSAIDS: PRIMARY ANALYSIS OF THE MAXIMISE TRIAL

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Background: Secukinumab (SEC) has provided significant and sustained improvement in the signs and symptoms of active psoriatic arthritis (PsA) and ankylosing spondylitis¹. Evidence on the efficacy of biologics in the treatment of PsA patients (pts) with axial manifestations affecting 30–70% of PsA pts is limited², particularly as validated classification criteria for this subtype of PsA are not yet available; an effort to develop criteria is being undertaken by ASAS/GRAPPA. MAXIMISE is an ongoing study evaluating the efficacy and safety of secukinumab 300 or 150mg in managing axial manifestations in PsA pts

Objectives: To report the primary analysis results at Week (Wk) 12 from MAXIMISE (NCT02721966) trial

Methods: This phase 3b, double blind, placebo (PBO)-controlled, multicentre 52-wk trial included 498 pts (aged $\geq$ 18 years) with PsA (CASPAR criteria), clinician-