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

James Cheng-Chung Wei[1], Tae-Hwan Kim[2], Mitsumasa Kishimoto[3], Takuya Morishige[4], Naoki Ogusu[4], Shigeto Kobayashi[5]. *[1]Chung Shan Medical University Hospital, Taichung, Taiwan, Republic of China*; *[2]Hanyang University Seoul Hospital, Seoul, Korea, Rep. of (South Korea)*; *[3]St. Luka's International Hospital, Tokyo, Japan*; *[4]Kyowa Hakko Kirin Co., Ltd., Tokyo, Japan*; *[5]Juntendo University Koshigaya Hospital, Tokyo, Japan*

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 inputation; BOCF, Baseline Observation Carried Forward; LS mean is based on ANCOVA model adjusted with the baseline, treatment group, strata of CRP level at screening (>= ULN and < ULN), region (Japan, Korea, Taiwan), and disease subpopulations (AS, nr-axSpA).

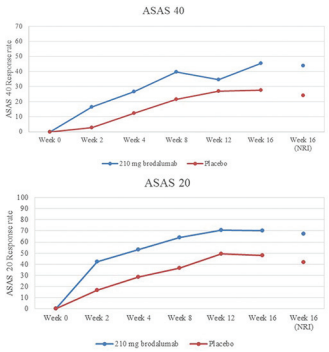

Figure. ASAS 20/40 response rate

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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

Xenofon Baraliakos[1], Laura C Coates[2], Laure Gossec[3], Sławomir Jeka[4], Antonio Mera Varela[5], Barbara Schulz[6], Michael Rissler[6], Ayan Das Gupta[7], Chiara Perella[6], Effie Pournara[6]. *[1]Rheumazentrum Ruhrgebiet, Ruhr University Bochum, Germany, Herne, Germany*; *[2]University of Oxford, Oxford, United Kingdom*; *[3]Sorbonne Universite, Hopital Pitie-Salpetriere, Paris, France*; *[4]2nd University Hospital, CM UMK, Bydgoszcz, Poland*; *[5]Santiago University Clinical Hospital, Santiago de Compostela, Spain*; *[6]Novartis Pharma AG, Basel, Switzerland*; *[7]Novartis Healthcare Pvt. Ltd, Hyderabad, India*

Background: Secukinumab (SEC) has provided significant and sustained improvement in the signs and symptoms of active psoriatic arthritis (PsA) and ankylosing spondylitis [1]. Evidence on the efficacy of biologics in the treatment of PsA patients (pts) with axial manifestations affecting 30–70% of PsA pts is limited[2], 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 ≥18 years) with PsA (CASPAR criteria), clinician-

diagnosed axial involvements, spinal pain VAS >40/100 and BASDAI >4 despite trial of at least two NSAIDs. Pts were randomised to subcutaneous (SC) SEC (300/150 mg) or PBO weekly for 4 wks and every 4 wks thereafter. At Wk 12, PBO pts were re-randomised to SC SEC 300/150 mg. The primary endpoint was proportion of pts achieving ASAS20 response with SEC 300 mg at Wk 12. The key secondary endpoint was ASAS20 response with SEC 150 mg at Wk 12 after superiority of 300 mg was established. Analyses used multiple imputation

Results: Demographic and baseline (BL) disease characteristics were comparable across groups (**Table**). Primary and key secondary endpoints were met; ASAS20 response rates at Wk 12 were 63.1% (SEC 300 mg; P<0.0001) and 66.3% (150 mg; P<0.0001) vs 31.3% (PBO; **Figure**). ASAS20 responses in pts using concomitant MTX were 65.1% [300 mg], 67.3% [150 mg] vs 33.9% [PBO] and corresponding values in No MTX group were 60.5%, 64.4% vs 27.1%. The safety profile was similar across groups through Wk 12

Conclusion: MAXIMISE is the first randomised controlled trial evaluating the efficacy of a biologic in the management of the axial manifestations of PsA. SEC 300 and 150 mg provided rapid and significant improvement in ASAS20 responses through Wk 12 in PsA pts with axial manifestations and inadequate responses to NSAIDs

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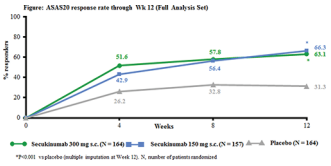
Demographics/BL Characteristics

Mean (SD) unless specified	SEC 300 mg SC (N = 167)	SEC 150 mg SC (N = 165)	PBO (N = 166)
Age (yrs)	46.2 (12.3)	46.9 (11.5)	46.6 (11.5)
Male, n (%)	77 (46.1)	81 (49.1)	88 (53.0)
Evidence of current psoriasis, n (%)	152 (91.0)	147 (89.1)	153 (92.2)
Time since first axial symptoms (yrs)	6.8 (7.7)	7.4 (7.6)	7.7 (9.5)
Total back pain score, VAS	72.5 (13.8)	73.6 (15.3)	74.0 (13.7)
Inflammatory back pain parameters, n (%)			
Onset of back pain is insidious	150 (89.8)	147 (89.1)	152 (91.6)
Back pain improving with exercise	148 (88.6)	139 (84.2)	146 (88.0)
Back pain worsening with rest	152 (91.0)	151 (91.5)	157 (94.6)
Night pain with improvement upon getting up	147 (88.0)	147 (89.1)	143 (86.1)
Awakening due to back pain in 2nd half of night	143 (85.6)	145 (87.9)	137 (82.5)
Alternating buttock pain	102 (61.1)	98 (59.4)	101 (60.8)
Back pain improved after NSAID intake in past	136 (81.4)	134 (81.2)	138 (83.1)
BASDAI	7.3 (1.2)	7.2 (1.4)	7.3 (1.2)
HLA-B27 positive, n/M (%)	31/85 (36.5)	24/82 (29.3)	26/74 (35.1)

M, number of pts with available HLA-B27 status



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OP0236

SIMILAR ONE-YEAR TREATMENT RETENTION OF ORIGINATOR AND BIOSIMILAR ETANERCEPT. RESULTS OF A NORDIC COLLABORATION INCLUDING 1015 PATIENTS WITH SPONDYLOARTHRITIS

Bente Glintborg[1], Ulf Lindström[2], Daniela DI Giuseppe[3], Johan Askling[3], Dan Nordström[4], Sella Aarrestad Provan[5], Björn Gudbjornsson[6], Merete L. Hetland[1], Kalle Aaltonen[7], Arni Jon Geirsson[6], Niels Steen Krogh[1], Lennart T. H. Jacobsson[2]. *[1]DANBIO, Copenhagen, Denmark; [2]Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; [3]Karolinska Institutet, Stockholm, Sweden; [4]ROB-FIN, Helsinki University and University Hospital, Helsinki, Finland; [5]Diakonhjemmet Hospital, Oslo, Norway; [6]ICEBIO and University of Iceland, Reykjavik, Iceland; [7]Ministry of Social Affairs and Health, Helsinki, Finland*

Background: The marketing approval of the etanercept biosimilar SB4 was based on phase III studies on patients with rheumatoid arthritis, but extended to all etanercept indications. Currently, no randomized controlled trials have compared etanercept originator (ETN) with SB4 in patients with spondyloarthritis (SpA). However, the uptake of etanercept biosimilars in the treatment of SpA has been exponential in the Nordic countries, with marked differences across the countries [1].

Objectives: To compare the one-year treatment retention in bio-naïve patients with SpA treated with ETN versus SB4. Furthermore, to explore baseline characteristics in the two patient groups.

Methods: Observational cohort study. Patients with SpA (ankylosing spondylitis (AS), non-radiographic axial SpA (nrax-SpA) or uSpA)), starting etanercept as their first ever TNFi Jan 2014 through Jun 2017 were identified in biologics registers in the five Nordic countries. Baseline characteristics were retrieved from each biological register and comorbidity data through linkage to national registers. The country-specific data were then pooled for further analysis. Comparisons of treatment retention between ETN and SB4 were assessed through survival probability curves and one-year retention rates.

Results: In total, 1015 patients were included, whereof 49% started ETN and 51% SB4. Baseline characteristics were similar in the two patient groups (Table 1).

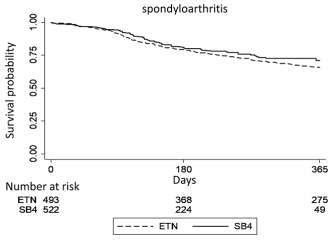
Table 1. Baseline characteristics of etanercept treated SpA patients

	ETN (N=493)	SB4 (N=522)
Age, years	41 (14)	41 (14)
Disease duration, years	12 (12)	11 (12)
Sex, men,%	48	50
AS,%	41	38
nrax-SpA or uSpA,%	59	62
Psoriasis*,%	7	5
Inflammatory bowel disease*,%	2	2
CRP, mg/L	11 (18)	10 (15)
VAS-pain, mm	59 (24)	59 (22)
ASDAS	3.05 (0.90)	2.98 (0.94)
BASDAI, mm	5.4(2.0)	5. 4 (1.9)
BASFI	4.1 (2.4)	4.1 (2.5)
Concomitant csDMARD,%	29	22

Numbers are means (standard deviations) unless otherwise stated
ETN=etanercept originator; SB4= etanercept biosimilar.
*) comorbidities only available from Sweden, Denmark and Finland.
csDMARD = conventional synthetic Disease Modifying anti-Rheumatic Drugs.

One-year survival probability curves were similar for ETN compared to SB4 (Figure 1), and the proportions of patients remaining on drug after one year were comparable: ETN 66% (95%CI: 61-70%) and SB4 73% (95%CI: 68-78%). Further confounder-adjusted analyses are planned and will be presented at the conference.

Figure 1. Treatment retention of etanercept in spondyloarthritis



Conclusion: In this observational study of 1015 patients with SpA from five Nordic countries, biologics-naïve patients starting treatment with originator versus biosimilar etanercept had similar baseline characteristics and similar one-year treatment retention rates, suggesting similar effectiveness and tolerability of the two drugs.