antibodies in SPA and PA, to recommend systematically the eviction of etanercept in subjects with a moderate risk of developing anterior uveitis.

Disclosure of Interest: None declared

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SAT0283

SECUKINUMAB 150 MG PROVIDES SUSTAINED IMPROVEMENTS IN THE SIGNS AND SYMPTOMS OF ACTIVE ANKYLOSING SPONDYLITIS WITH HIGH RETENTION RATE: 4-YEAR RESULTS FROM THE PHASE III TRIAL, MEASURE 2

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Background: Secukinumab, a fully human monoclonal antibody that neutralises IL-17A, has shown significant and sustained improvement in the signs and symptoms of active ankylosing spondylitis (AS) through 3 years in the MEASURE 2 study (NCT01649375).¹

Objectives: To report the longer-term (4 year) efficacy and safety of subcutaneous (s.c.) secukinumab 150 mg in the MEASURE 2 study.

Methods: AS patients (pts; n=219) were randomised to receive s.c. secukinumab 150 mg, 75 mg or placebo at baseline, Weeks (Wks) 1, 2 and 3 and every 4 weeks from Wk 4. At Wk 16, placebo-treated pts were re-randomised to receive secukinumab 150/75 mg. Efficacy results are reported for pts initially randomised to secukinumab 150 mg and those who switched from placebo to secukinumab 150 mg at Wk 16. Safety analyses included all pts who received ≥ 1 dose of secukinumab. Results are reported as observed.

Results: The retention rate from Wk 16 to 208 was 85% (85/100) for secukinumab 150 mg. Sustained improvements were observed with secukinumab 150 mg across all endpoints through 4 years (Table). These improvements were maintained regardless of prior exposure to anti-TNF therapy; greater responses were demonstrated in anti-TNF-naïve pts. Over the entire study period, the mean exposure ($\pm$ SD) to secukinumab was 1189.3 $\pm$ 452.9 days. Exposure-adjusted incidence rates (per 100 pt-years) with any secukinumab dose for selected adverse events were: serious infections/infestations (1.5), *Candida* infections (1.2), Crohn's disease (0.6), major adverse cardiovascular events (0.6), uveitis (0.6), and malignant/unspecified tumours (0.4).

Abstract SAT0283 – Table 1. Clinical improvements with secukinumab 150 mg at Weeks 52 and 208

Variable	Week	Secukinumab 150 mg ^a		
		Total	Anti-TNF-naïve	Anti-TNF-IR
ASAS20,% responders (n)	52	74.2 (93)	80.0 (60)	63.6 (33)
	208	73.3 (86)	74.6 (59)	70.4 (27)
ASAS40,% responders (n)	52	57.0 (93)	63.3 (60)	45.5 (33)
	208	60.5 (86)	62.7 (59)	55.6 (27)
BASDAI, mean change $\pm$ SD (n)	52	-3.2 $\pm$ 2.3 (93)	-3.3 $\pm$ 2.3 (60)	-3.0 $\pm$ 2.1 (33)
	208	-3.2 $\pm$ 2.3 (86)	-3.5 $\pm$ 2.4 (59)	-2.7 $\pm$ 2.0 (27)
SF-36 PCS, mean change $\pm$ SD (n)	52	7.6 $\pm$ 7.7 (94)	8.0 $\pm$ 7.5 (61)	6.9 $\pm$ 8.1 (33)
	208	8.3 $\pm$ 8.3 (85)	9.4 $\pm$ 8.5 (58)	6.2 $\pm$ 7.8 (27)
ASAS partial remission,% responders (n)	52	24.7 (93)	28.3 (60)	18.2 (33)
	208	27.9 (86)	32.2 (59)	18.5 (27)

^aIncludes placebo switchers. Data are reported as observed.

ASAS; Assessment in SpondyloArthritis International Society; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; IR, inadequate response; SD, standard deviation; SF-36 PCS, Short Form³⁶ Health Survey Physical Component Summary; TNF, tumour necrosis factor

Conclusions: Secukinumab 150 mg provided sustained improvement in the signs, symptoms and physical function in pts with AS through 4 years of treatment with 85% retention rate. The safety profile of secukinumab remained favourable and was consistent with previous reports.¹⁻³

REFERENCES:

- [1] Marzo-Ortega, et al. RMD Open 2017;3:e000592.
- [2] Marzo-Ortega, et al. Ann Rheum Dis 2016;75:812-3.
- [3] Baraliakos, et al. Clin Exp Rheumatol 2017.

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SAT0284

AN ADD-ON TRAINING PROGRAM INVOLVING BREATHING EXERCISES, COLD EXPOSURE, AND MEDITATION ATTENUATES INFLAMMATION AND DISEASE ACTIVITY IN AXIAL SPONDYLOARTHRITIS

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Background: A training program involving breathing exercises, cold exposure, and meditation (further referred to as: 'add-on training program') was shown to exert immunomodulating properties in healthy individuals undergoing experimental endotoxemia.

Objectives: Assessment of safety and anti-inflammatory effects of the add-on training program in patients with axial spondyloarthritis (axSpA).

Primary objectives: safety (24 weeks) and change in serum CRP levels (week 8). Secondary objectives: changes in erythrocyte sedimentation rate (ESR), serum calprotectin levels, disease activity as measured by the ASDAS-CRP and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), quality of life measures (SF-36, EQ-5D), and hospital anxiety and depression scale (HADS).

Methods: 24 patients with moderately active axSpA (ASDAS >2.1 and CRP >5 mg/L) were included in this trial. The intervention consisted of an 8 weeks add-on training program comprising three elements: breathing exercises (cyclic hyperventilation followed by breath retention), gradual cold exposure (immersions in ice cold water), and meditation (third eye meditation). An open-label randomised one-way crossover design was used to rule out regression to the mean by comparing an intervention group with a control group.

Results: There was no significant difference in adverse events between groups, with one serious adverse event (hypertensive crisis) occurring 8 weeks after end of the intervention and judged 'unrelated'. The study met its primary efficacy endpoint, with a significant decline in serum CRP at week 8 in the intervention group

(median [interquartile range] from 10.2 [6.5–17.1] to 6.0 [3.9–15.6] mg/L; $p=0.02$), but not in the control group (from 8.7 [5.2–17.2] to 13.2 [7.9–20.1] mg/L; $p=0.70$). A similar trend was seen for serum calprotectin ($p=0.065$ in intervention versus $p=0.31$ in control), but not for ESR. In addition, ASDAS-CRP ($p=0.02$), BASDAI ($p=0.04$), SF-36 physical component score ($p=0.01$), EQ-5D ($p=0.049$), and EQ-5D VAS ($p=0.02$) decreased significantly in the intervention group, but not the control group.

Conclusions: This proof-of-concept study in axSpA revealed a significant decrease in serum CRP levels upon add-on training program, in the absence of safety signals. Together with the significant improvement in disease activity and quality of life, these findings warrant full-scale randomised controlled trials of this novel therapeutic approach in patients with axSpA and other inflammatory conditions.

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SAT0285

EFFICACY OF EARLY VERSUS DELAYED INITIATION OF ANTI-TNF- α TREATMENT IN AXIAL SPONDYLOARTHRITIS. DATA FROM THE CZECH REGISTRY ATTRA

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Background: Anti-TNF- α agents are the mainstay of pharmacotherapy for patients with axial spondyloarthritis (AxSpA) who failed treatment with NSAIDs. A little is known about the influence of early versus delayed treatment initiation on their clinical efficacy.

Objectives: To compare change of disease activity in AxSpA patients on anti-TNF- α therapy based on symptom duration prior to treatment initiation.

Methods: Baseline demographic data and efficacy parameters of patients starting their first anti-TNF- α treatment ≤ 10 years (EARLY) or >10 years (DEALYED) after first symptoms of AxSpA from the Czech national registry ATTRA were compared. Mean $\pm$ SD and absolute/relative frequencies were used to describe continuous and categorical variables, respectively. P-value of Fisher's exact test and Mann-Whitney test is given when assessing difference between groups in categorical and continuous variables. ATTRA is a centralised prospective computerised registry of patients receiving bDMARD therapy for rheumatic diseases collecting data on efficacy, safety and quality of life of all patients treated in the Czech Republic. Anti-TNF- α therapy was indicated for patients with AxSpA who have failed treatment with NSAIDs with CRP ≥ 1 mg/dl and BASDAI score ≥ 4 .

Results: Data from 1290 axSpA patients were available for analysis. 618 patients started treatment ≤ 10 years (EARLY) and 672 >10 years (DEALYED) after the onset of AxSpA symptoms. There was no significant difference in gender distribution (71.4 vs 72.5% males; $p=0.67$) or age at AxSpA diagnosis (33.3 ± 10.4 vs 33.5 ± 10.4 ; $p=0.68$) between the two groups. At the time of anti-TNF- α initiation EARLY patients were significantly younger (36.4 ± 10.6 vs 44.0 ± 11.2 years; $p<0.001$) with shorter symptom duration (5.5 ± 2.7 vs 18.9 ± 8.1 ; $p<0.001$), but disease activity assessed by BASDAI (6.3 ± 1.8 vs 6.3 ± 1.6 ; $p=0.81$) and serum CRP levels (2.6 ± 2.5 vs 2.4 ± 2.0 mg/dL; $p=0.34$) were comparable in both groups. Mean change of BASDAI scores from baseline during anti-TNF- α therapy was significantly greater in the EARLY group at all time-points (3.7 ± 2.5 vs 3.4 ± 2.2 at month 3, 4.2 ± 2.5 vs 3.8 ± 2.3 at month 6, 4.4 ± 2.5 vs 4.0 ± 2.3 at month 12 and 4.4 ± 2.5 vs 4.0 ± 2.4 at month 24; $p<0.05$ for all) suggesting better treatment response. The difference in survival on therapy between the two groups was not statistically significant.

Conclusions: AxSpA patients starting anti-TNF- α therapy more than 10 years after onset of symptoms have significantly worse response to treatment compared to patients with earlier treatment initiation.

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SAT0286

RETENTION RATE AND SAFETY DATA OF BIOSIMILAR CT-P13 IN ANKYLOSING SPONDYLITIS PATIENTS: DATA FROM THE KOREAN COLLEGE OF RHEUMATOLOGY BIOLOGICS REGISTRY

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Background: CT-P13 is a biosimilar prescribed in a number of countries for indications approved for the reference infliximab (RINF), including ankylosing spondylitis (AS), rheumatoid arthritis, and inflammatory bowel diseases. Clinical data of CT-P13 have been analysed in previous clinical trials, demonstrating equivalence of efficacy and pharmacokinetic profile to RINF. However, there are few studies showing long-term data of its drug survival or safety.

Objectives: To investigate the drug retention rate and safety data of biosimilar CT-P13 in Korean AS patients.

Methods: Subjects were AS patients enrolled in the Korean College of Rheumatology biologics registry (KOBIO). Data from patients who received RINF and CT-P13 were included in the analysis^{Dec 2012 ~ Dec 2017}. Discontinuation was defined as switching or stopping the biologic agent. Kaplan-Meier curve and Cox proportional hazard model were used for further analysis. Reason for RINF or CT-P13 discontinuation was also assessed.

Results: Data from 399 AS patients (CT-P13; 256, RINF; 143) were analysed. The mean age of patients was 39.0 in the CT-P13 group, and 73% were males. The mean disease duration was 4.1 years. Eighty percent of patients were first-time biologic users. Discontinuation of CT-P13 occurred in 30.9% (switching in 17.6%) of patients during follow-up. The drug retention rate of first-line users of CT-P13 was marginally higher compared with second or more (≥ 2)-line users of CT-P13, first-line users of RINF, and ≥ 2 line users of CT-P13 in Korean AS patients ($p=0.0518$). The reason of discontinuation was inefficacy (42.7%), adverse events (20.2%), clinical improvement (7.9%), and others (18.0%) in the CT-P13 group. The incidence of adverse events of CT-P13, including infusion reaction ($n=10$), mycobacterial infection ($n=2$), and skin eruption ($n=1$) was comparable to that of RINF.

Conclusions: Our study demonstrates that the drug retention rate of CT-P13, especially in first-line users was relatively higher than that of RINF, [H1] and CT-P13 showed a reasonable long-term safety profile in Korean AS patients.

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