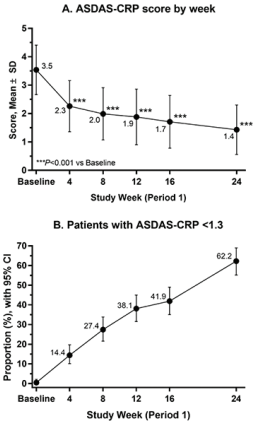
who were on a stable NSAID dose for ≥2 weeks. In Period 1, all patients received ETN (50 mg/week) plus NSAID for 24 weeks. At week 24, patients who achieved inactive disease qualified for Period 2 and were withdrawn from ETN treatment for 40 weeks. In Period 3, patients who experience a flare during Period 2 will be retreated with ETN for 12 weeks. Efficacy outcomes for Period 1 included the proportions of patients achieving inactive disease and 20% and 40% improvements in ASAS disease activity (ASAS20 and ASAS40), as well as the changes from baseline in the Spondyloarthritis Research Consortium of Canada (SPARCC) scores for the sacroiliac joint (SPARCC-SIJ) and the spine (SPARCC-Spine). Efficacy analyses presented here were performed on the observed cases.



Results: Of 209 treated patients, 112 (54%) were men, 186 (89%) white, 142 (68%) had MRI-evident sacroiliitis, and 162 (78%) were HLA-B27-positive. The mean baseline score for ASDAS-CRP was 3.5, 8.5 for SPARCC-SIJ, and 2.7 for SPARCC-Spine. Twenty-one (10%) patients discontinued the trial. A significant decrease in ASDAS-CRP score was observed at all post-baseline visits (Panel A). At Week 24, 62% (117/188) of patients achieved inactive disease (Panel B), 86% (163/190) and 76% (144/190) achieved ASAS20 and ASAS40, respectively, and there was a significant reduction from baseline in SPARCC-SIJ (-5.8; *P*<0.001) and SPARCC-Spine (-1.5; *P*=0.002). Seventy-nine (38%) patients experienced TEAEs, and 1 (0.5%) patient experienced a serious TEAE (cellulitis).

Conclusion: Majority of patients with active nr-axSpA and an inadequate response to NSAIDs achieved inactive disease and reduction of inflammation in both the SIJ and the spine with 24-week open-label ETN treatment. There were no unexpected safety signals.

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Acknowledgement: Medical writing assistance was provided by Vojislav Pejović of Engage Scientific Services and was funded by Pfizer.

Disclosure of Interests: Filip van den Bosch Consultant for: AbbVie, BMS, Galapagos, Janssen, Lilly, Merck, Novartis, Pfizer and UCB, Speakers bureau: AbbVie, BMS, Janssen, Lilly, Merck, Novartis, Pfizer and UCB., James Cheng-Chung Wei Grant/research support from: Abbvie, BMS, Celgene, Janssen, Novartis, Pfizer, and UCB pharma, Consultant for: TSH Taiwan, Speakers bureau: Janssen, Novartis, Pfizer and TSH, Peter Nash Grant/research support from: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant for: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Atul Deodhar Grant/research support from: AbbVie, Amgen, Eli Lilly, GSK, Janssen, Novartis, Pfizer, and UCB, Consultant for: AbbVie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Pfizer, and UCB, Francisco J. Blanco Consultant for: AbbVie, Bioiberica, BMS, GSK, Grünenthal, Janssen, Lilly, Pfizer, Regeneron, Roche, Sanofi, TRB Chemedica, and UCB, Jack F. Bukowski Shareholder of: Pfizer, Employee of: Former employee of Pfizer, Ronald Pedersen Shareholder of: Pfizer, Employee of: Pfizer, Bonnie Vlahos Shareholder of: Pfizer, Employee of: Pfizer

DOI: 10.1136/annrheumdis-2019-eular.1931

FRI0418

SECUKINUMAB PROVIDED SIMILAR EFFICACY IN MALES AND FEMALES WITH ACTIVE ANKYLOSING SPONDYLITIS OVER 52 WEEKS: POST HOC POOLED ANALYSIS OF THE MEASURE TRIALS

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Background: The burden of ankylosing spondylitis (AS) is reported to be higher in female patients (pts). In addition, females show less improvement in AS outcome measures as compared to males when treated with tumour necrosis factor (TNF) inhibitors.[1,2] Currently, there are no data available on the efficacy of secukinumab (SEC) in males versus females.
Objectives: To compare the efficacy of SEC in pts with active AS by gender (male vs female) from data pooled from four phase 3 studies (MEASURE 1-4).
Methods: This *post hoc* analysis pooled data from the MEASURE 1-4 trials. Baseline (BL) demographics and disease characteristics were summarized across genders. Efficacy outcomes assessed at Week (Wk) 16 and 52 were ASAS20, ASAS40, ASDAS-ID, BASDAI, BASMI, BASFI, SF-36 PCS and FACIT-F. BL predictor analysis used multivariable logistic regression (binary variables) or generalized linear model (continuous variables) to assess the impact of gender as an independent variable on ASAS40, ASDAS-ID, and BASDAI at Wk 52, after adjusting for treatment group and other baseline factors in a pooled analysis across studies and treatment groups.
Results: Overall, 647 males and 322 females who received SEC 300mg IV load (LD) (n=76), 150mg IV LD (n=199), 150mg s.c. LD (n=188), 150mg no LD (n=117), and placebo (n=389), respectively, were included in the analysis. At BL, significant differences in TNFi, HLA-B27, and smoking status were observed between genders. MASES scores were significantly higher in females; hs-CRP, BASMI-occiput to wall, and BASMI tragus to wall distance scores were significantly higher in males. Efficacy outcomes were generally similar in males and females (Figure 1). There was no significant impact of gender as an independent predictor of SEC efficacy at Wk 52 as measured by ASAS40 (Odds ratio [OR] 1.1; P=0.50), ASDAS-ID (OR 1.32; P=0.16) or change in BASDAI (treatment effect, -0.17; P=0.82).
Conclusion: Similar efficacy outcomes were observed in male and female patients with active ankylosing spondylitis treated with secukinumab over 52 weeks.

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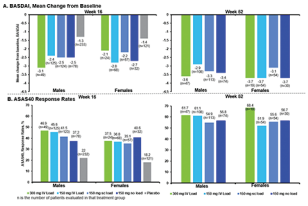

Figure 1. Summary of Efficacy Responses by Gender: A. BASDAI Mean Change from Baseline and B. ASAS40 Response Rates

Disclosure of Interests: Irene van der Horst-Bruinsma Grant/research support from: MSD, Pfizer, AbbVie, Consultant for: Abbvie, UCB, MSD, Novartis, Speakers bureau: BMS, AbbVie, Pfizer, MSD, Corinne Miceli Richard Grant/research support from: MSD, Pfizer, AbbVie, Biogen, UCB, Novartis, Consultant for: Abbvie, Novartis, BMS, Juergen Braun Shareholder of: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Grant/research support from: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Grant/research support from: Abbott, Bristol Myers Squibb, Celgene, Celltrion, Chugai, Johnson & Johnson, MSD, Novartis, Pfizer, Roche, UCB Pharma, Grant/research support from: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Grant/research support from: Abbvie (Abbott), Amgen, Baxter, Biogen, BMS, Boehringer, Celgene, Celltrion, Centocor, Chugai, Hexal, Janssen, Lilly, Medac, MSD (Schering-Plough), Mylan, Mundipharma, Novartis, Pfizer (Wyeth, Hospira), Roche, Sanofi-Aventis and UCB, Consultant for: Abbvie (Abbott), Amgen, Baxter,

Biogen, BMS, Boehringer, Celgene, Celltrion, Centocor, Chugai, Hexal, Janssen, Lilly, Medac, MSD (Schering-Plough), Mylan, Mundipharma, Novartis, Pfizer (Wyeth, Hospira), Roche, Sanofi-Aventis and UCB, Consultant for: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Consultant for: Abbott, Bristol Myers Squibb, Celgene, Celltrion, Chugai, Johnson & Johnson, MSD, Novartis, Pfizer, Roche, UCB Pharma, Speakers bureau: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Speakers bureau: Abbvie (Abbott), Amgen, Baxter, Biogen, BMS, Boehringer, Celgene, Celltrion, Centocor, Chugai, Hexal, Janssen, Lilly, Medac, MSD (Schering-Plough), Mylan, Mundipharma, Novartis, Pfizer (Wyeth, Hospira), Roche, Sanofi-Aventis and UCB, Speakers bureau: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Weibin Bao Employee of: Novartis, Brian Porter Shareholder of: Novartis, Employee of: Novartis, Effie Pournara Shareholder of: Novartis, Employee of: Novartis

DOI: 10.1136/annrheumdis-2019-eular.1834

FRI0419 OUTCOMES OF DOSE REDUCTION OF TNF-INHIBITORS IN AXIAL SPONDYLOARTHRITIS AT 24 MONTHS

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Background: Some patients with inflammatory arthritis who respond well to TNF inhibitor (TNFi) treatment continue to do so after dose reduction. In Axial Spondyloarthritis (axSpA) dose optimisation is desirable but the extent of benefit is unclear and predictors of therapeutic response to dose reduction are unknown.

Objectives: To observe responses to dose reduction of TNFi treatment in axSpA patients and to seek preliminary predictors of low-dose therapeutic response.

Methods: AxSpA Patients at 4 UK centres were allowed to reduce their doses of TNFi therapy if they had met UK (NICE) response criteria and remained well for at least 6 months and wished to do so. There was no predetermined dose-reduction schedule. The proportion of dose reduction was calculated as a percentage, in mg per month, of the original, standard dose. All patients completed BASDAI and BASFI questionnaires at each visit with annual BASMI measurement. CRP levels were measured frequently. Individuals who continued to take reduced-dose treatment throughout the 24-month period were designated "Remainers" (REM) and those who reverted to full-dose treatment were designated "Reverters" (REV). Data were collected at 6 timepoints; 1: immediately before starting TNFi therapy; 2: at the point of dose reduction; 3: at the point of reversion to full-dose treatment (REV only); 4: 6 months after dose reduction; 5:12 months after dose reduction; 6: 24 months after dose reduction.

Results: 58 patients (86%male) who had reduced their dose of TNFi treatment were observed for 24 months. 47 (81%) were REM and 11 (19%) were REV. Mean disease duration prior to biologic therapy was 22.6 years for remainers and 18.6 years for reverters. Mean dose reduction was 38% and 41%, respectively. These 47 REM (85%male) were of mean age 53.6 (range 36 to 71) years, compared with the 11 REV (63.6%male) whose mean age was 51.9 (range 39 to 71) years.

Mean BASDAI, BASFI and BASMI scores and CRP levels at the designated time points are shown in table1.

REM mean BASDAI scores reduced from 1.9 to 1.4 (28%) from dose reduction to 24 months whereas REV mean BASDAI scores increased from 1.8 to 2.4 (34%) from dose reduction to dose reversion.

REM mean BASFI scores reduced from 2.5 to 1.4 (43%) from dose reduction to 24 months whereas REV mean BASFI scores increased from 2.6 to 3.0 (17%) from dose reduction to dose reversion.

REM mean BASMI scores reduced from 3.4 to 2.3 (32%) from dose reduction to 24 months whereas REV mean BASMI scores increased from 2.8 to 3.3 (19%) from dose reduction to dose reversion.

REM mean CRP scores decreased from 4.1 to 0.7mg/dl (83%) from dose reduction to 24 months and REV mean CRP scores also decreased from 4.7 to 3.5mg/dl (25%) from dose reduction to dose reversion.

Conclusion: Amongst these selected patients with axSpA 85% continued to respond to TNFi treatment in spite of 38% dose reduction. Reverters were more likely to be female and to have relatively low CRP levels at the initiation of TNFi treatment; reversion was preceded by modest rises in BASDAI, BASFI and BASMI but by continued fall in CRP levels.

There is a need for randomised dose-reduction studies in axSpA and further research to understand the factors that lead to dose-reversion.

Disclosure of Interests: Liz Van Rossen Grant/research support from: UCB, Abbvie, Consultant for: Novartis, Speakers bureau: Abbvie, UCB, Novartis, Claire Harris Consultant for: Abbvie, Speakers bureau: Abbvie, Annie Gilbert Consultant for: Boehringer, Raj Sengupta Grant/research support from: AbbVie, Celgene Corporation, Merck Sharp & Dohme, Novartis, Pfizer, and UCB, Speakers bureau: AbbVie, Celgene Corporation, Merck Sharp & Dohme, Novartis, Pfizer, and UCB, Cathal Boyle: None declared, Karl Gaffney Grant/research support from: Abbvie, Pfizer, Consultant for: Abbvie, Lilly, Novartis, UCB, Speakers bureau: Abbvie, Biogen, Gilead, Lilly, Novartis, UCB, Pedro Machado Consultant for: Abbvie, BMS, Celgene, Janssen, MSD, Novartis, Pfizer, Roche and UCB, Speakers bureau: Abbvie, BMS, Celgene, Janssen, MSD, Novartis, Pfizer, Roche and UCB, Andrew Keat: None declared

DOI: 10.1136/annrheumdis-2019-eular.3985

TABLE

	No	T/P1	T/ P2	T/ P3	T/ P4	T/ P5	T/P 6
BASDAI REM	47	5.8	1.9	n/a	1.2	1.3	1.4
REV	11	5.2	1.7	2.4			
BASFI REM	47	4.5	2.5	n/a	1.6	1.4	1.4
REV	11	4.4	2.6	3.0			
BASMI REM	47	3.9	3.4	n/a	1.8	2.0	2.3
REV	11	4.0	2.7	3.3			
CRP REM	47	12.8	4.1	n/a	0.8	1.4	0.7
REV	11	6.7	4.7	3.5			

T/P Timepoint

FRI0420 IXEKIZUMAB SIGNIFICANTLY IMPROVES SELF-REPORTED OVERALL HEALTH IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS/RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: SF-36 RESULTS OF TWO PHASE 3 TRIALS

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Background: Using the Short Form-36 (SF-36) questionnaire, previous studies have determined that ankylosing spondylitis/radiographic axial spondyloarthritis (AS/r-axSpA) significantly impairs patients' health-related quality of life (HRQoL).[1] Ixekizumab (IXE), a humanized anti-interleukin-17A monoclonal antibody, improves disease signs and symptoms in patients with AS/r-axSpA.[2,3] Week 16 SF-36 results from two clinical trials with IXE are presented here (NCT02696785 and NCT02696798).

Objectives: To evaluate the efficacy of IXE versus placebo (PBO) in improving HRQoL assessed by the SF-36 questionnaire in patients with active AS/r-axSpA who were either naïve to biologic therapy or have failed or been intolerant of one or two TNF inhibitors (TNFi).

Methods: COAST-V and -W are randomized, double-blind, placebo-controlled clinical trials. Enrolled patients were adults with active AS/r-axSpA classified by ASAS criteria who fulfilled mNY of sacroiliitis (central reading), with Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and back pain $\geq$4. In COAST-V, patients naïve to biologic agents were randomized 1:1:1:1 to receive 80 mg IXE every 4 weeks (Q4W), 80 mg IXE every 2 weeks (Q2W), adalimumab 40 mg Q2W (ADA), or PBO. In COAST-W, patients who had failed on or were intolerant of one or two TNFi were randomized 1:1:1 to 80 mg IXE Q4W, 80 mg IXE Q2W, or PBO. In both studies, patients in the IXE arms were randomized to receive either 80 mg or 160 mg IXE as the starting dose. Comparisons of change from baseline to Week 16 in norm-based SF-36 scores between active groups and PBO were performed using mixed model for repeated measures.