THU0369 SECUKINUMAB 150MG PROVIDES SUSTAINED IMPROVEMENTS IN THE SIGNS AND SYMPTOMS OF ACTIVE ANKYLOSING SPONDYLITIS WITH HIGH RETENTION RATE: 3-YEAR RESULTS FROM PHASE III TRIAL, MEASURE 2

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Background: Secukinumab improved signs and symptoms of ankylosing spondylitis (AS) over 2 years in the MEASURE 2 study (NCT01649375).[1,2]
Objectives: To report the efficacy and safety of secukinumab over 3 years from the MEASURE 2 study.
Methods: 219 patients (pts) with active AS were randomised to subcutaneous secukinumab 150mg (72 pts), 75mg (73 pts) or placebo (PBO, 74 pts). At Week (Wk) 16, PBO treated pts were re-randomised 1:1 to secukinumab 150mg or 75mg, irrespective of clinical response. Pts initially randomised to secukinumab and those who switched from PBO to secukinumab at Wk 16 were included in the analysis (secukinumab 150mg, N=106 and secukinumab 75mg, N=105). Outcome measures at Wk 156 included ASAS20 and 40, ASDAS-CRP inactive disease, ASAS5/6, BASDAI, SF-36 PCS and ASAS partial remission. Data are reported as observed. Safety analyses included all pts who received ≥1 dose of secukinumab.
Results: At 156 wks, the completion rates for secukinumab 150mg was 81.1% (86/106) and 72.4% (76/105) for 75mg. Higher discontinuation rates for 75mg were in part due to lack of efficacy or patient/guardian decision. Efficacy observed across endpoints from Wks 52 to 156 are summarised in the Table. Higher responses were observed in the 150mg group (Table and Figure). Over the entire study period, the mean exposure [±SD] to secukinumab was 914.3±315.5 days. The exposure-adjusted incidence rates with Any secukinumab for infections/infestations, Crohn's disease, malignant/unspecified tumours and major adverse cardiovascular events were 1.5, 0.6, 0.6 and 0.6 per 100 pt-years, respectively.
Conclusions: Secukinumab 150mg provided sustained improvement in the signs & symptoms along with physical functions with over 80% retention rate through 3 years in pts with AS. Safety profile remained favourable and was consistent with previous reports.[1,2]
References:
[1] Baeten et al. N Engl J Med. 2015;373:2534–48.
[2] Marzo-Ortega et al. Ann Rheum Dis. 2016;75:812–3.
Disclosure of Interest: H. Marzo-Ortega Grant/research support from: Janssen and Pfizer, Consultant for: Abbvie, Celgene, Janssen, Novartis and UCB, Speakers bureau: Abbvie, Celgene, Janssen and UCB, C. Legerton Grant/research support from: AbbVie, Ablynx, Acerta, Amgen, AstraZeneca, Celgene, GSK, Janssen, E. Lilly, BMS, Pfizer, Novartis, Sandoz, UCB, Daiichi Sankyo, ChemoCentryx, Boehringer Ingelheim, Speakers bureau: Novartis, Celgene and Amgen, J. Sieper Grant/research support from: AbbVie, Pfizer and Merck, Consultant for: AbbVie, Pfizer, Merck, UCB and Novartis, Speakers bureau: AbbVie, Pfizer, Merck and UCB, A. Kivitz Consultant for: AbbVie, Pfizer, Genentech, UCB and Celgene, Speakers bureau: AbbVie, Pfizer, Genentech, UCB and Celgene, R. Blanco: None declared, M. Cohen Consultant for: Abbvie, Amgen, BMS, Celgene, Hospira, Janssen, Lilly, Merck, Novartis, Pfizer, Roche, Sanofi and UCB, Speakers bureau: Abbvie, Amgen, BMS, Celgene, Hospira, Janssen, Lilly, Merck, Novartis, Pfizer, Roche, Sanofi and UCB, E. M. Delicha Employee of: Novartis, S. Rohrer Shareholder of: Novartis, Employee of: Novartis, H. Richards Shareholder of: Novartis, Employee of: Novartis
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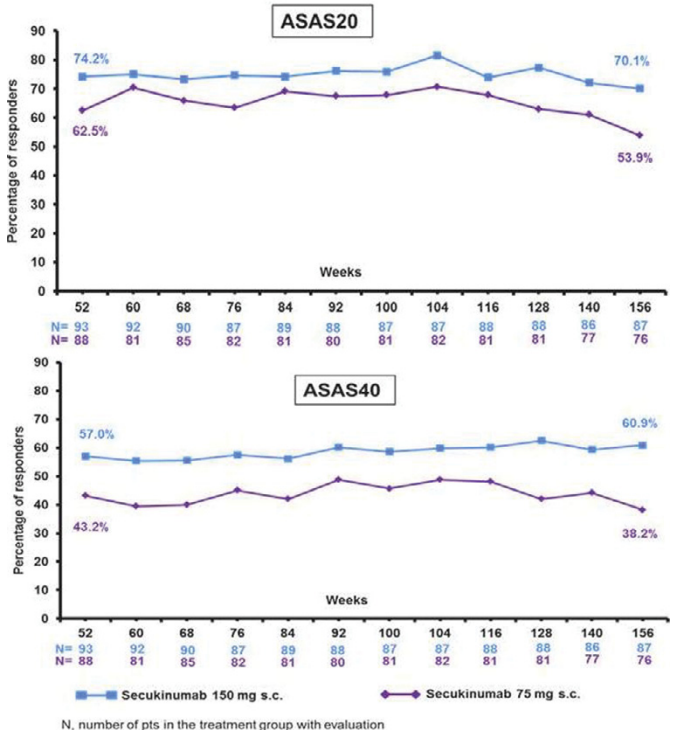
Table 1. Summary of Efficacy Results at Wks 52 and 156

Variable	Wk	Secukinumab	
		150mg	75mg
ASAS20, % responders (n/N)	52	74.2 (69/93)	62.5 (55/88)
	156	70.1 (61/87)	53.9 (41/76)
ASAS40, % responders (n/N)	52	57.0 (53/93)	43.2 (38/88)
	156	60.9 (53/87)	38.2 (29/76)
ASDAS-CRP Inactive Disease, % pts (n/N)	52	19.4 (18/93)	17.2 (15/87)
	156	25.6 (22/86)	12.0 (9/75)
ASAS 5/6, % responders (n/N)	52	61.3 (57/93)	49.4 (44/89)
	156	58.6 (51/87)	40.8 (31/76)
±SD (N)	52	-3.2±2.3 (93)	-2.5±2.2 (89)
	156	-3.3±2.5 (87)	-2.5±2.3 (76)
±SD (N)	52	7.6±7.7 (94)	6.4±7.3 (85)
	156	6.3±9.8 (84)	4.5±9.7 (72)
ASAS partial remission, % pts (n/N)	52	24.7 (23/93)	18.0 (16/89)
	156	32.2 (28/87)	11.8 (9/76)

ASAS, Assessment of Spondyloarthritis International Society criteria; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; hsCRP, high sensitivity C-reactive protein; n, number of responders; N, number of pts in the treatment group with evaluation SD, standard deviation; SF-36 PCS, Short Form-36 physical component summary.

Figure: ASAS20/40 response rate through Week 156



N, number of pts in the treatment group with evaluation

THU0370 INCREASED INTERLEUKIN-17A CONCENTRATION REMAINS HIGH IN PATIENTS WITH ANKYLOSING SPONDYLITIS TREATED WITH TUMOR NECROSIS α INHIBITORS WITHIN THE YEAR

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Background: Ankylosing spondylitis (AS) is associated with changes in the serum cytokines concentrations. During the treatment cytokines profile could change in different manner.
Objectives: The aim of the study was to evaluate the changes in concentration of interleukin-17A (IL-17A) in patients with AS, treated with tumor necrosis factor α inhibitors (anti-TNFα) during the year.
Methods: 30 patients with AS, fulfilled m. New-York criteria, with BASDAI ≥4.0 and NSAIDs non-responders were involved in the study. Mean age of AS patients at baseline was 38.35±9.19 years (M ± SD), the duration of AS was 11.4±9.6 years, 22 (73.3%) of patients – male. 20 healthy volunteers were involved as controls (mean age 40.1±7.7 years, male - 12 (60%). All AS patients were treated during the year with Remicade (infliximab, MSD®)) - 5 mg/kg at the recommended scheme. BASDAI, $ASDAS_{CRP}$ indices were calculated, C-RP, TNFα and IL-17A levels were measured before the treatment with anti-TNFα (baseline) and 52±2 weeks after the baseline. Number of patients achieved ASAS 20, ASAS 40 responses, and ASAS partial remission was evaluated. The statistics was performed with SPSS17.
Results: Baseline concentrations of TNFα and IL-17A in AS patients were higher than in healthy subjects (28.4±14.4 and 2.4±2.1, respectively, p<0.000). Significant reduction of AS activity, but not of IL-17A serum concentration was marked at week 52, Table 1.
24 (80%) achieved ASAS 20, 18 (60%) – ASAS 40, 12 (40%) of patients with