Table 1. Efficacy endpoints at Week 16 and Week 52 in TNFi-naïve patients with axSpA

Endpoints	Week	Any secukinumab 150 mg (N = 932)	Secukinumab 300 mg (N = 57)	Placebo (N = 569)
ASAS40, n (%)	16	399 (42.8) [†]	25 (43.9) [†]	134 (23.6)
	52	508 (54.5)	33 (57.9)	-
ASAS 5/6, n (%)	16	414 (44.4) [†]	24 (42.1) [†]	125 (22.0)
	52	508 (54.5)	33 (57.9)	-
ASAS partial remission, n (%)	16	166 (17.8) [†]	12 (21.1) [†]	35 (6.2)
	52	240 (25.8)	13 (22.8)	-
ASDAS-CRP major improvement, n (%)	16	266 (28.5) [†]	16 (28.1) [†]	43 (7.6)
	52	336 (36.1)	20 (35.1)	-
ASDAS-CRP ID, n (%)	16	171 (18.3) [†]	11 (19.3) [†]	31 (5.4)
	52	247 (26.5)	13 (22.8)	-
BASDAI50, n (%)	16	356 (38.2) [†]	22 (38.6) [§]	110 (19.3)
	52	459 (49.2)	27 (47.4)	-
Nocturnal back pain, mean change from baseline ± SE	16	-31.82 ± 0.87	-37.99 ± 3.56 [†]	-18.12 ± 1.13
	52*	-41.31 ± 27.58	-46.56 ± 24.30	-
Overall level of morning stiffness, mean change from baseline ± SE	16	-3.23 ± 0.09 [†]	-3.62 ± 0.35 [†]	-1.95 ± 0.11 [†]
	52*	-4.24 ± 2.75	-4.71 ± 2.74	-

Data presented as NRI. [†]P < 0.001; [§]P < 0.01 vs placebo; *mean change ± SD. ASAS, Assessment of SpondyloArthritis International Society; ASDAS, Ankylosing Spondylitis Disease Activity Score; axSpA, axial spondyloarthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CRP, C-reactive protein; ID, inactive disease; NRI, non-responder imputation; SD, standard deviation; SE, standard error; TNFi, tumour necrosis factor inhibitor.

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POS0926

NORMALIZATION OF HIGH SENSITIVITY CRP VERSUS CLINICAL RESPONSE TO IXEKIZUMAB AT WEEK 16 IN PATIENTS WITH RADIOGRAPHIC & NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: RESULTS FROM THE COAST STUDIES

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Background: C-reactive protein (CRP), an objective marker of inflammation, can be used to monitor treatment response to biologics in patients with axial spondyloarthritis (axSpA) in addition to evaluating signs & symptoms. CRP is not elevated in all patients with active axSpA questioning its validity as a universal biomarker of response. Ixekizumab (IXE) demonstrated efficacy in axSpA treatment irrespective of baseline (BL) CRP levels. However, response to IXE categorized on CRP change from BL is unknown.

Objectives: To evaluate response to IXE treatment from BL through week (wk) 16 in patients with axSpA categorized according to change in high sensitivity (hs) CRP.

Methods: COAST-V (NCT 02696785), -W (NCT02696798), & -X (NCT02757352), were phase 3, multicentre, randomized, controlled trials, investigating the efficacy of IXE 80mg every 4 & 2 wks in patients with: r-axSpA naïve to biologic disease-modifying antirheumatic drugs (bDMARDs; COAST-V); or who were inadequate responders/intolerant to tumour necrosis factor inhibitors (TNFi;

COAST-W); or who fulfilled Assessment of SpondyloArthritis International Society (ASAS) criteria for non-radiographic (nr)axSpA (COAST-X). This post hoc analysis focuses on approved dosing regimens. Depending on BL and wk 16 hsCRP values, patients were categorised as stable low (hsCRP ≤5 mg/L at BL & ≤5 mg/L at wk 16), normalized (hsCRP >5 mg/L at BL & ≤5 mg/L at wk 16) or elevated (hsCRP >5 mg/L at wk 16, irrespective of BL hsCRP). An absolute cutoff of 5 mg/L was used as the stratification factor in all COAST studies. Data were analyzed by treatment arm. Each trial was analyzed separately. For hsCRP subgroups, patient demographics & other characteristics at BL, as well as trajectory over time for the endpoints ASAS40 & Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) 50 are described. Non-responder imputation was used for missing values.

Results: In all studies at BL, disease activity & MRI SPARCC score were higher in normalized & elevated subgroups compared to the stable low subgroup - a. In COAST-V, ASAS40 & BASDAI50 response was observed in IXE-treated patients regardless of hsCRP change status by wk 16 vs placebo. The highest ASAS40 & BASDAI50 response rate was reported in patients with normalized hsCRP - b. Similar findings were observed in COAST-W & -X.

Table 1. Baseline Patient demographics & other characteristics - ITT population, per CRP subgroup

Parameter	COAST-V (r-axSpA, bDMARD naïve)			COAST-W (r-axSpA, inadequate responders/intolerant to TNFi)			COAST-X (non-radiographic axSpA, bDMARD naïve)		
	Stable low (n=79)	Normal- ized (n=80)	Elevated (n=98)	Stable low (n=58)	Normal- ized (n=34)	Elevated (n=126)	Stable low (n=78)	Normal- ized (n=40)	Elevated (n=81)
Age (years)	43.7 (12.1)	38.9 (10.9)	42.7 (12.0)	50.4 (13.3)	46.1 (13.8)	45.7 (12.5)	44.0 (12.8)	37.2 (14.6)	38.7 (12.8)
Male gender, n (%)	63 (79.7)	71.0 (88.8)	78 (79.6)	39.0 (67.2)	30 (88.2)	109 (86.5)	35 (44.9)	23 (57.5)	34 (42)
Duration of symptoms since axSpA onset (years)	17.5 (11.2)	14.4 (9.3)	16.1 (9.9)	21.7 (12.9)	16.8 (11.6)	18.9 (10.9)	12.1 (9.9)	10.3 (9.7)	9.5 (9.0)
HLA-B27 positive, n (%)	69 (87.3)	75.0 (93.8)	89 (90.8)	31.0 (91.2)	101 (80.2)	101 (80.2)	48 (61.5)	31 (77.5)	67 (82.7)
BASDAI Total Score	6.5 (1.4)	6.7 (1.5)	7.0 (1.1)	7.4 (1.5)	7.3 (1.3)	7.4 (1.3)	6.9 (1.5)	7.1 (1.6)	7.2 (1.5)
ASDAS Total Score	3.1 (0.5)	3.9 (0.6)	4.2 (0.7)	3.5 (0.6)	4.3 (0.6)	4.4 (0.8)	3.2 (0.6)	4.2 (0.8)	4.2 (0.9)
Spinal Pain due to AS	7.0 (1.5)	7.0 (1.5)	7.5 (1.3)	7.8 (1.5)	7.7 (1.5)	7.9 (1.4)	7.2 (1.7)	7.5 (1.7)	7.5 (1.6)
Patients with peripheral articular manifestations (>=1 TJC or >=1 SJC)	47 (59.5)	40 (50)	62 (63.3)	43 (74.1)	24 (70.6)	86 (68.3)	56 (71.8)	33 (82.5)	66 (81.5)
MRI SPARCC Score	6.7 (11.2)	21.8 (27.3)	20.7 (25.7)	1.2 (2.3)	7.0 (7.6)	10.4 (17.0)	5.2 (6.6)	6.1 (8.2)	6.2 (10.5)
MRI Spine SPARCC Score									
MRI SIJ SPARCC Score

Conclusion: IXE reduced clinical disease activity in patients with axSpA irrespective of hsCRP change from BL to wk 16. Improvement in hsCRP level was associated with overall response rates.

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POS0927

EFFECTIVENESS AND SAFETY OF SECUKINUMAB IN NAÏVE OR TNF-INHIBITORS FAILURE AXIAL SPONDYLOARTHRITIS PATIENTS IN REAL LIFE: A 24-MONTHS PROSPECTIVE MULTICENTRIC STUDY

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Background: Axial Spondyloarthritis (axSpA) can be distinguished in radiographic axSpA (r-axSpA) and non-radiographic (nr-axSpA). Secukinumab (SEC) is a novel treatment for axSpA, but data from real-life are still missing.

Objectives: 1) to evaluate the effectiveness and safety of a wide cohort of axSpA patients on SEC followed in 8 Italian Rheumatologic centers for 24-months; 2) to compare the features and disease-activity indices of SEC-treated axSpA patients subdivided in naïve biological drugs (**group A**) and in TNF-inhibitors failure patients (**group B**).

Methods: Consecutive patients with active axSpA (diagnosis according Assessment of SpondyloArthritis International Society ASAS criteria), who started SEC treatment, were evaluated prospectively. Data on disease characteristics, previous/ongoing treatments and imaging were collected. Disease-activity/functional/clinical scores and biochemical values were recorded at baseline (T0), at 6 (T6), 12 (T12), and 24 (T24) months. Effectiveness was evaluated over-time with descriptive statistics. Anova (Kruskal Wallis) and generalized linear models were used to compare variables over-time. Infections, adverse events were collected.

Results: One-hundred-seven patients [49.53% men; median age 49years; median treatment duration 18.5years] were enrolled; 53(49.53%) had HLA-B27, 47.66% were r-axSpA and 52.34% nr-axSpA. Signs of sacroiliitis were present on MRI in 97 (90.65%) and X-rays in 51 (47.66%). SEC was prescribed as first line biologic treatment in 32 (29.9%) patients and as second or more line biological treatment in 75 (70.1%) patients (Figure 1). In all population significant decrease was achieved in: Visual Analogue Scale of pain and general-health; Leeds Enthesitis Index; Health Assessment Questionnaire modified for spondyloarthritis (HAQ-s); Bath Ankylosing Spondylitis Functional Index (BASFI); C-reactive protein. Bath Ankylosing Spondylitis Metrology Index and Erythrocyte-sedimentation-rate not significantly decreased. Effectiveness was associated to an improvement in Ankylosing Spondylitis disease activity score (ASDAS) [T0=3.4 (2.9-3.9) vs T24=1.9 (1.2-2.7); p=0.02] and in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [T0=6.6 (5.0-7.8) vs T24=3.2 (2.0-5.0); p=0.03]. At T0 **group B** had a longer disease duration (p=0.04), a greater prevalence of peripheral arthritis (p=0.02), enthesitis (p=0.04) and psoriasis (p=0.05) and was mostly male (p=0.05), while no significant difference was observed for functional and disease-activity indices and signs of sacroiliitis on MRI/X-rays. At T24 **group A** showed better physical functioning and lower disease activity compared to **group B** [HAQs A vs. B=0.1(0.0-0.5) vs 0.3(0.1-0.8); BASFI A vs B=1.6(0.8-4.8) vs 4.0(2.5-4.6); BASDAI A vs B=2.2(1.0-3.8) vs 3.9(2.7-5.0); ASDAS A vs B=1.3(1.0-2.2) vs 2.1(1.6-2.9)]. After T24 of treatment 70.2% of **Group A** and 68.4% of **Group B** had a low disease activity, accordingly to ASDAS <2.1. Twenty-three patients (21.5%) stopped the treatment during the follow-up mainly because of primary (7) or secondary loss of

efficacy (9). Only 7 patients suspended SEC because of adverse events. A low number of episodes of mild infections (19) occurred; SEC was instead permanently discontinued in 4 cases for: oral refractory mucositis (2); recurrent aphthosis (1); recurrent broncopneumoniae (1). The retention rate at T24 was good in the whole population (73%). Survival curves for **Group A** and **B** were similar (log-rank test=0.81; p=0.69).

Conclusion: In a real-life clinical setting, SEC was safe and effective in axSpA, as shown by a significant decrease of BASDAI and ASDAS over a 24-months follow-up.

Baseline characteristics of 107 axSpA patients treated with secukinumab in the period January 2017- December 2020.

axSpA Features	Total patients	GROUP A	vs.	GROUP B	p
Male sex (N, %)	53 (49.53%)	23 (71.88%)		30 (40%)	0.05
Age (years), median (IQR)	49 (40.5-58)	44 (35.75-58)		52 (42-58.5)	0.04
Age of diagnosis (years), median (IQR)	43 (32.5-51)	39.5 (30.5-50)		43 (33.5-53)	ns
Age of disease onset (years), median (IQR)	39 (29.5-49)	36.5 (22.75-46)		40 (30.5-49)	ns
Disease duration (years), median (IQR)	9 (4-13.5)	7 (2-14.25)		10 (6-13)	0.04
axSpA (n, %)	107	32 (29.91%)		75 (70.09%)	NA
r-axSpA	51 (47.66%)	15 (46.88%)		36 (48%)	ns
nr-axSpA	56 (52.34%)	17 (53.13%)		39 (52%)	ns
HLA-B27 positive, N (%)	53 (49.53%)	16 (50%)		37 (49.33%)	ns
SII-MRI positive, N (%)	97 (90.65%)	28 (87.5%)		69 (92%)	ns
SII-X-rays positive, N (%)	51 (47.66%)	15 (46.9%)		36 (48%)	ns
Peripheral arthritis, N (%)	62 (57.94%)	15 (46.9%)		47 (62.67%)	0.02
Enthesitis, N (%)	66 (61.68%)	17 (53.13%)		49 (65.33%)	0.04
Dactylitis, N (%)	14 (13.08%)	5 (15.63%)		9 (12%)	ns
Psoriasis, N (%)	50 (46.73%)	13 (40.63%)		37 (49.33%)	0.05
Onicopathy, N (%)	22 (20.56%)	6 (18.75%)		16 (21.33%)	ns
IBD, N (%)	4 (3.74%)	2 (6.25%)		2 (2.67%)	ns
Uveitis, N (%)	5 (4.67%)	0 (0%)		5 (6.67%)	ns
Familial history with psoriasis or SpA	36 (33.64%)	12 (37.5%)		24 (32%)	ns
Smoking, N (%)	26 (24.30%)	8 (25%)		18 (24%)	ns
Weight (kg), median (IQR)	70 (60.5-82)	70.50 (64.5-82.25)		70 (60-81.5)	ns
Height (cm), median (IQR)	169 (161-177)	174 (165-178)		168 (160-175.5)	ns
BMI, median (IQR)	24.69 (21.95-28.05)	23.97 (22.65-26.20)		24.9 (21.79-28.24)	ns
BASMI [0-10], median (IQR)	3 (1-6)	2 (0-4)		4 (1-7)	0.03
LEI [0-6], median (IQR)	1 (0-2)	0 (0-1.5)		1 (0-2)	ns
ESR [0-25] (mm/h), median (IQR)	16 (9-28)	13.5 (5-27.25)		18.5 (10-28)	ns
CRP [0-6] (mg/L), median (IQR)	5 (2.9-11)	3.45 (2.4-15.3)		5 (2.9-11)	0.04
VAS-pain [0-10], median (IQR)	7 (6-8)	6.65 (6-7.45)		7 (6-8)	ns
VAS-gh [0-10], median (IQR)	5.6 (4-7)	5.0 (4.25-7.0)		6 (4-7.1)	ns
HAQ-s [0-8], median (IQR)	1 (0.5-1.5)	0.75 (0.2-1.0)		1 (0.75-1.50)	0.05
BASFI [0-10], median (IQR)	6 (4.95-7.03)	5.5 (3.63-7.05)		6 (5.1-7.0)	ns
BASDAI [0-10], median (IQR)	6.6 (5-7.8)	6 (3.7-6.95)		7 (5.25-8.2)	ns
ASDAS [0-6], median (IQR)	3.35 (2.85-3.86)	3.33 (2.67-3.68)		3.35 (2.90-3.86)	ns
Mean treatment duration (months), median (IQR)	18.5 (12-32.5)	18.10 (12-30)		18.93 (12-32.5)	ns
Dosage 300 mg/injection (N, %)	33 (30.84%)	6 (18.75%)		27 (36%)	0.04
Dosage 150 mg/injection (N, %)	74 (69.16%)	26 (81.25%)		48 (64%)	0.04
1 st line (N, %)	32 (29.91%)	32 (100%)		0 (0%)	NA
Failure biological drugs (N, %)	75 (70.10%)	0 (0%)		75 (100%)	NA
2 nd line (N, %)	33 (30.84%)	0 (0%)		33 (44%)	NA
3 rd line (N, %)	23 (21.50%)	0 (0%)		23 (30.67%)	NA
4 th line (N, %)	13 (12.15%)	0 (0%)		13 (17.33%)	NA
>5 th line (N, %)	6 (5.61%)	0 (0%)		6 (8%)	NA
Concomitant NSAIDs, N (%)	68 (63.55%)	21 (65.63%)		47 (62.67%)	ns
Concomitant glucocorticosteroid, N (%)	22 (20.56%)	6 (18.75%)		16 (21.33%)	ns
Concomitant csDMARDs, N (%)	23 (21.50%)	6 (18.75%)		17 (22.67%)	ns

Legend: Data are expressed as median (interquartile range) unless otherwise specified; range of possible values are indicated in square brackets. p < 0.05. GROUP A= naïve to anti-TNFα inhibitors; GROUP B= TNFα failure inhibitors; SpA, Spondyloarthritis; axSpA, axial Spondyloarthritis; r-axSpA, radiographic axial Spondyloarthritis; nr-axSpA, non-radiographic axial Spondyloarthritis; IBD, Inflammatory bowel disease; HLA-B27, Human leukocyte antigen (HLA) B27; SII, Sacroiliac Joints; MRI, Magnetic Resonance Imaging; X-rays, Conventional Radiography; Kg, kilogram; cm, centimeter; BMI, body mass index; BASMI, Bath Ankylosing Spondylitis Metrology Index; LEI, Leeds Enthesitis Index; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein; VAS, Visual Analogue Scale; gh, Global Health; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; ASDAS, Ankylosing Spondylitis disease activity score; HAQ-s, Health Assessment Questionnaire modified for spondyloarthritis; NSAIDs, non-steroidal anti-inflammatory drugs; csDMARDs, conventional synthetic disease-modifying antirheumatic drugs. ns=not statistical significant. NA=not applicable

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POS0928

NETAKIMAB EFFICACY IN ANTI-TNF-NAÏVE AND ANTI-TNF-EXPERIENCED PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: RESULTS OF SUBANALYSIS OF PHASE 3 ASTERA TRIAL

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