Table 1. Number of Patients with AEs per 100 PY and Incidence of AEs of Interest

Time Period	24 Weeks				1 Year*			
Treatment Group	PBO	GUS SC 100 mg		PBO to GUS [‡]	GUS SC 100 mg			
Dosing Schedule	Matching	q8w	q4w	GUS Combined [‡]	q4w	q8w	q4w	GUS Combined [‡]
N	372	375	373	748	352	375	373	1100
Total PY Follow-Up	173	173	172	346	204	384	385	589
Patients with AEs per 100 PY, n (95% CI)								
≥1 AE	143 (123, 166)	148 (127, 171)	154 (132, 178)	151 (136, 167)	92 (77, 108)	114 (100, 130)	115 (101, 131)	109 (100, 117)
≥1 Serious AE	7.1 (3.7, 12)	4.1 (1.6, 8.4)	4.7 (2.0, 9.3)	4.4 (2.5, 7.3)	7.0 (3.8, 11.8)	4.8 (2.9, 7.6)	4.0 (2.2, 6.6)	4.9 (3.6, 6.6)
≥1 Infection	50 (39, 62)	47 (37, 59)	52 (42, 65)	49 (42, 58)	39 (31, 49)	41 (34, 48)	38 (31, 45)	39 (35, 44)
≥1 Serious Infection	1.7 (0.4, 5.1)	0.6 (0.0, 3.2)	1.8 (0.4, 5.1)	1.2 (0.3, 3.0)	2.5 (0.8, 5.8)	1.3 (0.4, 3.1)	0.8 (0.2, 2.3)	1.3 (0.7, 2.3)
Discontinued due to AE	4.1 (1.6, 8.4)	2.9 (1.0, 6.8)	4.7 (2.0, 9.3)	3.8 (2.0, 6.5)	3.5 (1.4, 7.1)	2.1 (0.9, 4.1)	2.6 (1.3, 4.8)	2.6 (1.7, 3.8)
AEs of Interest[§], n (%)								
Death	2 (0.5)	0	0	0	0	0	0	0
Malignancy	1 (0.3)	2 (0.5)	0	2 (0.3)	1 (0.3)	2 (0.5)	0	3 (0.3)
Major Adverse Cardiac Events	1 (0.3)	0	1 (0.3)	1 (0.1)	0	0	1 (0.3)	1 (0.1)
Opportunistic Infections	0	0	0	0	0	0	0	0
Tuberculosis	0	0	0	0	0	0	0	0
Inflammatory Bowel Disease	1 (0.3)	0	0	0	0	0	0	0
Injection-Site Reaction	1 (0.3)	5 (1.3)	4 (1.1)	9 (1.2)	4 (1.1)	6 (1.6)	9 (2.4)	19 (1.7)
Anti-GUS Antibody [*]	-	6/373 (1.6)	9/371 (2.4)	15/744 (2.0)	14/350 (4.0)	18/373 (4.8)	17/371 (4.6)	49/1094 (4.5)

*Through w60 for DISCOVER 1 and w52 for DISCOVER 2; [‡]Combined GUS q8w and q4w; [‡]For patients who switched from PBO to GUS, only data on and after first GUS administration were included in this group; [§]PBO N=370. AE, adverse event; CI, confidence interval; GUS, guselkumab; PBO, placebo; PY, patient year; q4w, every 4 weeks; q8w, every 8 weeks; SC, subcutaneous; w, week

Methods: Adults with active PsA (DISCOVER 1: ≥3 tender/swollen joints and C-Reactive protein [CRP] ≥0.3mg/dL; DISCOVER 2: ≥5 tender/swollen joints and CRP ≥0.6mg/dL) were randomized to subcutaneous GUS 100mg at w0, w4, then every 8 w (q8w); GUS 100mg q4w; or PBO. At w24, PBO pts switched to GUS 100mg q4w. Pts were biologic naive except ~30% pts in DISCOVER 1. Safety was reported through w60 in DISCOVER 1 and through w52 in DISCOVER 2.

Results: Baseline characteristics were similar between treatment groups in the pooled studies. Through w24 and 1 year, numbers of pts per 100 patient years with ≥1 event were similar among treatment groups for adverse events (AEs), serious AEs, infections, serious infections, and discontinuations due to AE (Table 1). At 1 year, there were no cases of active tuberculosis, opportunistic infections (including candida), or inflammatory bowel disease in GUS-treated pts; 2 deaths in PBO pts; and low incidences that were similar across treatment groups for malignancy, major adverse cardiac events, and injection-site reactions. Incidence of anti-GUS antibodies was 4.5%, and most were not neutralizing. Mild elevations in serum hepatic transaminases and decreases in neutrophil counts were consistent at 1 year with the results at w24 (Table 1).

Conclusion: GUS regimens of q8w and q4w were well tolerated in PsA pts through 1 year of treatment in the phase-3 DISCOVER trials, consistent with the w24 results. No meaningful differences between incidences of AEs were reported in the q8w and q4w groups. The safety profile of GUS in PsA pts is generally comparable with the previously established safety profile of GUS.

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AB0539 IXEKIZUMAB TREATMENT RESPONSE: CONSISTENCY OVER TIME AND AT EACH VISIT IN PSORIATIC ARTHRITIS

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Background: Ixekizumab (IXE), a high-affinity monoclonal antibody targeting IL-17A, has demonstrated superiority in achieving the combined endpoint of ACR50 and PASI100 at week (Wk) 24 compared to adalimumab (ADA) in the SPIRIT-H2H trial [1]. In this analysis, we looked at the efficacy responses at the individual patient (pt) level to assess consistency over time and at each visit.

Objectives: To determine the American College of Rheumatology 50% (ACR50) response and Disease Activity in psoriatic arthritis (PsA) (DAPSA) response in pts treated with IXE and describe response consistency over time and at each visit from Wk 24 through Wk 52.

Methods: This post-hoc analysis used data from SPIRIT-H2H (NCT03151551), a phase3b/4 randomised, open-label parallel-group study between IXE and ADA. Pts were randomised to receive either IXE 80mg, every 4 Wks (IXE Q4W) or ADA 40mg, every 2 Wks (ADA Q2W). The proportion (%) of pts in the intent-to-treat population who achieved each endpoint, either ACR50 or DAPSA₁₄, at Wk 24 and at each post-baseline visit out to Wk 52 was assessed. Nine pts with active psoriasis and body surface area (BSA) ≥3% were assessed as PASI=0 at baseline, a medical inconsistency that was resolved using medical judgement. These pts were considered PASI100 responders if PASI=0 and BSA=0 at post baseline visits.

Results: A total of 566 patients enrolled in the trial received either IXE (N=283) or ADA (N=283). Of the 143 pts treated with IXE who achieved ACR50 at Wk 24, 65% (N=93) maintained ACR50 at every visit. In total, 83% (N=118) of the ACR50 achievers at Wk 24 maintained ACR50 with some (18% (N=25)) fluctuations, between ACR50 and

ACR20 (Figure 1). Of the 132 pts treated with ADA who achieved ACR50 at Wk 24, 55% (N=72) maintained ACR50 at every visit. In total, 80% (N=105) of ACR50 achievers maintained ACR50 with some (25% (N=33)) fluctuations between ACR50 and ACR20 (Table 1). Furthermore, of the 174 pts treated with IXE who achieved low DA (DAPSA≤14) at Wk 24, 68% (N=119) maintained low DA at every visit. Of the low DA achievers at Wk 24, 82% (N=142) of pts maintained low DA with some (13% (N=23)) fluctuations between moderate and low DA (Figure 1B). Of the 171 pts treated with ADA who achieved low DA at Wk 24; 57% (N=97) maintained low DA at every visit. In total, 77% (N=131) of low DA achievers at Wk 24 maintained low DA with some (20% (N=34)) fluctuations between moderate and low DA (Table 1).

Conclusion: This analysis demonstrates that a numerically higher proportion of pts treated with IXE versus ADA show consistency of response, as measured by ACR50 and DAPSA responses, over time and for each visit at the pt level.

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Table 1. Consistency over time of the effect of ADA in pts with PsA.

	IXE Q4W (N=283)		ADA Q2W (N=283)	
	ACR50 Response, % (n)	DAPSA≤14 low DA, % (n)	ACR50 Response, % (n)	DAPSA≤14 low DA, % (n)
Patients who achieved the response at Wk 24	51% (143)	61% (174)	47% (132)	60% (171)
Achieved endpoint at Wk 24 and maintained out to Wk 52 with some fluctuations*	83% (N=118)	82% (N=142)	80% (105)	77% (131)
Maintained endpoint at every visit	65% (N=93)	68% (N=119)	55% (72)	57% (97)
Had some fluctuations*	18% (N=25)	13% (N=23)	25% (33)	20% (34)

* fluctuations between ACR50 and ACR20, or between low and moderate disease activity.

Figure 1. Heatmap diagram describing consistency over time of the effect of IXE in pts with PsA who achieved DAPSA≤14 (low disease activity) at Wk 24.

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AB0540

COMPARISON OF EQ-5D HEALTH STATUS IN PSORIATIC ARTHRITIS PATIENTS WITH OR WITHOUT AXIAL DISEASE: RESULTS OF SUBANALYSIS OF THE PATERA STUDY

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Background: Netakimab (NTK) is an anti-interleukin-17A monoclonal antibody approved for psoriasis, ankylosing spondylitis, psoriatic arthritis (PsA) in Russia and Belarus. PATERA is an ongoing phase 3 international double-blind, placebo-controlled clinical study of NTK in PsA (NCT03598751).

Objectives: A subanalysis was performed to assess the effect of NTK on domains of the 5-level EuroQol 5 Dimensions questionnaire (EQ-5D-5L) in patients with inflammatory back pain (IBP) (IBP+) and without (IBP-) at baseline according to self-reported ASAS IBP criteria, 2009.

Methods: 194 adult patients with PsA (CASPAR criteria, 2006) with inadequate response to csDMARD or one TNFi, were randomly assigned to receive NTK 120mg or placebo at weeks 0,1,2,4,6,8,10,14,18,22. The proportion of patients reported >1 problem in each domain was evaluated. Patients with missing values were considered as non-responders in the analysis.

Results: 97 PsA patients (N=54 IBP+, N=43 IBP-) received NTK. The subpopulations didn't differ significantly in gender, age, and PsA activity at baseline. Comparable percentage of patients reported any problems for each domain at baseline (p>0.05) (data not shown). IBP- subpopulation had a greater improvement for all domains except of anxiety/depression. The absolute declines for IBP+ vs IBP- patients were as followed: 24.1% vs 41.9% (mobility), 18.5 vs 41.9% (self-care), 24.0% vs 51.1% (usual activities), 24.1% vs 37.2% (pain/discomfort), 33.3% vs 9.3% (anxiety/depression). However, the only significant difference between IBP+ and IBP- was observed in usual activity (Figure 1).

Conclusion: NTK resulted in the growing improvement of each EQ-5D-5L domain through 24 weeks irrespectively of the presence of IBP. IBP- subjects showed trend to greater benefit compared to IBP+.

Figure 1 Percentage of patients reported any problems in (A) pain/discomfort, (B) in usual activity at each visit

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