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Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease associated with substantial psychosocial burden and health-related quality of life (HRQoL) and functional ability impairments.

Objectives: To characterize the profile of patients with PsA initiating therapy with apremilast in routine care settings, in terms of the physician-assessed clinical disease burden and the patient-reported generic and disease-related HRQoL and functional disability.

Methods: This is an ongoing 52-week multicenter, prospective study conducted in the Greek healthcare environment. Eligible patients are bio-naïve adults with active peripheral PsA, inadequate (within the first 12 months of treatment) response/intolerance to a prior conventional synthetic disease-modifying antirheumatic drug (csDMARD), and no prior use of tofacitinib, initiating apremilast as per the approved label. Data are being collected by physician assessments, as performed in routine clinical practice, and by patient-reported outcomes. 170 patients enrolled in the study; data at apremilast initiation (baseline) from the first 100 eligible consenting patients are presented in this interim analysis as per protocol.

Results: 99 evaluable patients were consecutively enrolled in 19 rheumatology departments between 15-Apr-2019 and 13-Jan-2020. At baseline (Table 1) [mean (SD) age: 53.8 (11.7) years], 43.4% of the patients had at least one (30.3% had ≥2) ongoing comorbidity other than PsA/PSO. The median [interquartile range (IQR)] PsA and psoriasis duration were 1.9 (1.0-3.5) and 7.5 (3.9-16.8) years, respectively. All subjects were on csDMARD while 24.2% received combination therapy, oral non-steroid anti-inflammatory drugs (32.3%), topical treatments (20.2%) and systemic steroids (11.1%). Based on the Clinical Disease Activity in PsA (cDAPSA) score, 58.6% of the patients had moderate, and 29.3% high disease activity. In the EuroQol (EQ) 5-Dimensions (5D) 5-Levels questionnaire, 93.9, 82.8, 82.8, 73.7, and 51.5% of the patients reported problems in 'pain/discomfort', 'anxiety/depression', 'usual activities', 'mobility', and 'self-care', respectively. The median (IQR) baseline UK-weighted EQ-5D index and EQ-Visual Analogue Scale scores were 0.55

Table 1. Baseline characteristics

	N	%/Mean/ Median
Women, %	57/99	57.6
Peripheral joint involvement only, %	92/99	92.9
Polyarthritis (≥5 joints), %	69/99	69.7
cDAPSA (range: 0-154), median (IQR)	99	22.0 (16.0-29.0)
Number of SJC (0-66) / TJC (0-68), median (IQR)	99	4 (2-8) / 6 (2-10)
Active psoriasis (BSA>0%), %	83/99	83.8
BSA score, median (IQR)	77/83	5.0 (2.0-12.0)
Nail involvement, %	38/96	39.6
Enthesitis and/or dactylitis, %	30/95	31.6
Dactylitis, %	11/95	11.6
Finger and toe Dactylitis Severity Score (DSS) (range: 0-60), median (IQR)	10/11	2.0 (1.0-6.0)
Enthesitis, %	22/95	23.2
LEI score (range: 0-14), median (IQR)	22	2.0 (1.0-2.0)
Extra-articular manifestations (mainly fatigue), %	10/99	10.1
Comorbidities in ≥15% of the patients		
Hypertension, Essential hypertension, %	23/99	23.2
Dyslipidemia, hypercholesterolemia, (type V) hyperlipidemia, %	15/99	15.2
Total PsAID12 score (range: 0-10), mean (SD)	98	4.6 (2.0)
Total HAQ-DI score (range: 0-3), median (IQR)	99	1.0 (0.5-1.4)

(0.44-0.70) and 50.0 (40.0-70.0), respectively. The median (IQR) Health Assessment Questionnaire-Disability Index (HAQ-DI) and mean (SD) PsA Impact of Disease 12-item (PsAID12) scores were 1.0 (0.5-1.4) and 4.6 (2.0), respectively.

Conclusion: More than 8 out of 10 bio-naïve patients initiated on apremilast in the routine clinical care in Greece have at least moderate disease activity, active psoriasis, and problems with pain/discomfort, anxiety/depression, and performance of usual activities at a median of 2 years post-diagnosis. HAQ-DI and PsAID12 scores indicate moderate impairment of physical functionality and PsA-related HRQoL. The findings underscore considerable disease burden early in the disease course.

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POOLED SAFETY RESULTS FROM TWO PHASE-3 TRIALS OF GUSELKUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS THROUGH 1 YEAR

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Background: DISCOVER 1 & 2, two double-blind, phase-3, psoriatic arthritis (PsA) trials of guselkumab (GUS, an IL-23 inhibitor), demonstrated significant improvement with GUS vs placebo (PBO) in signs and symptoms of PsA, with good tolerability, at week (w) 24 during the PBO-controlled period.^{1,2} Beyond w24, all patients (pts) switched to GUS. Continued treatment maintained efficacy through w52.^{3,4}

Objectives: To describe pooled safety results from the DISCOVER 1 & 2 trials through 1-year of GUS treatment.

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		GUS	
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