Table 1. Treatment-Emergent AEs During PBO-controlled Period and Through 1Yr: VOYAGE & DISCOVER Trials

Time Period	Pooled VOYAGE 1&2				Pooled DISCOVER 1&2				
	W0-16		Through 1Yr		W0-24 ^b		Through 1Yr		
	PBO (N=)	GUS Q8W (N=)	Combined GUS ^a (N=)	PBO ^c (N=)	GUS Q8W (N=)	GUS Q4W (373) (N=)	GUS Q8W (N=)	GUS Q4W (373) (N=)	Combined GUS† (1100) (N=)
Total pt-yrs of follow-up	128	255	974	173	173	172	384	385	973
Incidence/100 pt-yrs (95% CI) ^d									
AEs	317 (287,349)	330 (308,353)	259 (249, 270)	219 (198,243)	256 (232,281)	221 (200, 245)	218 (203,233)	177 (164,191)	191 (182, 199)
SAEs	5 (2, 10)	6 (4, 10)	6 (5, 8)	9 (5, 15)	4 (2, 8)	5 (2, 10)	6 (4, 9)	4 (2, 7)	6 (4, 7)
AEs leading to study agent d/c	3 (0.9, 8)	4 (2, 8)	2 (2, 4)	4 (2, 8)	3 (1, 7)	7 (4, 12)	2 (1, 4)	4 (2, 6)	3 (2, 5)
Infections	86 (71, 104)	98 (86, 111)	98 (92, 104)	58 (48, 71)	58 (47, 71)	63 (51, 76)	58 (50, 66)	53 (46, 61)	55 (50, 60)
Serious Infections	0.8 (0, 4)	0.4 (0, 2)	1 (0.5, 2)	4 (2, 8)	0.6 (0, 3)	2 (0.4, 5)	2 (0.6, 3)	1 (0, 2)	2 (0.9, 3)
All Malignancy	0 (0, 2)	0.4 (0, 2)	1 (0.4, 2)	0.6 (0, 3)	1 (0, 4)	0 (0, 2)	0.5 (0, 2)	0 (0, 0.8)	0 (0, 1)
MACE	0 (0, 2)	0.4 (0, 2)	0.4 (0, 1)	0.6 (0, 3)	0 (0, 2)	0.6 (0, 3)	0 (0, 0.8)	0.3 (0, 1.4)	0.1 (0, 0.6)
% pts with ≥1 injection site rxn	3.1	4.5	5.0	0.3	1.3	1.1	1.6	2.4	1.7

^aPlacebo crossover pts were included in the combined GUS column after crossover to GUS^bFor all pts who d/c study treatment early with the last dose of PBO/GUS prior to W24 and who did not receive any PBO/GUS at or after Wk24, all data including the final safety follow-up visit collected through 1yr were included^cFor pts in PBO group who switched to GUS due to cross-over or inadvertently, only data prior to first administration of GUS were included.^dCI based on an exact method assuming observed number of events follows a Poisson distribution

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AB0529

CHARACTERIZATION OF REMISSION IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH UPADACITINIB: POST-HOC ANALYSIS FROM TWO PHASE 3 TRIALS

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Background: For patients (pts) with PsA, several disease activity measures are available including very low/minimal disease activity (VLDA/MDA), cutoffs based on the Disease Activity in PsA (DAPSA) score, and on the Psoriatic Arthritis Disease Activity Score (PASDAS) score.

Objectives: To assess the rates of pts achieving these remission or low disease activity (LDA) criteria at Wk 24 using data from the SELECT-PsA 1 and SELECT-PsA 2 phase 3 studies.^{1,2} Additionally, we assessed the distribution of individual MDA components among pts who did or did not achieve MDA criteria at Wk 24.

Methods: In SELECT-PsA 1 and SELECT-PsA 2, pts with PsA and prior inadequate response (IR) or intolerance to ≥1 non-biologic DMARD (N=1705) or ≥1 biologic DMARD (N=642), respectively, were randomized to once daily upadacitinib (UPA) 15mg, UPA 30mg, adalimumab (ADA) 40mg every other week (SELECT-PsA 1 only), or placebo (PBO). Remission and LDA were assessed using VLDA/MDA, DAPSA scores of ≤4/≤14, and PASDAS scores of ≤1.9/≤3.2, at Wk 24 (Table 1). Non-responder imputation (NRI) was used for handling missing data; pts rescued at Wk 16 were considered non-responders. Pairwise comparisons between UPA doses and PBO or ADA were conducted using the Cochran-Mantel-Haenszel test.

Results: Overall, 2345 pts were analyzed; mean age 51 years, 53% female. In both studies, higher rates of remission and LDA were observed with both UPA doses vs PBO at Wk 24 (nominal P-values <0.05 for both time points; Table 1). Generally, higher rates of remission and LDA were also observed with UPA30 vs ADA in non-biologic DMARD-IR pts (nominal P-values <0.05). Greater rates of MDA/VLDA were observed at Wk 24 with UPA15 and UPA30 vs PBO in both studies and with UPA30 vs ADA in non-biologic DMARD-IR pts (nominal P-values <0.05 for all comparisons). The proportion of responder or non-responder pts receiving UPA15 or UPA30 was similar for each of the MDA components in both studies. At Wk 24, more responder and non-responder pts in both studies achieved Swollen Joint Count (SJC) 66 ≤1, Psoriasis Area and Severity Index (PASI) ≤1 or Body Surface Area-Psoriasis (BSA-Ps) ≤3%, and Leeds Enthesitis Index (LEI) ≤1 (Figure 1). Conversely, the proportion of pts Achieving Tender Joint Count (TJC) 68 ≤1 and Pt's Global Assessment of Pain ≤1.5 tended to be lower.

Conclusion: Regardless of previous biologic DMARD failure, pts treated with UPA15 or UPA30 achieved a higher rate of remission or LDA measured by various disease activity measures vs PBO at Wk 24; higher rates of response were observed in most of the remission and LDA measures with UPA30 vs ADA in non-biologic DMARD-IR pts. Among pts who did or did not achieve MDA criteria at Wk 24, a greater proportion of UPA-treated pts achieved physician derived measures such as SJC ≤ 1 , PASI ≤ 1 or BSA-Ps $\leq 3\%$, and LEI ≤ 1 .

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Table 1. Proportion of Patients Achieving Remission and LDA Measures at Week 24

Endpoint, n (%)	SELECT-PsA 1				SELECT-PsA 2			
	PBO N=423	ADA 40mg EOW N=429	UPA 15mg QD N=429	UPA 30mg QD N=423	PBO N=212	UPA 15mg QD N=211	UPA 30mg QD N=218	
MDA	52 (12.3)	143 (33.3)	157 (36.6) *, #	192 (45.4) *, #	6 (2.8)	53 (25.1) *, #	63 (28.9) *, #	
≥ 6 VLDA components	25 (5.9)	90 (21.0)	105 (24.5) *	134 (31.7) *, †	3 (1.4)	26 (12.3) *	44 (20.2) *	
VLDA	11 (2.6)	62 (14.5)	55 (12.8) *	72 (17.0) *	3 (1.4)	16 (7.6) *	21 (9.6) *	
DAPSA REM	9 (2.1)	43 (10.0)	47 (11.0) *	79 (18.7) *, †	1 (0.5)	15 (7.1) *	28 (12.8) *	
DAPSA LDA	70 (16.5)	198 (46.2)	204 (47.6) *	235 (55.6) *, †	14 (6.6)	73 (34.6) *	91 (41.7) *	
PASDAS REM	12 (2.8)	51 (11.9)	60 (14.0) *	91 (21.5) *, †	4 (1.9)	20 (9.5) *	31 (14.2) *	
PASDAS LDA	63 (14.9)	168 (39.2)	195 (45.5) *	211 (49.9) *, †	9 (4.2)	69 (32.7) *	82 (37.6) *	

*P ≤ 0.05 for UPA15 and UPA30 vs PBO; †P ≤ 0.05 for UPA30 vs ADA; #Statistically significant in the multiplicity-controlled analysis. MDA (5/7) and VLDA (7/7): TJC ≤ 1 ; SJC ≤ 1 ; PASI ≤ 1 or BSA-Psoriasis $\leq 3\%$; Patient's Assessment of Pain NRS ≤ 1.5 ; PtGA-Disease Activity NRS ≤ 2.0 ; HAQ-DI score ≤ 0.5 ; and tender entheseal points ≤ 1 . DAPSA REM ≤ 4 ; DAPSA LDA ≤ 14 . PASDAS REM ≤ 1.9 ; PASDAS LDA ≤ 3.2 .

ADA, adalimumab; BSA, body surface area; CI, confidence interval; EOW, every other week; HAQ-DI, Health Assessment Questionnaire - Disability Index; LEI, Leeds Enthesitis Index; MDA, minimal disease activity; NRS, numerical rating scale; PASI, Psoriasis Area Severity Index; Ps, psoriasis; PtGA, Patient's Global Assessment of Disease Activity; QD, once daily; SJC, Swollen Joint Count; TJC, Tender Joint Count; UPA, upadacitinib.

Figure 1

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AB0530 EFFECT OF SKIN SYMPTOMS ON DISEASE IMPACT IN PATIENTS WITH PSORIATIC ARTHRITIS RECEIVING THE IL-17/23 INHIBITOR USTEKINUMAB OR TNF INHIBITORS IN THE REAL-WORLD PSABIO STUDY

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Background: Psoriatic arthritis (PsA) is characterised by musculoskeletal symptoms, and patients (pts) with PsA usually experience psoriasis concurrently. Real-world data reflecting impact of skin symptoms on PsA disease burden are limited.

Objectives: Analyse effectiveness of ustekinumab (UST) and tumour necrosis factor inhibitor (TNFi) therapy on extent of skin involvement, and the impact this has on PsA disease burden and drug persistence.

Methods: PsABio (NCT02627768) is a prospective, observational study of 1st/2nd/3rd-line UST or TNFi treatment in PsA in 8 European countries. Extent of skin involvement was categorised as body surface area (BSA): clear/almost clear; <3% but not clear/almost clear; 3–10%; or >10%. Pt-reported disease impact was evaluated by PsAID-12, including assessment of two skin-related domains (D): D3 (skin problems, including itching) and D10 (embarrassment and/or shame because of appearance). Estimated persistence at 1 year was assessed against baseline (BL) BSA categories.

Results: At BL, significantly more pts receiving UST than TNFi had BSA >10% (Figure 1). BL disease impact (PsAID-12) was worse in pts with BSA >10% than <3% in D3, D10 and total (non-overlapping 95% CIs suggest significance) (Table 1). BSA improved from BL to 1 year with both treatments. At 1 year, 64% of pts in both groups had clear/almost clear skin and only 3% had BSA >10% (Figure 1). At 1 year, both treatments significantly reduced disease impact (PsAID-12 total), and D3 and D10 scores, irrespective of BL BSA category, but most markedly in pts with higher BL BSA (Table 1). Worse BL psoriasis was generally associated with longer persistence for both treatments; however, at 1 year, pts