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AB0560

EFFECT OF DEUCRAVACITINIB ON THE PSORIATIC ARTHRITIS IMPACT OF DISEASE (PsAID) QUESTIONNAIRES 12 AND 9: ANALYSIS OF A PHASE 2 STUDY OF ACTIVE PSORIATIC ARTHRITIS

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Background: Tyrosine kinase 2 (TYK2) is an intracellular kinase that mediates IL-23, IL-12, and IFN α/β signaling. Deucravacitinib is a novel, oral selective inhibitor of TYK2 via the TYK2 regulatory domain. Phase 2 results showed deucravacitinib was efficacious and well tolerated versus placebo (PBO) in patients (pts) with active psoriatic arthritis (PsA). The Psoriatic Arthritis Impact of Disease (PsAID) questionnaire is a EULAR-developed, validated instrument designed to specifically assess the impact of PsA on health-related quality of life (HRQL) from the pt's perspective and is available as separate versions for clinical practice (PsAID-12) and clinical trials (PsAID-9).¹

Objectives: To compare the effect of deucravacitinib vs PBO on PsAID-12 and PsAID-9 responses and to assess relationships between PsAID scores and clinical and pt-reported outcome (PRO) measures.

Methods: This is an ongoing, 1-year, double-blind, Phase 2 trial (NCT03881059). Pts with active PsA were randomized 1:1:1 to deucravacitinib 6mg or 12mg once daily, or PBO for 16 weeks (wk). PsAID-12 and PsAID-9, other PROs, and clinical response outcomes were assessed at baseline (BL) and Wk 16. Mean changes from BL in PsAID-12 and PsAID-9 total scores at Wk 16 were determined for each treatment group as well as by response outcomes (ie, achievement of response at Wk 16 for PROs and select clinical response outcomes; Table 1). Spearman correlations between PsAID-12 and PsAID-9 scores and clinical and PRO measures were also assessed.

Results: 203 pts were randomized and BL characteristics were similar across groups. Adjusted mean changes from BL in PsAID-12 and PsAID-9 scores at Wk 16 were significantly greater in the deucravacitinib groups vs PBO (Figure 1). Adjusted mean changes from BL in PsAID-12 and PsAID-9 scores at Wk 16 were significantly improved with deucravacitinib vs PBO in pts who achieved response for PROs, as well as PASDAS low disease activity and PASI 75 response (Table 1). Adjusted mean changes from BL were generally similar with deucravacitinib vs PBO in nonresponders. Spearman correlation analysis revealed significant correlations at BL and Wk 16 between PsAID-12 and PsAID-9 scores and clinical and PRO measures ($P < 0.0001$).

Conclusion: With deucravacitinib vs PBO, PsAID-12 and PsAID-9 scores were significantly improved vs BL at Wk 16. PsAID detected additional improvements among pts achieving response for multiple other PROs and select clinical outcome measures.

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Figure. Adjusted mean change from baseline in PsAID-12 and PsAID-9 total scores at Wk 16

* $P < 0.002$ vs PBO; † $P < 0.0005$ vs PBO. PBO, placebo; PsAID-9, 9-item Psoriatic Arthritis Impact of Disease questionnaire; PsAID-12, 12-item Psoriatic Arthritis Impact of Disease questionnaire; QD, once daily.

Table 1. Adjusted mean change from BL in PsAID-12 total scores at Wk 16 in patients who achieved PRO or clinical response

Response Definition	Mean change from BL in PsAID-12 total score				
	PBO n=66	Deucravacitinib 6mg QD n=70	P value vs PBO	Deucravacitinib 12mg QD n=67	P value vs PBO
PROs					
Patient global VAS (≤ -10.0)	-1.6 (n=40)	-2.8 (n=54)	0.0008	-2.9 (n=48)	0.0003
Patient pain VAS (≤ -10.0)	-2.3 (n=32)	-3.4 (n=44)	0.004	-3.3 (n=45)	0.004
HAQ-DI (≤ -0.35)	-2.8 (n=10)	-3.8 (n=27)	0.09	-3.8 (n=27)	0.11
FACIT-Fatigue (≥ 4.0)	-2.4 (n=27)	-3.3 (n=36)	0.02	-3.6 (n=41)	0.002
SF-36 PCS (≥ 2.5)	-1.7 (n=35)	-2.7 (n=44)	0.02	-3.1 (n=43)	0.001
SF-36 MCS (≥ 2.5)	-2.1 (n=21)	-3.5 (n=33)	0.005	-3.8 (n=31)	0.0009
Clinician assessments					
PASDAS (≤ 3.2)	-3.1 (n=6)	-4.2 (n=14)	0.004	-4.5 (n=15)	0.0006
PASI 75 ($\geq 75\%$ improvement from BL)	-2.4 (n=11)	-3.7 (n=25)	0.05	-3.9 (n=31)	0.02

PsAID-9 results were generally consistent with PsAID-12 (data not shown). Response definitions based on published literature. Higher FACIT-Fatigue scores indicate less fatigue. Higher SF-36 PCS and SF-36 MCS scores indicate less disability. BL, baseline; FACIT, Functional Assessment of Chronic Illness Therapy; HAQ-DI, Health Assessment Questionnaire-Disability Index; MCS, Mental Component Summary; NA, not applicable; PASDAS, Psoriatic Arthritis Disease Activity Score; PASI, Psoriasis Area and Severity Index; PCS, Physical Component Summary; PRO, patient-reported outcome; QD, once daily; SF-36, 36-item Short Form Health Survey; VAS, visual analog scale.

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AB0561 DISEASE DURATION AND HLA-B27 POSITIVITY ALTER LONGTERM RETENTION RATE OF CERTOLIZUMAB PEGOL IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: Several factors such as effectiveness, safety and compliance affect the drug survival in chronic disorders. Physicians take care of long-term retention rate and responses for discontinuation of candidate drug. Identification of predictors of clinical response to certolizumab-pegol (CZP) may aid the decision-making process for treating patients psoriatic arthritis (PsA).

Objectives: The purpose of this study to assess the drug survival of certolizumab pegol (CZP) in patients with PsA and to identify the predictors and reasons for discontinuation.

Methods: Data on patient characteristics, demographics, diagnosis, disease duration, treatment and outcomes have been collected since 2011 in Turkish Biologic (TURKBIO) Registry. By the end of December 2020, 68 PsA patients received CZP and were included. Kaplan Meier plot was used for drug survival analysis. Cox regression analysis was performed to evaluate the predictors associated with drug survival.

Results: During the median 47 months follow-up, 17 patients discontinued the CZP treatment. The reasons for discontinuation were ineffectivity (35.3%), adverse event (17.6%) and pregnancy (5.9%). The baseline characteristics of the patients who continued and discontinued CZP were shown in the Table 1. Patients who discontinued CZP had higher mean age and disease duration. HLA-B27 positive patients had lower retention rate while bDMARD naive patients had higher retention rate. At the month 36, retention rate of CZP was 61.6% on patients with PsA (Figure 1).

Conclusion: Real life experience from this nationwide TURKBIO registry show that the retention rate of CZP in PsA are lower in older patients and with longer disease duration. Moreover, bDMARD naive patients have higher retention rate.

Figure 1. Drug survival of CZP in patients with PsA

Table 1. Baseline characteristics of PsA patients who continue and discontinue CZP

	All Patients (n=68)	Continue to CZP (n=51)	Discontinue to CZP (n=17)	p
Females, n (%)	52 (76,5)	37 (72,5)	15 (88,2)	0,322
Age, years	44 (36-57)	40 (35-53)	51 (42-60)	0,012
Disease Duration, years	9 (5-13)	8 (5-12)	14 (10,5-17)	0,002
Symptom duration, years	11 (7-16)	10 (7-15)	15,5 (11,5-20)	0,014
Order of CZP in bDMARDs	1 (1-2)	1 (1-2)	2 (1-2)	0,062
HLA-B27, n (%)	9 (28,1)	3 (14,3)	6 (54,5)	0,035
ESR, mm/h	23,5 (11-37)	23 (9-35)	24 (17-52)	0,246
Swollen Joint Counts, n	0 (0-2)	0 (0-2)	1 (0-2)	0,480
Tender Joint Counts, n	2 (0-4)	1 (0-4)	2 (1-5)	0,143
CRP, mg/dl	4 (3-13,65)	3,14 (3-13)	5 (3-19)	0,107
HAQ	0,63 (0,25-1)	0,63 (0,25-1)	0,75 (0,63-0,94)	0,097
VAS-Physicians	20 (12-31,5)	20 (12-26)	30 (15-50)	0,074
VAS-Patient Global	50 (27-70)	50 (20-70)	61,5 (46,5-70)	0,342
VAS-Patient Pain	53 (28-75)	50 (20-75)	69 (49,5-75)	0,122
DAS-28-CRP	3,35 (2,2-3,9)	2,85 (2-3,8)	3,6 (2,9-4,4)	0,086
BASFI	15 (8-27)	14 (5-26)	23,5 (12-30,5)	0,133
BASDAI	28 (16-40)	27,5 (14-36)	39 (22,5-41,5)	0,060
ASDAS	2,7 (1,9-3,2)	2,6 (1,9-3,1)	3 (2,35-3,4)	0,122
DAPSA-28	15,35 (7,2-21,9)	14,9 (6,1-21,17)	18,9 (14,15-29,3)	0,108

Disclosure of Interests: None declared.

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AB0562 POTENTIAL BIOMARKERS OF PERSONALIZED TREATMENT BASED ON CARDIOVASCULAR-RELATED COMORBIDITIES IN PSORIATIC ARTHRITIS

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Background: Psoriatic Arthritis (PsA) displays increased traditional cardiovascular (CV) risk factors, such as insulin resistance (IR), metabolic syndrome or obesity. Thus, it is an urgent need to treat and manage these