Efficacy and safety of deucravacitinib through week 52 in patients with active psoriatic arthritis: impact of concomitant methotrexate use in a pooled analysis of the pivotal phase 3 POETYK PsA trials

POS0288

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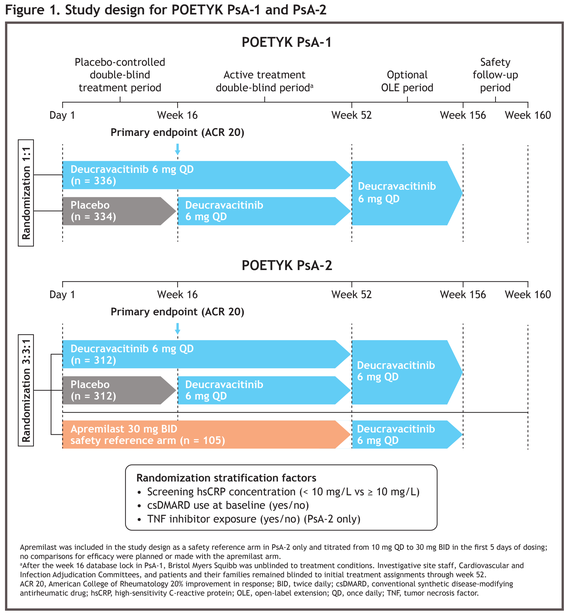
Background

- Psoriatic arthritis (PsA) is a heterogeneous inflammatory disease characterized by joint and skin manifestations. Multiple proinflammatory cytokine pathways contribute to disease pathogenesis[1,2]
- Tyrosine kinase 2 (TYK2) is a key mediator of signaling for cytokines, including interleukin (IL)-23, IL-12, and type I interferon, which are important in PsA pathophysiology[3]
- Deucravacitinib is a first-in-class, oral, selective TYK2 inhibitor that is approved for treatment of active PsA and moderate-to-severe plaque psoriasis[4]
  - Superior efficacy of deucravacitinib was observed at week 16 compared with placebo in the POETYK PsA-1 (NCT04908202) and PsA-2 (NCT04908189) phase 3 trials with sustained responses through week 52[5,6]
  - Safety in the phase 3 PsA-1 and PsA-2 studies was consistent with the established deucravacitinib profile, with no new safety signals[5-8]
- This post hoc pooled analysis from the POETYK PsA-1 and PsA-2 studies evaluated the impact of concomitant methotrexate (MTX) use on clinical efficacy, patient-reported outcomes, and safety observed in patients treated with deucravacitinib at week 52

Methods

- Study details for POETYK PsA-1 and PsA-2 have been described previously[5,6] (**Figure 1**)
  - Briefly, eligible patients had active PsA per CASPAR classification criteria with active or documented history of psoriasis
  - Patients were biologic disease-modifying antirheumatic drug—naive or had prior inadequate response to a tumor necrosis factor inhibitor (PsA-2 only)

Figure 1. Study design for POETYK PsA-1 and PsA-2

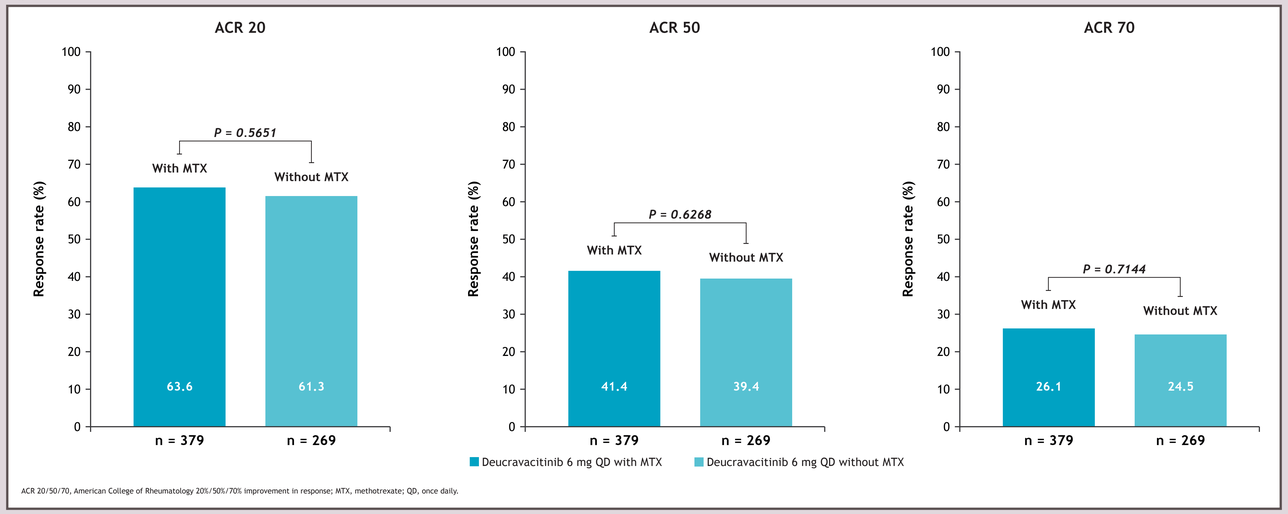


Apremilast was included in the study design as a safety reference arm in PsA-2 only and titrated from 10 mg QD to 30 mg BID in the first 5 days of dosing; no comparisons for efficacy were planned or made with the apremilast arm.
[a]After the week 16 database lock in PsA-1, Bristol Myers Squibb was unblinded to treatment conditions. Investigative site staff, Cardiovascular and Infection Adjudication Committees, and patients and their families remained blinded to initial treatment assignments through week 52.
ACR 20, American College of Rheumatology 20% improvement in response; BID, twice daily; csDMARD, conventional synthetic disease-modifying antirheumatic drug; hsCRP, high-sensitivity C-reactive protein; OLE, open-label extension; QD, once daily; TNF, tumor necrosis factor.

- For this post hoc analysis, efficacy data at week 52 were pooled from POETYK PsA-1 and PsA-2 for patients who received continuous deucravacitinib
- Efficacy endpoints (American College of Rheumatology 20%/50%/70% improvement in response [ACR 20/50/70], minimal disease activity [MDA], enthesitis resolution by Spondyloarthritis Research Consortium of Canada [SPARCC] criteria and Leeds Enthesitis Index [LEI], dactylitis resolution, and ≥ 75% improvement in Psoriasis Area and Severity Index [PASI 75]) were evaluated by concomitant MTX use in all patients treated with continuous deucravacitinib
- Patient-reported outcomes (Health Assessment Questionnaire-Disability Index [HAQ-DI] clinically meaningful improvement, Functional Assessment of Chronic Illness Therapy-Fatigue [FACIT-Fatigue], and Pain visual analog scale [VAS]) and safety were also evaluated by concomitant MTX use
- Binary endpoints were analyzed using Fisher's exact test, with missing data handled through nonresponder imputation. Continuous endpoints were assessed using independent-sample t tests, where missing change-from-baseline values were imputed as zero
- *P* values represent descriptive comparisons between patients with and without concomitant MTX use and were not adjusted for multiple comparisons
- Safety data, including adverse events (AEs) and serious AEs (SAEs), were summarized by concomitant MTX use for both patients treated with continuous deucravacitinib and patients who switched from placebo to deucravacitinib at week 16; incidence rates per 100 person-years of exposure were calculated for the cumulative treatment period
  - The cumulative treatment period included treatment-emergent AEs that occurred after deucravacitinib administration began

Deucravacitinib showed comparable efficacy at week 52 for ACR 20, ACR 50, and ACR 70 responses, with or without concomitant methotrexate use

Figure 2. ACR 20/50/70 responses at week 52 by MTX use



ACR 20/50/70, American College of Rheumatology 20%/50%/70% improvement in response; MTX, methotrexate; QD, once daily.

Results

Baseline patient demographics and clinical characteristics

- Baseline and clinical characteristics were consistent across treatment arms (**Table 1**)
- Concomitant use of MTX was reported in 58.3% of the pooled PsA-1 and PsA-2 population

Table 1. Pooled POETYK PsA-1 and PsA-2 baseline demographic and clinical characteristics by MTX use

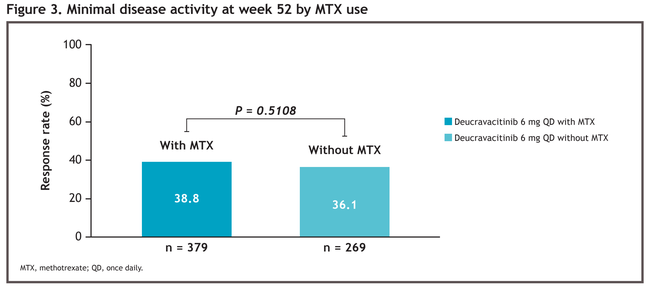
Characteristic	With concomitant MTX use		Without concomitant MTX use	
	Placebo (n = 374)	Deucravacitinib 6 mg QD (n = 381)	Placebo (n = 272)	Deucravacitinib 6 mg QD (n = 267)
Age, mean (SD), years	50.8 (12.7)	50.3 (12.2)	50.8 (11.9)	50.2 (12.3)
BMI, mean (SD), kg/m²	30.0 (6.2)	30.0 (6.3)	30.0 (5.9)	30.3 (6.9)
Baseline csDMARD use,[a] n (%)	360 (96.3)	369 (96.9)	67 (24.6)	62 (23.2)
Duration of disease since diagnosis, mean (SD), years	7.0 (7.4)	6.4 (7.2)	7.0 (7.3)	5.9 (7.6)
hsCRP, mean (SD), mg/L	13.3 (17.2)	11.7 (15.1)	13.1 (18.3)	13.3 (19.3)
DAS28-CRP, mean (SD)	5.0 (0.9)	4.9 (1.0)	4.9 (0.9)	4.8 (0.9)
HAQ-DI score, mean (SD)	1.3 (0.6)	1.3 (0.7)	1.2 (0.6)	1.2 (0.6)
PASI score > 1, n (%)	276 (73.8)	305 (80.1)	229 (84.2)	217 (81.3)
PASI score, mean (SD)	5.1 (6.2)	5.2 (5.8)	5.8 (6.8)	5.5 (6.3)
BSA > 3%, n (%)	189 (50.5)	203 (53.3)	161 (59.2)	139 (52.1)
Tender joint count (68), mean (SD)	18.0 (12.6)	17.7 (12.4)	17.7 (13.1)	16.4 (11.6)
Swollen joint count (66), mean (SD)	10.3 (7.9)	10.3 (7.0)	9.6 (7.0)	9.5 (6.4)
Enthesitis, LEI, mean (SD), n (%)	2.3 (1.4)	2.3 (1.4)	2.3 (1.4)	2.5 (1.6)
Enthesitis, SPARCC, mean (SD), n (%)	4.0 (3.0)	4.6 (3.4)	4.3 (3.6)	4.4 (3.6)
Tender dactylitis count ≥ 1, n (%)	102 (27.3)	126 (33.1)	86 (31.6)	84 (31.5)
FACIT-Fatigue score, mean (SD)	31.3 (11.5)	30.9 (11.1)	30.9 (11.5)	31.6 (11.3)
SF-36 PCS score, mean (SD)	34.9 (8.8)	35.4 (8.2)	36.3 (8.2)	35.8 (7.9)

[a]As recorded on the case report form.
BMI, body mass index; BSA, body surface area; csDMARD, conventional synthetic disease-modifying antirheumatic drug; DAS28-CRP, Disease Activity Score 28-C-reactive protein; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy-Fatigue Scale; HAQ-DI, Health Assessment Questionnaire Disability Index; hsCRP, high-sensitivity C-reactive protein; LEI, Leeds Enthesitis Index; MTX, methotrexate; PASI, Psoriasis Area and Severity Index; QD, once daily; SD, standard deviation; SF-36 PCS, 36-item short form health survey physical component summary; SPARCC, Spondyloarthritis Research Consortium of Canada.

Efficacy

- Irrespective of concomitant MTX use, deucravacitinib demonstrated comparable efficacy at week 52 for ACR 20 (*P* = 0.5651), ACR 50 (*P* = 0.6268), and ACR 70 (*P* = 0.7144) (**Figure 2**)
- MDA was also comparable, irrespective of concomitant MTX use (*P* = 0.5108) (**Figure 3**)
- No significant differences by MTX use were observed for resolution of enthesitis by SPARCC (*P* = 0.2162), though enthesitis resolution by LEI showed a nominally significant difference (*P* = 0.0485)
- Dactylitis resolution (*P* = 1.0) and PASI 75 response (*P* = 0.2921) showed no differences by MTX use (**Table 2**)
- Patient-reported outcomes were also similar between groups, including changes from baseline in HAQ-DI (*P* = 0.9218), FACIT-Fatigue (*P* = 0.2808), and Pain VAS (*P* = 0.8812) (**Table 3**)

Figure 3. Minimal disease activity at week 52 by MTX use



MTX, methotrexate; QD, once daily.

Table 2. Enthesitis, dactylitis, and PASI 75 outcomes at week 52 by MTX use

Endpoint at week 52	Deucravacitinib 6 mg QD (N = 648)		*P* value
	With concomitant MTX use (n = 379)	Without concomitant MTX use (n = 269)	
Enthesitis (SPARCC) resolution, n/N (%)[a]	135/238 (56.7)	78/155 (50.3)	0.2162
Enthesitis (LEI) resolution, n/N (%)[b]	120/189 (63.5)	67/129 (51.9)	0.0485
Dactylitis resolution, n/N (%)[c]	89/126 (70.6)	60/84 (71.4)	1.0
PASI 75, n/N (%)[d]	120/192 (62.5)	70/124 (56.5)	0.2921

[a]Enthesitis resolution (SPARCC) was defined as an achievement of a score of 0. Assessed in patients with enthesitis at baseline by SPARCC.
[b]Enthesitis resolution (LEI) was defined as an achievement of a score of 0. Assessed in patients with enthesitis at baseline by LEI.
[c]Dactylitis resolution was defined as a tender dactylitis count of 0. Assessed in patients with a tender dactylitis count ≥ 1 at baseline.
[d]PASI 75 was assessed in patients with ≥ 3% body surface area and static Physician Global Assessment ≥ 2 at baseline.
LEI, Leeds Enthesitis Index; MTX, methotrexate; PASI 75, ≥ 75% improvement in Psoriasis Area and Severity Index; QD, once daily; SPARCC, Spondyloarthritis Research Consortium of Canada.

Table 3. Patient-reported outcomes at week 52 by MTX use

Endpoint at week 52[a]	Deucravacitinib 6 mg QD (N = 648)		*P* value
	With concomitant MTX use (n = 379)	Without concomitant MTX use (n = 269)	
HAQ-DI; mean CFB in score (SD)	−0.4 (0.6)	−0.4 (0.6)	0.9218
FACIT-Fatigue; mean CFB in score (SD)	4.8 (9.3)	4.0 (9.8)	0.2808
Pain VAS; mean CFB in score (SD)	−26.9 (27.7)	−26.6 (29.0)	0.8812

[a]Missing data for change from baseline at week 52 are imputed as change from baseline = 0.
CFB, change from baseline; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy - Fatigue; HAQ-DI, Health Assessment Questionnaire Disability Index; MTX, methotrexate; QD, once daily; SD, standard deviation; VAS, visual analog scale.

Safety

- Rates of AEs and SAEs through week 52 were similar with deucravacitinib, regardless of concomitant MTX use (**Table 4**)
  - AEs occurred in 73.6% of patients with concomitant MTX use and 74.6% of patients without concomitant MTX use
  - SAEs occurred in 5.4% of patients with concomitant MTX use and 6.7% of patients without concomitant MTX use

Table 4. Safety summary through week 52 by MTX use

AE category	With concomitant MTX use				Without concomitant MTX use			
	Placebo (n = 344)		Deucravacitinib 6 mg QD (n = 379)		Placebo (n = 300)		Deucravacitinib 6 mg QD (n = 265)	
Placebo-controlled period	n (%)	IR/100 PY	n (%)	IR/100 PY	n (%)	IR/100 PY	n (%)	IR/100 PY
AEs	171 (49.7)	244.6	294 (77.6)	206.9	161 (53.7)	286.0	220 (83.0)	264.4
Serious AEs	5 (1.5)	4.8	23 (6.1)	6.8	6 (2.0)	7.2	21 (7.9)	9.1
	Placebo-deucravacitinib 6 mg QD (n = 344)		All deucravacitinib (n = 723)		Placebo-deucravacitinib 6 mg QD (n = 254)		All deucravacitinib (n = 519)	
Cumulative treatment period	n (%)	IR/100 PY	n (%)	IR/100 PY	n (%)	IR/100 PY	n (%)	IR/100 PY
AEs	238 (69.2)	206.2	532 (73.6)	206.5	167 (65.7)	188.7	387 (74.6)	225.4
Serious AEs	16 (4.7)	7.3	39 (5.4)	7.0	14 (5.5)	8.7	35 (6.7)	8.9

AEs were treatment-emergent AEs with an onset date on or after the first dose date of study treatment up to 30 days after the last dose date of treatment in the study. The cumulative treatment period included events that occurred after the start of deucravacitinib for the deucravacitinib 6 mg QD group and after the switch from placebo to deucravacitinib 6 mg QD for the placebo-deucravacitinib 6 mg QD group.
AE, adverse event; IR, incidence rate; MTX, methotrexate; PY, person-years of exposure based on time to first onset; QD, once daily.

Conclusions

- This post hoc pooled analysis from the POETYK PsA-1 and PsA-2 studies demonstrated that deucravacitinib delivered sustained and comparable efficacy in improving clinical responses, controlling disease activity, enthesitis resolution by SPARCC, and dactylitis resolution and improvements in key patient-reported outcomes at week 52, regardless of concomitant MTX use
- Deucravacitinib demonstrated a consistent and favorable safety profile, with comparable rates of AEs[5,6] regardless of concomitant MTX use, and no new safety signals were observed
- These findings support deucravacitinib as a well-tolerated early oral treatment option for patients with active PsA, including as monotherapy in those with MTX intolerance, contraindications, or a preference to avoid MTX

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