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Effect of Apremilast on Imaging, Patient-Reported, and Dermatological Clinical Outcomes in Patients With Psoriatic Arthritis: Results From the MOSAIC Study

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Introduction & Objectives: Psoriatic arthritis (PsA) is associated with a negative impact on quality of life and physical function, as well as potentially progressive joint destruction. Clinical joint assessments and imaging are important to recognize and diagnose patients (pts) with early PsA. Apremilast (APR) is an oral phosphodiesterase 4 inhibitor with a unique immunomodulatory mechanism of action that is approved for the treatment of PsA and/or psoriasis. MRI is a sensitive tool that allows for the assessment of inflammation and structural changes in PsA. The objective of the MOSAIC study was to evaluate the impact of APR on inflammation using MRI, patient-reported, and dermatological clinical outcomes in pts with PsA.

Materials & Methods: MOSAIC (NCT03783026) was a phase 4, multicenter, single-arm, open-label study in pts with active PsA (met CASPAR criteria for PsA; ≥3 months but ≤5 years since diagnosis). Pts received APR 30 mg BID (either monotherapy or with stable methotrexate) for 48 weeks. Contrast-enhanced MRI of the hand was performed at baseline (BL), Week 24, and Week 48. Experienced blinded readers adjudicated all images. The primary endpoint was change from BL in the composite score of bone marrow edema (osteitis), synovitis, and tenosynovitis, as assessed using the validated PsA MRI score (PsAMRIS*) scoring system, at Week 24 (score range: 0–216). Secondary and exploratory endpoints included change from BL in the PsAMRIS composite score at Week 48, change from BL in the 12-item PsA Impact of Disease (PsAID-12†) score at Weeks 24 and 48, the achievement of ≥50% or ≥75% reduction from BL in Psoriasis Area and Severity Index (PASI) score (PASI-50 or PASI-75) in pts with BL affected body surface area (BSA) >3% at Weeks 24 and 48, the change from BL in total PASI score at Weeks 24 and 48. Safety was evaluated.

Results: A total of 122 pts were enrolled and received APR treatment. The mean age was 46.6 years and 54.9% were women (**Table 1**). The mean duration of PsA was 1.9 years, and the mean (SD) PsAMRIS composite score at BL was 18.5 (17.8). At Week 24, the least-squares (LS) mean change from BL in the PsAMRIS composite score was −2.3 (95% CI: −4.7, 0.1; **Figure 1**); at Week 48, the LS mean change was −2.9 (95% CI: −5.5, −0.4). Mean change from BL in PsAID-12 score was −1.4 (95% CI: −1.7, −1.0) at Week 24 and −1.6 (95% CI: −2.0, −1.3) at Week 48 (**Figure 2**). Of the 122 pts, 24 (19.7%) had a BSA >3% at BL and had PASI assessments. At Weeks 24 and 48, 42.9% and 50.0% of pts on APR had achieved PASI-50, respectively (**Figure 3**). PASI-75 was achieved by 33.3% of evaluable pts at Week 24 and by 31.3% at Week 48. Mean (95% CI) percent change from BL in PASI score was −29.1% (−61.3, 3.1) at Week 24 and −43.6% (−73.5, −13.7) at Week 48. The most common treatment-emergent adverse events were diarrhea (33.6%), nausea (12.3%), and headache (10.7%). There were no new safety signals.

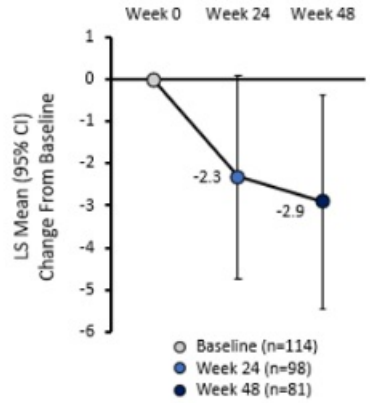
Conclusions: APR treatment led to improvements in MRI, patient-reported, and dermatological clinical outcomes in pts with ≤5-year history of PsA. Inflammation of the hand was reduced at Week 24, as measured by the PsAMRIS composite score, with further reduction at Week 48. The impact of PsA symptoms on daily life was lessened following APR treatment, as measured by PsAID-12. Pts with BSA >3% at BL experienced improvement in skin symptoms, as measured by PASI. Taken together, results from MOSAIC highlight the benefit of APR across PsA and psoriasis endpoints, as well as the value of using MRI and PsAMRIS to monitor inflammatory disease and response to treatment.

Table 1. Demographics and Baseline Disease Characteristics

Characteristic	N=122
Age, mean (SD), years	46.6 (12.9)
Women, n (%)	67 (54.9)
BMI, mean (SD), kg/m^2	29.6 (6.8)
Duration of psoriatic arthritis, mean (SD), years	1.9 (1.7)
BSA %, mean (SD)	4.5 (12.2)
PsAMRIS* composite score of bone marrow edema, synovitis, and tenosynovitis, mean (SD)	18.5 (17.9)
PsAID-12† score, mean (SD)	4.8 (1.9)
PASI score, mean (SD)	10.6 (12.4)‡

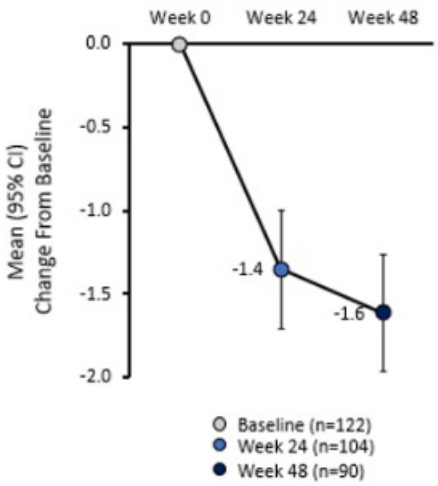
*PsAMRIS is a validated scoring system used to assess the images from the MRI of the most affected hand. †PsAID-12 contains 12 physical and psychological domains perceived by patients as particularly important for their health, each based on a 0–10 numerical rating scale and with a different weight. ‡Reported for patients with a baseline BSA >3% (n=24).
BMI=body mass index; BSA=body surface area; PASI=Psoriasis Area and Severity Index; PsA=psoriatic arthritis; PsAID-12=12-item PsA Impact of Disease; PsAMRIS=PsA MRI score.

Figure 1. Primary Endpoint: Change From Baseline in PsAMRIS Composite Score of Bone Marrow Edema (Osteitis), Synovitis, and Tenosynovitis With Apremilast Treatment



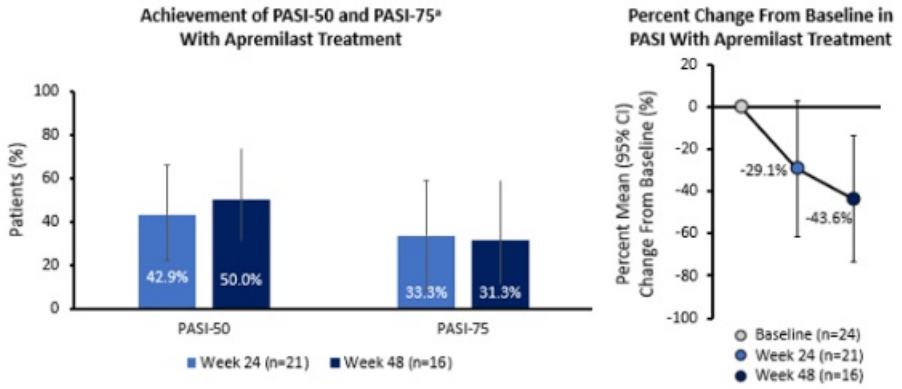
Includes patients from the full analysis set (defined as all enrolled patients who received ≥1 dose of study medication) with a composite score at baseline and at the specified timepoint. Based on the mixed-effect model for repeated measures with change from baseline as the response variable, including scanner type and time as fixed effects and baseline composite score as a covariate.
LS=least squares; PsAMRIS=PsA MRI score.

Figure 2. Change From Baseline in PsAID-12 Score With Apremilast Treatment



Includes patients from the full analysis set (defined as all enrolled patients who received ≥1 dose of study medication) with a PsAID-12 score at baseline and at the specified timepoint (patients with a baseline score of 0 were excluded). Two-sided 95% CI of mean changes from baseline and mean percentage changes from baseline are derived based on t-statistics.
PsAID-12=Psoriatic Arthritis Impact of Disease 12-domain Questionnaire.

Figure 3. Effect of Apremilast Treatment on PASI



Includes patients from the full analysis set (defined as all enrolled patients who received ≥1 dose of study medication) with baseline BSA >3% and a PASI score at baseline and at the specified timepoint.
ªError bars represent two-sided 95% CI, based on the Clopper-Pearson Method.
PASI=Psoriasis Area Severity Index; PASI-50/PASI-75=a ≥50%/75% reduction from baseline in PASI score.