

# 166 LONG-TERM (156-WEEK) IMPROVEMENTS IN DACTYLITIS AND ENTHESITIS WITH APREMILAST IN PSORIATIC ARTHRITIS SUBJECTS: ANALYSIS OF A LARGE, POOLED PALACE 1-3 DATABASE

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**Background:** PALACE 1, 2, and 3 assessed apremilast (APR) efficacy/safety in subjects with active psoriatic arthritis (PsA) despite prior conventional disease-modifying anti-rheumatic drugs (DMARDs) and/or biologics. We report the impact of long-term APR 30 mg BID (APR30) on pre-existing dactylitis and enthesitis in the studies.

**Methods:** Subjects were randomised (1:1:1) to placebo, APR30, or APR 20 mg BID stratified by baseline DMARD use (yes/no). After the 24-week placebo-controlled phase, all subjects received APR and could enroll in long-term follow-up. Data for subjects with pre-existing dactylitis or enthesitis were pooled across PALACE 1-3. Dactylitis count (range: 0-20) was used to assess dactylitis improvement. Evaluation of enthesitis used the Maastricht Ankylosing Spondylitis Enthesitis Score (MASES; range: 0-13). Analyses utilised the last-observation-carried-forward methodology at week 24 and data as observed for weeks 52 and 156.

**Results:** Among subjects with dactylitis (n=610) or enthesitis (n=915) at baseline and ≥1 post-baseline value, baseline mean dactylitis counts and MASES ranged from 3.2 to 3.4 and 4.4 to 4.8, respectively. At week 24, mean change in dactylitis count was -1.8 (APR30) vs. -1.3 (placebo) (P=0.0097); more APR30 vs. placebo subjects achieved dactylitis counts=0. Mean change in MASES was -1.3 (APR30) vs. -0.9 (placebo) (P=0.0194); more APR30 vs. placebo subjects achieved MASES=0. The effect on enthesitis was confirmed in the ACTIVE study of APR subjects with ≤1 prior DMARD using the

Gladman Enthesitis Index, focusing on more peripheral sites of activity; significant effect for APR vs. placebo was seen as early as week 2; at week 24, mean change was -1.5 vs. -0.5 (P=0.0032, mixed-model repeated-measure). Sustained improvements in dactylitis and enthesitis severity were seen with continued APR treatment at week 156 in PALACE 1-3: 79.6% achieved dactylitis count=0 and mean percent change was -83.6%; 55.0% of APR subjects achieved MASES=0 and mean percent change was -65.2% (Table 1).

**Conclusion:** At baseline, 63% of PALACE 1-3 subjects had enthesitis and 42% had dactylitis. With continued treatment, APR30 demonstrated early and long-term benefit (≤156 weeks) in treating dactylitis and enthesitis, including resolution of baseline disease in many subjects.

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TABLE 1: Outcomes for Dactylitis Count and MASES at Week 24, Week 52, and Week 156

	Week 24		Week 52	Week 156
Dactylitis Count*	Placebo n = 205	APR30 n = 221	APR30 n = 249	APR30 n = 181
Baseline, mean	3.3	3.2	3.4	3.4
Mean change from baseline	-1.3	-1.8 <sup>‡</sup>	-2.5	-3.0
Mean % change from baseline	-38.2	-48.6	-67.9	-83.6
Median % change from baseline	-66.7	-79.3	-100.0	-100.0
Subjects achieving score of 0, %	39.0	46.2	67.5	79.6
MASES <sup>§</sup>	Placebo n = 311	APR30 n = 327	APR30 n = 377	APR30 n = 278
Baseline, mean	4.8	4.4	4.4	4.2
Mean change from baseline	-0.9	-1.3 <sup>‡</sup>	-2.0	-2.7
Mean % change from baseline	-7.0	-23.6 <sup>‡</sup>	-43.5	-65.2
Median % change from baseline	-21.1	-50.0 <sup>‡</sup>	-66.7	-100.0
Subjects achieving score of 0, %	22.5	27.5	37.7	55.0

The n at Week 24 represents subjects with a baseline value >0. The n at Week 52 and Week 156 represents the number of subjects taking APR, regardless of when treatment started (baseline, Week 16, or Week 24), with a baseline value >0 and a value at Week 52 or Week 156. \*Dactylitis count is the sum of all scores (0=absence of dactylitis; 1=presence of dactylitis) from each of the 20 digits. <sup>§</sup>MASES ranges from 0 to 13, with 0 indicating no pain at any assessed entheses and 13 indicating pain at all assessed entheses. <sup>‡</sup>P<0.05 vs placebo. <sup>‡</sup>P<0.01 vs placebo.