166 LONG-TERM (156-WEEK) IMPROVEMENTS IN DACTYLITIS AND ENTHESITIS WITH APREMILAST INPSORIATIC 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‖	−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§	**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‡	−2.0	−2.7
Mean % change from baseline	−7.0	−23.6‡	−43.5	−65.2
Median % change from baseline	−21.1	−50.0‡	−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. §MASES ranges from 0 to 13, with 0 indicating no pain at any assessed enthesis and 13 indicating pain at all assessed entheses. ‡P<0.05 vs placebo. ‖P<0.01 vs placebo.