Abstract #: 11

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Characterization of Clinical Benefits in Subjects Classified as ACR20 Non-responders at Week 104 of Apremilast Treatment: Subanalysis of 3 Long-term, Phase III Trials

Objective(s): The PALACE 1, 2, and 3 studies have evaluated apremilast (APR) efficacy and safety in subjects with active psoriatic arthritis (PsA) despite prior conventional disease-modifying anti-rheumatic drugs and/or biologics. The aim of this analysis is to further characterize the clinical benefits associated with long-term APR exposure in subjects who failed to achieve an ACR20 response at Week 104.

Method(s): Subjects were randomized (1:1:1) to placebo (PBO), APR 30 mg BID (APR30), or APR 20 mg BID at baseline. Subjects randomized to APR30 at baseline and classified as ACR20 non-responders (ACR20NRs) at Week 104 were considered for this analysis. At Weeks 24, 52, and 104, ACR core components were examined as well as the proportions of subjects achieving PASI-75/PASI-50 among those with psoriasis involvement ≥3% of the body surface area (BSA) at baseline and dactylitis count and MASES of 0 among those with dactylitis or enthesitis, respectively, at baseline. Safety is described for the overall PALACE 1-3 population.

Result(s): 109 subjects randomized to APR30 at baseline were ACR20NRs at Week 104. Baseline ACR core components were similar for ACR20NRs and ACR20 responders at Week 104. Among these ACR20NRs, several core components of ACR response showed sustained improvements from baseline through Week 104 with continued treatment: swollen/tender joint counts (mean % change, −58.0%/−41.7%) and Physician's Global Assessment of Disease Activity (visual analog scale) scores (mean % change, −44.3%). Importantly, of those with psoriasis BSA involvement ≥3% at baseline, 50.0% achieved a PASI-50 response and 36.0% achieved a PASI-75 response after continued treatment with APR30 through Week 104. Among ACR20NRs with baseline dactylitis (n=44) or enthesitis (n=74), 68.2% achieved a dactylitis count of 0 and 33.8% achieved a MASES of 0 at Week 104, respectively. More limited improvements in Subject's Global Assessment of Disease Activity, Subject's Assessment of Pain, Health Assessment Questionnaire-Disability Index, and C-reactive protein outcomes most commonly had an impact on subjects' ability to achieve an ACR20 response. In the overall subject population, no new safety concerns were identified through 104 weeks.

Conclusion(s): ACR20NRs receiving APR30 demonstrated significant improvements in core PsA domains. The data may explain why subjects who failed to achieve an ACR20 response remained on long-term APR treatment. These findings suggest some subjects with PsA may experience meaningful clinical improvements not completely captured by assessment of ACR20 response criteria. Outcome measures specifically designed for PsA subjects may be more suitable to evaluate treatment response in PsA subjects.