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Abstract #: 13

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Long-term (4-Year) Efficacy and Safety of Apremilast Monotherapy in DMARD-Naïve Subjects With Active Psoriatic Arthritis

Objective(s): Apremilast (APR) is an oral phosphodiesterase 4 inhibitor that helps regulate the immune responses that cause joint inflammation and other manifestations of psoriatic arthritis (PsA), including skin disease. We describe the long-term efficacy and safety of APR monotherapy in DMARD-naïve subjects in PALACE 4 for up to 208 weeks.

Method(s): Subjects were randomized (1:1:1) to placebo, APR 30 mg BID (APR30), or APR 20 mg BID (APR20). At Week 16, subjects were eligible for early escape. At Week 24, all subjects remaining on placebo were switched to APR. Double-blind treatment continued to Week 52, with open-label APR treatment for up to 4 additional years.

Result(s): A total of 527 subjects were randomized and received ≥1 dose of placebo (n=176), APR30 (n=176), or APR20 (n=175). Of the subjects entering the fourth year of study, 96.3% (259/269) completed the Week 208 visit. At Week 52, 58.0% (119/205) of subjects receiving APR30 achieved a ≥20% improvement in modified American College of Rheumatology (ACR20) response. At Week 208, rates of improvement in PsA signs and symptoms and physical function were sustained with continued APR treatment: swollen joint count, −84.2%; tender joint count, −71.5%; and HAQ-DI, −0.37. Of the subjects still receiving study drug, 68.2%, 43.4%, and 23.1% achieved a modified ACR20, ACR50, and ACR70 response, respectively. Of subjects with dactylitis at baseline, 80.9% achieved a dactylitis count of 0; for those with enthesitis at baseline, 64% achieved a MASES of 0. Of subjects with psoriasis body surface area involvement ≥3% at baseline, 40.5% and 67.6% achieved ≥75% and ≥50% reduction from baseline Psoriasis Area and Severity Index (PASI-75 and PASI-50) responses, respectively. During Weeks >156 to ≤208 of APR30-exposure, the most common adverse events (AEs) were upper respiratory tract infection (4.3%) and nasopharyngitis (6.5%); serious AEs occurred in 5.8% of subjects; serious infection was reported by 1 subject and no opportunistic infections were reported. In general, no change in the types of AEs and no increase in the incidence and severity of AEs were seen with longer-term exposure. The APR20 safety profile was similar to that of APR30.

Conclusion(s): Over 208 weeks, APR monotherapy demonstrated sustained response and improvements in PsA signs and symptoms, including swollen and tender joint counts, enthesitis, dactylitis, physical function, and psoriasis. APR continued to demonstrate an acceptable safety profile and was generally well tolerated.