15. Apremilast, an Oral Phosphodiesterase 4 Inhibitor, Improves Nail and Scalp Psoriasis and PASI Scores in Patients With Moderate to Severe Plaque Psoriasis

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Nail and scalp psoriasis are difficult-to-manage manifestations of psoriasis and psoriatic arthritis. In the ESTEEM 1 (NCT01194219) and 2 (NCT01232283) phase 3 trials, PASI-75 response (primary endpoint) was significantly higher with apremilast 30 mg BID (APR) vs. placebo at Week 16 in patients with moderate to severe plaque psoriasis (Papp et al. JAAD. 2015;73:37-49; Paul et al. Br J Dermatol. 2015;173:1387-1399). Of 1,255 patients randomized in the ESTEEM trials, 65.7% had nail involvement and 66.3% had moderate to severe scalp involvement at baseline. We report APR efficacy in patients with nail and scalp psoriasis.

Patients were randomized (2:1) to APR or placebo. At Week 16, placebo patients switched to APR. All patients received APR through Week 32, followed by a randomized treatment withdrawal phase up to 52 weeks in patients randomized to APR at baseline and identified as responders at Week 32. Improvements in nail and scalp psoriasis were assessed in patients with Nail Psoriasis Severity Index (NAPSI) ≥1 in the target nail and Scalp Physician Global Assessment (ScPGA) ≥3 at baseline at Week 16 (LOCF) and Week 52 (as observed).

At Week 16, improvements in mean percent change in NAPSI score were greater with APR in ESTEEM 1 and 2 (−22.5% and −29.0%) vs. placebo (+6.5% and −7.1%; P<0.0001, P=0.0052). Achievement of NAPSI-50 was higher at Week 16 with APR (33.3% and 44.6%) vs. placebo (14.9% and 18.7%; both P<0.0001), as was achievement of ScPGA of 0 (clear) or 1 (minimal) with APR (46.5% and 40.9%) vs. placebo (17.5% and 17.2%; both P<0.0001). These improvements were sustained among patients randomized to APR at baseline who had PASI-75 (ESTEEM 1)/PASI-50 (ESTEEM 2) response at Week 32 and continued APR through Week 52. At Week 52, mean percent changes in NAPSI were −60.2% (ESTEEM 1) and −59.7% (ESTEEM 2); NAPSI-50 was achieved by 70.7% and 68.6% of patients; and ScPGA 0 or 1 was achieved by 83.3% and 62.5% of patients. Common adverse events (AEs; ≥5%) with APR were diarrhea, nausea, URTI, nasopharyngitis, tension headache, and headache during 0 to 16 weeks. Most AEs were mild or moderate in severity; no increase in incidence or severity was noted with up to ≥52 weeks of treatment.

APR was effective in improving nail and scalp psoriasis and skin involvement, with maintenance of these improvements over time. The safety profile is consistent with the known safety profile for APR.