Treat-to-Target Outcomes and Measures of Treatment Success in Three Phase 3 Trials of Tapinarof Cream 1% Once Daily for Mild to Severe Plaque Psoriasis

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Introduction: Treat-to-target strategies are used in several chronic diseases to improve outcomes. Treatment goals for psoriasis have been recommended by the US National Psoriasis Foundation (e.g., achieving a percent body surface area [%BSA] affected of ≤1% at 3 months) and the European S3-Guidelines on the Systemic Treatment of Psoriasis (e.g., a ≥75% decrease in Psoriasis Area and Severity Index [PASI] within 3–4 months). Current topical treatments alone are generally insufficiently efficacious to achieve these goals. Tapinarof cream 1% once daily (QD), a non-steroidal, topical, aryl hydrocarbon receptor agonist, demonstrated statistically significant efficacy versus vehicle and was well-tolerated in adults with mild to severe plaque psoriasis in PSOARING 1 and 2, two 12-week, phase 3 trials. Efficacy continued to improve, beyond the 12-week trials in PSOARING 3, the long-term extension trial, with a high rate (40.9%; n=312) of complete disease clearance (Physician Global Assessment [PGA]=0), ~4-month remittive effect off therapy, and durability on therapy for up to 52 weeks.

Objective: To present analyses of treat-to-target outcomes for patients treated with tapinarof in the PSOARING trials.

Methods: Pooled analyses explored more-aggressive targets, including patients achieving a %BSA affected of ≤1.0% or ≤0.5%, or an absolute PASI score of ≤1, ≤2 or ≤3. Time-to-event analyses are based on Kaplan–Meier estimates using observed cases among all patients in the PSOARING trials with a baseline PGA≥2 before tapinarof treatment. Safety analyses are based on all patients who received tapinarof in the PSOARING trials.

Results: Efficacy analyses included 915 patients. At baseline, 78.1% had PGA=3 (moderate), mean PASI was 8.7, and mean %BSA was 7.8%. The analyses indicated that 61.3% of patients (n=561) achieved %BSA ≤1.0%, median time to target of 120 days (95% confidence interval [CI], 113–141), while 49.7% (n=455) achieved %BSA ≤0.5%, median time to target of 199 days (172–228). A %BSA ≤1.0% was achieved by 40% (95% CI, 37–43%) of patients at 90 days (3 months). In addition, 75.0% (n=686) achieved PASI≤3, with median time to target of 58 days (95% CI, 57–63); 66.9% (n=612) achieved PASI≤2, median time to target of 87 days (85–110); and 50.3% (n=460) achieved PASI≤1, median time to target of 185 days (169–218). Among all patients who received tapinarof in the PSOARING trials (N=936), most treatment-emergent adverse events (TEAEs) were mild to moderate. Most common TEAEs (≥5%) were folliculitis, contact dermatitis, and nasopharyngitis.

Conclusion: Together with previously reported tapinarof efficacy and safety, these findings demonstrate that a high percentage of patients treated with tapinarof cream 1% QD alone can achieve and exceed ambitious treatment targets.

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