Treatment of atopic dermatitis with tapinarof cream: Secondary outcomes from a phase 2b, randomized parallel-group study

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Background: Despite available options for treating atopic dermatitis (AD), there is a need for effective topical therapies that can be used without concerns about body surface area (BSA) restrictions or long treatment duration. Tapinarof is a therapeutic aryl hydrocarbon receptor modulating agent (TAMA) under investigation for the treatment of AD and psoriasis.

Objective: This phase 2b, double-blind, six-arm, vehicle-controlled randomized study (NCT02564055) assessed the efficacy and safety of tapinarof in subjects with AD. Tapinarof is a therapeutic aryl hydrocarbon receptor modulating agent (TAMA) under investigation for the treatment of AD and psoriasis.

Methods: Subjects (aged 12–65 years) with ≥5% and ≤35% BSA involvement and Investigator Global Assessment (IGA) score ≥3 (moderate to severe) were randomized 1:1:1:1:1:1 to tapinarof cream 0.5% or 1% once (QD) or twice daily (BID) or vehicle QD or BID for 12 weeks with a 4-week follow up. The primary endpoint was the proportion of subjects achieving IGA score 0 or 1 and ≥2-grade improvement in IGA score from baseline to Week 12, which has been reported elsewhere.1 Secondary efficacy outcomes reported here include mean change in % BSA affected and total severity score (TSS; sum of severity of erythema, induration/papulation, lichenification, oozing/crusting, and scaling) from baseline to each study visit. Safety monitoring was conducted throughout the study.

Results: Of 247 randomized subjects, 77% completed the study. Overall, most subjects had a reduction in % BSA affected during the study period. At Week 12, the mean reduction in % BSA affected (± standard deviation [SD]) from baseline in the tapinarof groups was –11.2 (±8.6) and –11.6 (±9.7) in the 1% BID and QD groups and –12.2 (±9.6) and –9.8 (±7.7) in the 0.5% BID and QD groups, respectively, vs –6.0 (±8.4) and –5.4 (±8.1) in the vehicle BID and QD groups, respectively. Mean change in TSS was reduced from baseline to each study visit, but greater reductions were observed with tapinarof compared with vehicle from Week 2 onwards. At Week 12, mean change in TSS (±SD) from baseline in the tapinarof groups was –5.8 (±2.9) and –5.5 (±2.6) in the 1% BID and QD groups and –7.0 (±2.4) and –5.5 (±2.6) in the 0.5% BID and QD groups, respectively, vs –4.6 (±2.6) and –5.2 (±3.0) in the vehicle BID and QD groups, respectively. The most frequently reported treatment-emergent adverse events (≥5%) across all treatment groups were nasopharyngitis (8%), folliculitis (7%) and AD (6%).

Conclusion: Treatment with tapinarof cream was efficacious and well tolerated in adolescents and adults with AD as assessed by mean reductions in % BSA affected and TSS.

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