Tapinarof cream for the treatment of plaque psoriasis: Efficacy and safety by baseline disease characteristics and skin type in a phase 2b randomized study

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Tapinarof is a therapeutic aryl hydrocarbon receptor modulating agent (TAMA) in development for the treatment of psoriasis and atopic dermatitis. In a previously reported phase 2b efficacy and safety study (NCT02564042), Physician Global Assessment (PGA) responses (0 or 1 and ≥2-grade improvement from baseline) at Week 12 were significantly higher in all tapinarof cream groups vs vehicle. Tapinarof cream demonstrated durable PGA responses through 4 weeks after the end of study treatment.[1]

A *post-hoc* analysis of PGA response stratified by baseline % body surface area (BSA) affected, psoriasis duration, and Fitzpatrick skin type was conducted to evaluate the efficacy and safety of tapinarof cream vs vehicle across subgroups.

Overall, mean baseline disease characteristics were comparable across groups. Most subjects (80%) had a baseline PGA score of 3 (moderate). Mean baseline Psoriasis Area and Severity Index score was 8.8. Stratified by baseline BSA, PGA response at Week 12 in subjects treated with tapinarof 1% twice daily (BID), 1% once daily (QD), 0.5% BID, and 0.5% QD vs vehicle BID and vehicle QD was: 67%, 60%, 33%, and 35% vs 13% and 6%, respectively (1 to <10% BSA affected; n=102); and 64%, 40%, 75%, and 38% vs 0% and 0%, respectively (≥10% BSA affected; n=39). Stratified by psoriasis duration, PGA response at Week 12 in subjects treated with tapinarof 1% BID, 1% QD, 0.5% BID, and 0.5% QD vs vehicle BID and vehicle QD was: 50%, 80%, 50%, and 29% vs 0% and 0%, respectively (6 months to <5 years; n=27); 67%, 50%, 20%, and 50% vs 25% and 0% (5 years to <10 years; n=32); and 73%, 50%, 53%, and 33% vs 8% and 8% (≥10 years; n=82). Stratified by Fitzpatrick skin type, PGA response at Week 12 in subjects treated with tapinarof 1% BID, 1% QD, 0.5% BID, and 0.5% QD vs vehicle BID and vehicle QD was: 60%, 67%, 50%, and 25% vs 0% and 10%, respectively (Fitzpatrick skin type I/II; n=41); 54%, 47%, 60%, and 44% vs 18% and 0% (Fitzpatrick skin type III/IV; n=73); and 100%, 75%, 25%, and 25% vs 0% and 0% (Fitzpatrick skin type V/VI; n=27). Incidence and type of adverse events were generally comparable across groups and consistent with those observed in the overall population.

Tapinarof cream was efficacious and well tolerated across subgroups regardless of baseline % BSA affected, psoriasis duration, or Fitzpatrick skin type. A phase 3 study of tapinarof cream 1% QD in psoriasis is ongoing (NCT03956355).

1. Robbins K et al. *J Am Acad Dermatol.* 2019;80:714–721.