Rapid and early onset of itch relief with tapinarof cream 1% once daily in two pivotal phase 3 trials in adults and children down to two years of age with atopic dermatitis

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Introduction: Itch is the most bothersome symptom for patients with atopic dermatitis (AD), and has a significant negative impact on health-related quality of life. Rapid onset of pruritus relief with sustained efficacy is a key outcome for AD therapies. In ADORING 1 and 2, two identical pivotal phase 3, double-blind, vehicle-controlled trials, tapinarof cream 1% once daily (QD) demonstrated efficacy and was well tolerated in adults and children down to 2 years of age with AD.
Objective: Here, we evaluate time to onset of itch relief in the pivotal phase 3 trials.

Methods: In ADORING 1 and 2, patients with a Validated Investigator Global Assessment for Atopic Dermatitis™ score of ≥3 (moderate or severe), an Eczema Area and Severity Index score of ≥6, and body surface area involvement of 5–35% were randomized 2:1 to tapinarof cream or vehicle QD for 8 weeks. Itch relief was assessed by changes in Peak Pruritus Numerical Rating Scale (PP-NRS) score, daily and by visit, from baseline through Week 8. PP-NRS considers itch over the past 24 hours; lower scores indicate less pruritus.

Results: 407 and 406 patients were randomized in ADORING 1 and 2. At baseline, mean PP-NRS scores were 6.7 and 6.8 in both trials, respectively. For daily evaluations of itch from baseline, greater reductions in mean PP-NRS scores for tapinarof versus vehicle were observed as early as Day 1, 24 hours after initial application in ADORING 1 (−1.2 vs −0.9), and Day 2 in ADORING 2 (−1.6 vs −1.4). Daily itch improvements continued through Week 8 in both trials. Statistically significant reductions in mean weekly PP-NRS scores occurred as early as Week 1 (earliest assessment) with tapinarof versus vehicle (−2.0 vs −1.2 [P<0.0001]) and (−2.0 vs −1.3 [P=0.0010]) in ADORING 1 and 2, respectively. Significantly greater reductions in mean PP-NRS scores with tapinarof versus vehicle were seen for all visits through Week 8 (−4.1 vs −2.6 and −4.1 vs −2.4 [both P<0.0001]).

Conclusions: Tapinarof cream 1% QD demonstrated rapid, significant, and clinically meaningful pruritus relief from 24 hours after initial application, with improvements increasing through Week 8 in both trials in adults and children down to 2 years with AD.
Keywords: Tapinarof cream 1% QD, rapid itch relief, atopic dermatitis, eczema, adults and children.

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