**Efficacy of Tapinarof Cream by Body Region in Subjects With Plaque Psoriasis in a Phase 2b Randomized Controlled Study**

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**INTRODUCTION**

Psoriasis is a chronic, immune-mediated disease characterized by scaly, erythematous, and pustular plaques that can be painful and disfiguring. Plaque localization can impact quality of life, and response to treatment may also vary by body region. Although multiple options are available for the treatment of plaque psoriasis, there is a need for effective topical therapies that can be used without body surface area (BSA) restrictions or precautions for the duration of treatment. Tapinarof is a therapeutic and hydrolysis receptor modulating agent (TARMA) under investigation for the treatment of plaque psoriasis (NCT01389456; NCT01338446) and atopic dermatitis. The previously published phase 2a dose-finding study (NCT02129432) was designed to assess the efficacy and safety of tapinarof in subjects with plaque psoriasis. This analysis was conducted to explore whether the efficacy and safety of tapinarof varied across body regions.

**OBJECTIVES**

- To report efficacy outcomes by mean change in Psoriasis Area and Severity Index (PASI), by body area, and by body region

**METHODS**

**Study Design**

- In this multicenter (United States, Canada, and Japan), phase 2b, double-blind, vehicle-controlled, randomized study, adult subjects with plaque psoriasis were randomized 1:1:1:1 to receive tapinarof 0.5% or 1% once daily (QD) or twice daily (BID) or vehicle QD for 12 weeks followed by 4 weeks without treatment (Figure 1: Table 1).

**Study Outcomes and Statistical Analysis**

- The primary endpoint was Physician Global Assessment (PGA) response rate at 12 weeks, defined as the proportion of subjects with a PGA score of clear (0) or almost clear (1) and 2-grade improvement in PGA score from baseline to Week 12.
- Additional post hoc analyses reported here include mean change in PASI from baseline overall and by body region (upper extremities, lower extremities, head/neck, and trunk).
- Incidence, frequency, and rate of adverse events (AEs) and serious AEs were collected from the start of study treatment until the end-of-study visit at Week 16.

**RESULTS**

**Subject Disposition**

- A total of 327 subjects (191 screened) were randomized to intent-to-treat population, and of those randomized, 175 subjects (71%) completed the study, including the Week 16 follow-up visit.

**Baseline Characteristics**

- Table 1. Baseline Subject Demographics and Characteristics

**Primary Efficacy Outcomes**

- PGA Response Rates

- Mean PASI improvements in the upper extremities at Week 12 were significantly greater in all tapinarof groups vs vehicle groups (Δ−8.8 (1% BID), −7.95 (0.5% BID), −7.0 (0.5% QD), −6.74 (1% QD), −6.04 (0.5% QD); −4.88 (vehicle BID) and −1.61 (vehicle QD); significant improvements were maintained in all tapinarof groups for 4 weeks after the last application through Week 16 (Figure 3)

- Lower extremity PASI improvements in the lower extremities at Week 12 were significantly greater in all tapinarof groups vs vehicle groups (Δ−8.5 (1% BID), −7.16 (0.5% BID), −6.23 (0.5% QD) vs −2.77 vehicle BID) and −2.93 vehicle QD; significant improvements were maintained in all tapinarof groups for 4 weeks after the last application through Week 16 (Figure 4).

**Conclusions**

- Tapinarof cream was generally well tolerated.
- Treatment-emergent AEs (TEAEs) were mostly mild to moderate in severity.
- The most common treatment-related TEAEs were folliculitis (10% tapinarof vs 1% vehicle), contact dermatitis (3%, all treatment groups), and headache (1%, all treatment groups).

**References**


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