INTRODUCTION

Psoriasis is a chronic, immune-mediated disease characterized by scaly, erythematous, and pruritic plaques that can be painful and disfiguring. 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 concerns for the duration of treatment.

Tapinarof cream is a therapeutic aryl hydrocarbon receptor modulating agent (TAMA) under investigation for the treatment of psoriasis (ClinicalTrials.gov ID: NCT02996355) and atopic dermatitis (NCT03026442) was designed to assess the efficacy and safety of tapinarof cream in subjects with plaque psoriasis.

Factors related to disease characteristics and skin type may influence clinical outcomes in psoriasis.

This post-hoc analysis was conducted to explore whether the efficacy and safety of tapinarof cream varied across subgroups based on baseline disease characteristics and skin type.

OBJECTIVE

To evaluate the efficacy and safety of tapinarof through post-hoc analysis from a phase 2b study in subjects with plaque psoriasis stratified by baseline disease characteristics, including % BSA affected, duration of psoriasis, and Fitzpatrick skin type.

METHODS

Study Design

In this multicenter (United States, Canada, and Japan), phase 2b, double-blind, vehicle-controlled randomized study, adult subjects with psoriasis were randomized 1:1:1:1:1 to receive tapinarof cream 0.5% or 1% once (QD) or twice daily (BID) or vehicle QD or BID for 12 weeks and followed up for 4 more weeks (Figure 1).

Figure 1. Study Design

Study Outcomes and Statistical Analysis

The primary endpoint was Physician Global Assessment (PGA) response rates at Week 12, defined as the proportion of subjects with a PGA score of 0 or 1 and ≥2-grade improvement at Week 12 were significantly higher (at a 0.05 significance level) in the tapinarof cream groups than the vehicle groups (65% [1% BID], 56% [1% QD], 46% [0.5% BID], 59% [0.5% QD]) vs 11% [vehicle BID] and 9% [vehicle QD] and were maintained for 4 weeks after the end-of-study treatment in all active treatment groups except for the 0.5% BID group.

PGA Response Rates by Baseline % BSA Affected

PGA response rates at Week 12 were higher in tapinarof cream groups than vehicle groups, regardless of Fitzpatrick skin type (Figure 4).

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CONCLUSIONS

Higher PGA response rates at Week 12 were observed in the 1% QD tapinarof cream group vs vehicle across all subgroups.

These findings support the previously reported efficacy and safety outcomes of the overall population.

PGA response rates at Week 12 were higher in tapinarof cream groups than vehicle groups, regardless of Fitzpatrick skin type.

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