SYNOPSIS

- Tapinarof is a first-in-class, non-steroidal, topical therapeutic aryl hydrocarbon receptor modulating agent (TAMA) in development for the treatment of psoriasis and atopic dermatitis.

- In two identical, randomized, double-blind Phase 3 trials, PSOARING 1 and PSOARING 2, tapinarof cream 1% once daily (QD) demonstrated highly statistically significant efficacy versus vehicle at 12 weeks and was well tolerated in adults with mild to severe plaque psoriasis.

OBJECTIVE

- To present results for the pivotal Phase 3 primary efficacy endpoint (proportion of patients who achieved a Physician Global Assessment (PGA) response at Week 12) by baseline disease characteristics and demographics using pooled data from PSOARING 1 and PSOARING 2.

METHODS

Study Design

- Patients with mild to severe plaque psoriasis were randomly assigned 2:1 to receive tapinarof cream 1% QD or vehicle QD for 12 weeks in two identical, Phase 3, multicenter (US and Canada), double-blind, vehicle-controlled trials (Figure 1).

- Following the double-blind period, patients could enroll in a separate open-label, long-term extension study for an additional 40 weeks of treatment, or complete a follow-up visit 4 weeks after the end of treatment (Week 16).

Endpoints and Statistical Analysis

- The primary endpoint was PGA response at Week 12, defined as the proportion of patients with a PGA score of clear (0) or almost clear (1) and ≥2-grade improvement in PGA score from baseline to Week 12.

- The incidence, frequency, and nature of adverse events (AEs) and serious AEs were monitored from the start of study treatment until the time of clinical assessment.

RESULTS

Patient Disposition and Baseline Characteristics

- The pooled analysis population included 1025 patients randomized to tapinarof cream 1% QD (n=683) or vehicle QD (n=342) in PSOARING 1 and 2 (ITT population).

- Baseline disease characteristics and demographics in the pooled population were comparable across treatment groups (Table 1).

- Overall, at baseline, 82% had a PGA score of 3 (moderate), 57% had psoriasis for >10 years, and 26% had ≥10 body surface area (BSA) affected.

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