Novel Tretinoin 0.05% lotion for the once-daily treatment of moderate-to-severe acne vulgaris in a Hispanic population

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Background

- Acne vulgaris (acne) is the most common dermatologic diagnosis seen in a Hispanic population
- Despite their growing demographics in the US, there are few studies evaluating acne treatment in this population
- Potential for skin irritation and dryness, as well as pigmentary changes are key concerns
- A new lotion formulation of tretinoin has recently been developed leveraging polymerized emulsion technology with the aim to improve both efficacy and tolerability.

Objective

- To determine the efficacy and safety of tretinoin 0.05% lotion in treating moderate-to-severe acne in a Hispanic population.

Methods

- Post hoc analysis of two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies in moderate or severe acne
- Hispanic subjects (aged 11 to 50 years, N=766) were randomized (1:1) to receive tretinoin 0.05% lotion or vehicle, once-daily for 12 weeks
- CeraVe® hydrating cleanser and CeraVe® moisturising lotion (L'Oreal, NY) were provided for optimal moisturization/cleaning of the skin
- Efficacy assessments included changes in baseline inflammatory and noninflammatory lesions and treatment success (at least 2-grade reduction in Evaluator's Global Severity Score [EGSS] and clear/almost clear)
- Safety, adverse events (AEs) and cutaneous tolerability were evaluated throughout.

Results

- At Week 12, mean percent reduction in inflammatory and noninflammatory lesion counts were 60.1% and 53.0% respectively compared with 51.1% and 38.7% with vehicle (P≤0.001) in the Hispanic population, Figures 1 and 2
- Treatment success was achieved by 19.6% of patients by Week 12, compared with 12.7% on vehicle (P=0.015), Figure 3
- The majority of AEs were mild and transient. There were four serious AEs (SAEs) reported (two each group)
- The most frequently reported treatment related AEs with tretinoin 0.05% lotion were application site pain (2.0%), dryness (1.4%) and erythema (1.2%), Table 1
- Local cutaneous safety and tolerability assessments were generally mild-to-moderate at baseline and improved by Week 12
- Slight increases in mean scores were observed for scaling and burning within the first four weeks and appeared to be transient.

Figure 1: Percent Change in Inflammatory Lesions from Baseline to Week 12 in Hispanic Subpopulation (ITT population pooled data, LS Mean)

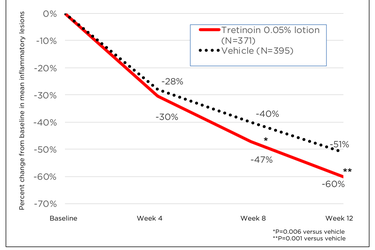

Figure 2: Percent Change in Noninflammatory Lesions from Baseline to Week 12 Hispanic Subpopulation (ITT Population, LS Mean)

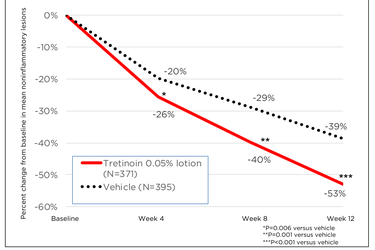

Figure 3: Evaluator's Global Severity Scores. Patients with at least a 2-grade improvement and 'clear' or 'almost clear at each study visit Hispanic Subpopulation (ITT Population pooled data)

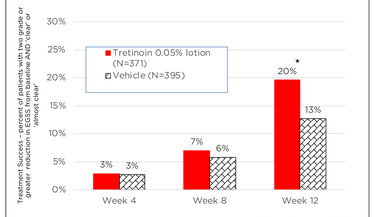

Table 1: Treatment-Emergent and Related Adverse Event (AE) Characteristics through Week 12 (Pooled Data – Safety Population) HISPANICS

	Tretinoin 0.05% Lotion (N=345)	Vehicle Lotion (N=379)
Patients reporting any TEAE	47 (13.6%)	67 (17.7%)
Patients reporting any SAE	2 (0.6%)	2 (0.5%)
Patients who died	0 (0.0%)	0 (0.0%)
Patients who discontinued due to TEAE	3 (0.9%)	0 (0.0%)
Severity of AEs reported		
Mild	36 (10.4%)	42 (11.1%)
Moderate	9 (2.6%)	19 (5.0%)
Severe	2 (0.6%)	6 (1.6%)
Relationship to study drug		
Related	15 (4.3%)	7 (1.8%)
Unrelated	32 (9.3%)	60 (15.8%)
Treatment Related AEs reported by ≥1% patients		
Application site pain	7 (2.0%)	0 (0.0%)
Application site dryness	5 (1.4%)	1 (0.3%)
Application site erythema	4 (1.2%)	0 (0.0%)

Conclusion

Tretinoin 0.05% lotion was significantly more effective than its vehicle in achieving treatment success and reducing inflammatory and noninflammatory acne lesions in a Hispanic population. The new lotion formulation was well-tolerated, and all treatment-related AEs were both mild and transient in nature.

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