Tretinoin 0.05% Lotion for the Once-Daily Treatment of Moderate-to-Severe Acne Vulgaris in Females: Effect of Age on Efficacy and Tolerability

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SYNOPSIS
- Acne is a prevalent disease, occurring in 85% of adolescents.
- Prevalence in adults is increasing and it occurs more often in females than males.
- In addition, older age and female sex are associated with a greater impact on quality of life (QoL).
- The first lotion formulation of tretinoin 0.05%, developed utilizing novel/green extraction technology, was efficacious and well tolerated in a two phase trial of patients 19 years of age with moderate-to-severe acne (NCT01922396, NCT01705465).

OBJECTIVE
- To assess efficacy and tolerability of tretinoin 0.05% lotion in female patients of various age groups with moderate-to-severe acne.

METHODS
- In two phase 3 double-blind, randomized, multicenter, parallel-group, vehicle-controlled studies, patients 19 years of age with moderate-to-severe acne were randomized (1:1) to tretinoin 0.05% lotion or vehicle once daily for 12 weeks.
- In the study, Cerave hydrating cleanser and Cerave moisturizing lotion (Cerave, Inc., New York, NY) were provided as needed for optimal moisturization/cleaning of the skin.
- Data from these 2 studies were pooled and abstracted post-hoc in a subset of female patients by age: 13-19 years, 20-29 years, and 30+ years.

RESULTS

Participants
- The pooled population included 865 female patients: 13-19 years (n=173), 20-29 years (n=189), and 30+ years (n=80).
- The majority of patients in each age group had an EDDS score of 3 (moderate) at baseline (13-19 y: 57.0%, 20-29 y: 56.3%, 30+ y: 63.4%, p=0.15).

Efficacy

Age-Related Differences in Efficacy
- At week 12, least-squares mean reductions from baseline in inflammatory and noninflammatory lesion counts were significantly greater versus vehicle in the tretinoin-treated 20-29-year age group, compared with baseline versus vehicle in the 30+ age group.
- The greatest improvements in QoL occurred in the 20-29 and 30+ age groups, compared with the 13-19 group; these differences did not reach statistical significance.

Safety
- All ages and genders had return to baseline values or improved (0% vs vehicle).
- There were no significant differences across the 3 age groups at weeks 4, 8, or 12.
- Reductions in inflammatory or noninflammatory lesion counts and the percent of participants with ≥2-grade reduction in Evaluator’s Global Severity Scores (Evaluator’s Global Severity Score [EGSS]) were generally greater in the older age groups (20-29 and 30+ years) compared with the younger age group (13-19 years).

Figure 1. LS Mean Percent Reduction From Baseline in Inflammatory and Noninflammatory Lesion Counts by Age Group and Visit (ITT Population, Pooled)

Figure 2. Percentage of Participants Achieving ≥2-Grade Reduction in Evaluator's Global Severity Scores by Age Group and Visit (ITT Population, Pooled)

Figure 3. Mean Change From Baseline at Week 12 in Quality of Life by Age Group (ITT Population, Pooled)

CONCLUSIONS
- In adult and adolescent females with moderate-to-severe acne, tretinoin 0.05% lotion was effective versus vehicle in reducing noninflammatory lesions at week 12; in addition, tretinoin significantly reduced inflammatory lesions in adolescents at week 12.
- Reductions in acne lesions/EDDS scores and improvements in QoL, domain scores were generally greater in the older age groups (20-29 and 30 years) compared with younger females (13-19 years), although these differences did not reach statistical significance.
- Tretinoin 0.05% lotion was well tolerated by all age groups.

REFERENCES

Author Disclosures
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