

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

Linda Stein Gold, MD<sup>1</sup>; David M Pariser, MD<sup>2</sup>; Marci Levy, PA-C<sup>3</sup>; Eric Guenin, PharmD, PhD, MPH<sup>4</sup>

<sup>1</sup>Henry Ford Hospital, Detroit, MI; <sup>2</sup>Virginia Clinical Research Center, Norfolk, VA; <sup>3</sup>Gold Skin Care Center, Nashville, TN; <sup>4</sup>Ortho Dermatologics\*, Bridgewater, NJ  
\*Ortho Dermatologics is a division of Bausch Health US, LLC.

## SYNOPSIS

- Acne is a prevalent disease, occurring in 85% of adolescents<sup>1</sup>
- Prevalence in adults is increasing and it occurs more often in females than males<sup>2,3</sup>
- In addition, older age and female sex are associated with a greater impact on quality of life (QoL)<sup>4</sup>
- The first lotion formulation of tretinoin 0.05%, developed by utilizing novel polymeric emulsion technology, was efficacious and well tolerated in two phase 3 studies of patients ≥9 years of age with moderate-to-severe acne (NCT02932306, NCT02965456)<sup>5</sup>

## OBJECTIVE

- To assess efficacy and safety of tretinoin 0.05% lotion in females of various age groups with moderate-to-severe acne

## METHODS

- In two phase 3 double-blind, randomized, multicenter, parallel-group, vehicle-controlled studies, patients ≥9 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 this study, CeraVe<sup>®</sup> hydrating cleanser and CeraVe<sup>®</sup> moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- Data from these 2 studies were pooled and analyzed post hoc in a subset of female patients by age: 13-19 years, 20-29 years; and 30+ years
- Efficacy assessments included reductions in inflammatory and noninflammatory lesions, percentage of patients achieving ≥2-grade reduction in Evaluator's Global Severity Scores (EGSS), and Acne-Specific Quality of Life Questionnaire (Acne-QoL)
- Cutaneous safety and tolerability were also evaluated

## RESULTS

### Participants

- The pooled population included 865 female patients
  - 13-19 years (tretinoin, n=173; vehicle, n=184)
  - 20-29 years (tretinoin, n=163; vehicle, n=189)
  - 30+ years (tretinoin, n=80; vehicle, n=76)
- The majority of patients in each age group had an EGSS score of 3 (moderate) at baseline (13-19 y, 93.3%; 20-29 y, 88.9%; 30+ y, 95.5%)

### Efficacy

#### Within Age Groups (Treatment versus Vehicle)

- At week 12, least-squares mean percent reductions from baseline in inflammatory and noninflammatory lesion counts were significant versus vehicle in the tretinoin-treated 13-19 year group; in the tretinoin-treated older age groups, reductions from baseline versus vehicle were only significant for noninflammatory lesions, which may be due to the limited number of patients in each group (Figure 1)
- The percentage of patients achieving ≥2-grade EGSS reduction in each age group was greater with tretinoin treatment versus vehicle, though differences were not significant (Figure 2)

- QoL improvements at week 12 were significant versus vehicle in the tretinoin-treated 20-29 group for self-perception, role-emotional, and acne symptoms (Figure 3)
- Across Age Groups
  - Reductions in inflammatory or noninflammatory lesion counts and the percent of participants with ≥2-grade EGSS reduction were generally greater in the 20-29 and 30+ age groups compared with the 13-19 age group, although these differences were not statistically significant (Figures 1 and 2)
  - The greatest improvements in QoL domains occurred in the 20-29 and 30+ groups compared with the 13-19 group; these differences did not reach statistical significance (Figure 3)

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

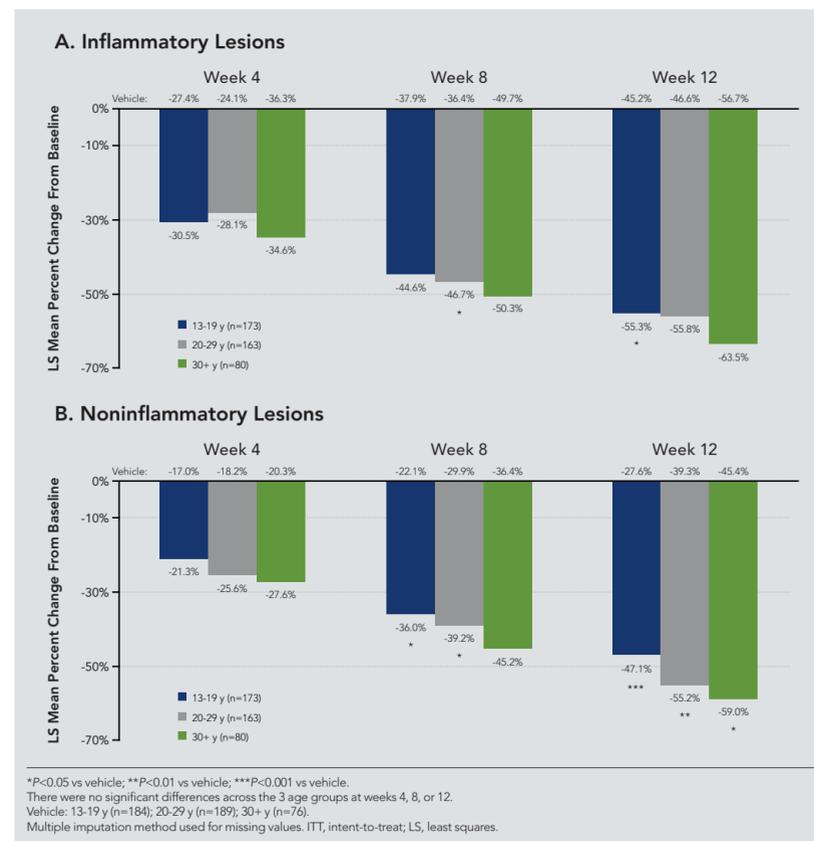


FIGURE 2. Percentage of Participants Achieving ≥2-Grade Reduction in Evaluator Global Severity Scores by Age Group and Visit (ITT Population, Pooled)

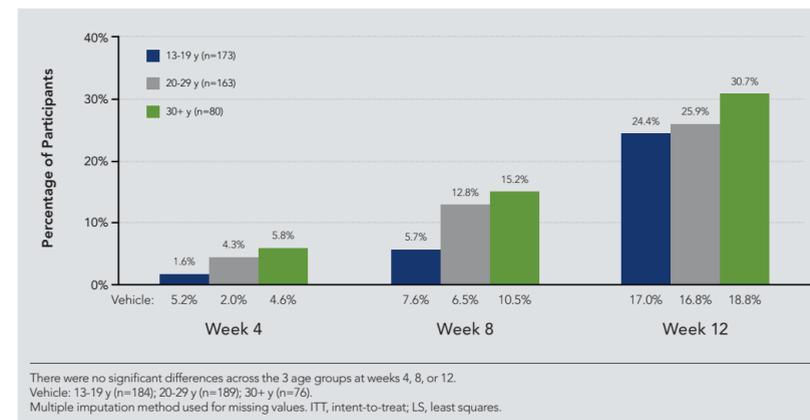
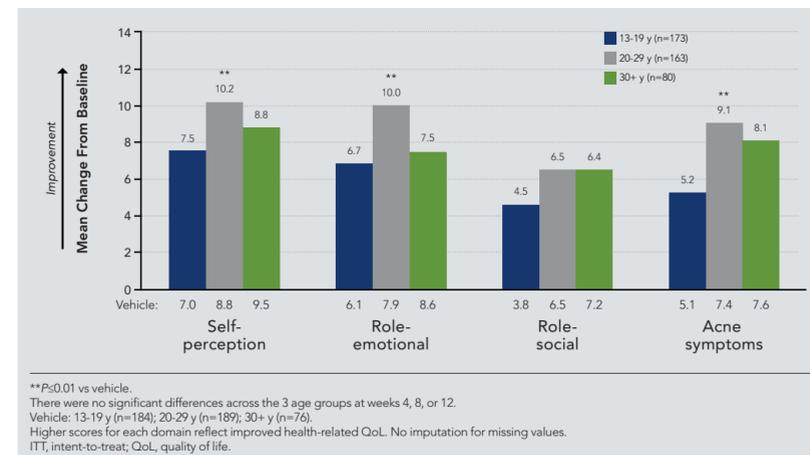


FIGURE 3. Mean Change From Baseline at Week 12 in Quality of Life by Age Group (ITT Population, Pooled)

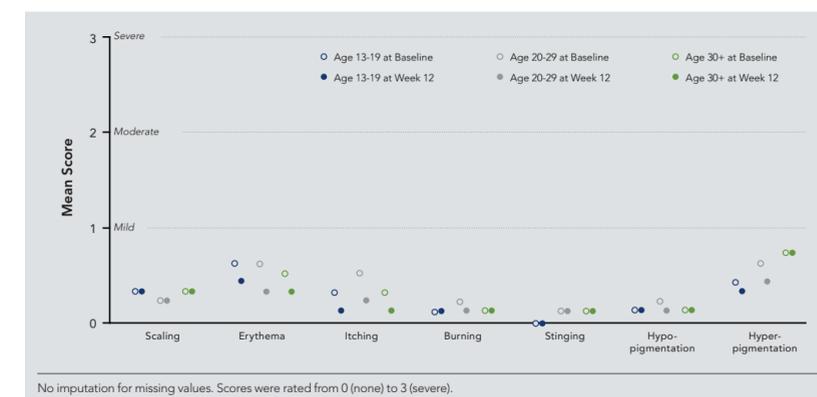


### Safety

- In the tretinoin-treated group, mean cutaneous safety and tolerability ratings were all between none (0) or mild (1) within each age group at weeks 4, 8, and 12
- By week 12, any mild, transient increases in cutaneous safety and tolerability in each age group had returned to baseline values or improved (Figure 4)

- Age-related trends were observed with hyperpigmentation, in which older females had higher mean baseline values; however, mean ratings were still below mild (1) at baseline and did not increase by week 12

FIGURE 4. Mean Cutaneous Safety and Tolerability Scores in Tretinoin-Treated Females by Age Group and Visit (Safety 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 lotion significantly reduced inflammatory lesions in adolescents at week 12
- Reductions in acne lesions/EGSS scores and improvements in QoL domains 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

- Zaenglein AL, et al. *J Am Acad Dermatol.* 2016;74(5):945-973.e933.
- Skroza N, et al. *J Clin Aesthet Dermatol.* 2018;11(1):21-25.
- Collier CN, et al. *J Am Acad Dermatol.* 2008;58(1):56-59.
- Tan JK, et al. *J Cutan Med Surg.* 2008;12(5):235-242.
- Tyring SK, et al. *J Drugs Dermatol.* 2018;17(10):1084-1091.

## AUTHOR DISCLOSURES

Linda Stein Gold has served as investigator/consultant or speaker for Ortho Dermatologics, LEO, Dermavant, Incyte, Novartis, AbbVie, and Lilly. David M Pariser has served as consultant to Atacama Therapeutics, Bickel Biotechnology, Biofrontera AG, Celgene, Dermira, LEO, Regeneron, Sanofi, TDM SurgiTech, TheraVida, and Ortho Dermatologics; investigator for Abbott Laboratories, Almirall, Amgen, AOBiome, Asana Biosciences, Bickel Biotechnology, Celgene, Dermavant, Dermira, Eli Lilly, LEO, Menlo Therapeutics, Merck & Co., Novartis, Novo Nordisk A/S, Ortho Dermatologics, Pfizer, Regeneron, and Stiefel; on advisory board for Pfizer; and on the data monitoring board for BMS. Marci Levy has nothing to disclose. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.