SYNOPSIS

- Acne is a prevalent disease, occurring in 85% of adolescents.1
- Prevalence in adults is increasing and it occurs more often in females than males.2
- In addition, older age and female sex are associated with a greater impact on quality of life.3
- 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).4

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, Caral® (hydrating cleanser and Caral® moisturizing lotion (O/C)) were provided as needed for optimal moisturizing/cleaning of the skin.

RESULTS

- 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=111; vehicle, n=76).
- The majority of patients in each age group had an EGS score of 3 (moderate) at baseline (13-19, 93.3%; 20-29, 90.9%; 30+, 95.9%).

Efficacy

- Within Age Groups (Treatment vs Vehicle)
- At week 12, least-squares mean percent reductions from baseline in inflammatory and noninflammatory lesions 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 EGS reduction in each age group was greater in the tretinoin treatment versus vehicle, though differences were not significant.
- QoL improvements at week 12 were significant versus vehicle in the tretinoin-treated 20-29 year group for self-perception, role-emotional, and acne symptoms (Figure 2).
- Reductions in inflammatory or noninflammatory lesion counts and the percent of participants achieving ≥2-grade EGS 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.
- 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.

CONCLUSIONS

- Tretinoin 0.05% lotion was well tolerated by all age groups.
- Age-related trends were observed with hygropigmentation, 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.

REFERENCES


AUTHOR DISCLOSURES

Dr. Linda Stein Gold has served as a consultant/travel support for Ortho Dermatologics, Joven, Novartis, Abbvie, and J. Dr. David Pariser has served as a consultant for Joven, Promius, and Medpharm Research. Dr. Eric Guenin is an employee of Ortho Dermatologics and may hold stock in Ortho Dermatologics.