Novel Tretinoin 0.05% Lotion for the Once-Daily Treatment of Moderate-to-Severe Acne Vulgaris in Asians

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SYNOPSIS

- Acne is a common problem among Asian adolescents and adults.
- Generally, Asian skin is more pigmented than white people of European descent, and Asians have a high risk of acne sequelae such as post-inflammatory hyperpigmentation.

METHODS

- In two phase 3, double-blind, vehicle-controlled 12-week studies, eligible participants aged 19-55 years with moderate to severe acne were randomized (1:1) to receive once-daily tretinoin 0.05% lotion versus vehicle.
- In these studies, CosmeLTX® hydrating cleanser and Cerave® moisturizing lotion (L'Oreal, NY) were provided as needed to maintain hydration of the skin.
- Assessments were similar to or greater than the overall study population.

RESULTS

- Efficacy:
  - At week 12, noninflammatory lesion counts versus vehicle in Asian participants, similar to the overall study population.
  - Treatment-emergent adverse events (TEAEs) were recorded in 14.7% of Asian participants and 0% of all participants.

- Safety:
  - In tretinoin-treated participants, treatment-emergent adverse events (TEAEs) were reported in 14.7% of Asian and 6.6% of all participants (Table 1).
  - Mild hyperpigmentation was reported at baseline for Asian participants (mean score 0.7) and remained mild throughout the study (0.6-0.7).

CONCLUSIONS

- Data pooled from two phase 3 studies showed that treatment with tretinoin 0.05% lotion provided statistically greater reductions in noninflammatory lesion counts versus vehicle in Asian participants, similar to the overall study population.
- The lack of statistical significance versus vehicle for inflammatory lesions and treatment success in Asian participants may be due to the small number (n=85) in this analysis, as mean values for these efficacy assessments were similar to or greater than the overall study population.
- Tretinoin 0.05% lotion was well tolerated in Asian and all participants, with mean cutaneous safety and tolerability ratings between none and mild, including hyperpigmentation.

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REFERENCES


AUTHOR DISCLOSURES

Dr. George Han has nothing to disclose. Dr. April Armstrong has served as a research investigator and/or consultant for Alexion, Arena, LEO, Leukotellix, Ortho Dermatologics, Derm-Onc, Dermgen, Regeneron, Bausch, Dermagen, and Medicine. Dr. Seemal Desai has served as a research investigator and/or consultant for Bioredox, Ortho Dermatologics, Galderma, Allergan, Dermgen, Dermalliance, Akantor, and Women’s Choice. Dr. Eric Guepin is an employee of Ortho Dermatologics and may hold stock or stock options in the company.