

# Efficacy of a Novel Tretinoin 0.05% Lotion in the Treatment of Moderate-to-Severe Acne by Gender and Race: Pooled Analysis of Two Phase 3 Studies

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## SYNOPSIS

- Acne is the most common dermatologic issue in patients with skin of color<sup>1</sup>
- Additionally, the prevalence of acne in adults is increasing, and it occurs more often in adult females than males<sup>2,3</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>4</sup>

## OBJECTIVE

- To assess efficacy of this novel tretinoin 0.05% lotion in participants by gender as well as black and white race (self-identified)

## METHODS

- In two phase 3, randomized, multicenter, double-blind, parallel-group, vehicle-controlled studies, participants with moderate-to-severe acne were equally randomized to tretinoin 0.05% lotion or vehicle lotion once daily for 12 weeks
  - In these studies, 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
- A pooled post hoc analysis was conducted to evaluate the effect of gender and race on the efficacy of tretinoin 0.05% lotion
- Efficacy assessments included change from baseline in inflammatory/noninflammatory lesion counts and percentage of participants achieving treatment success, defined as ≥2-grade reduction in the Evaluator Global Severity Score (EGSS) and a clear/almost clear score

## RESULTS

### Participants

- A total of 1,640 participants were included in the pooled analysis
  - Females (tretinoin, n=433; vehicle, n=476): white females (tretinoin, n=286; vehicle, n=336); black females (tretinoin, n=111; vehicle, n=98)
  - Males (tretinoin, n=386; vehicle, n=345): white males (tretinoin, n=307; vehicle, n=283); black males (tretinoin, n=54; vehicle, n=45)
- Mean age was slightly higher for females than males (mean age [standard deviation]):
  - Females (22.4 years [8.2]): white females (22.0 [7.9]); black females (23.6 [8.7])
  - Males (18.1 years [5.2]): white males (18.0 [4.9]); black males (18.8 [6.4])

### Efficacy

#### Females and Males: Overall

- At week 12, all tretinoin-treated females and males had significantly greater mean percent reduction from baseline versus vehicle in inflammatory (Figure 1A) and noninflammatory lesion counts (Figure 1B) and a larger percentage achieved treatment success versus vehicle (Figure 2)
- Compared with males, tretinoin-treated females had greater mean percent reductions in noninflammatory lesion counts at week 12 (51.7% vs 46.1%;  $P<0.05$ ) and a larger percentage achieved treatment success (23.6% vs 16.1%;  $P<0.05$ )

#### Females and Males: By Race

- At week 12, there were significant reductions in inflammatory and noninflammatory lesion counts with tretinoin treatment versus vehicle in white females, white males, and black males (Figures 3A and 3B)
- Compared with vehicle, significantly more tretinoin-treated white females and males achieved treatment success at week 12 (Figure 2)
- The percentages of tretinoin-treated black males and females achieving treatment success were greater than vehicle, but these differences were not significant (Figure 2)

FIGURE 1. Mean Percent Reduction from Baseline in Inflammatory (A) and Noninflammatory (B) Lesion Counts by Gender and Visit (ITT Population, Pooled)

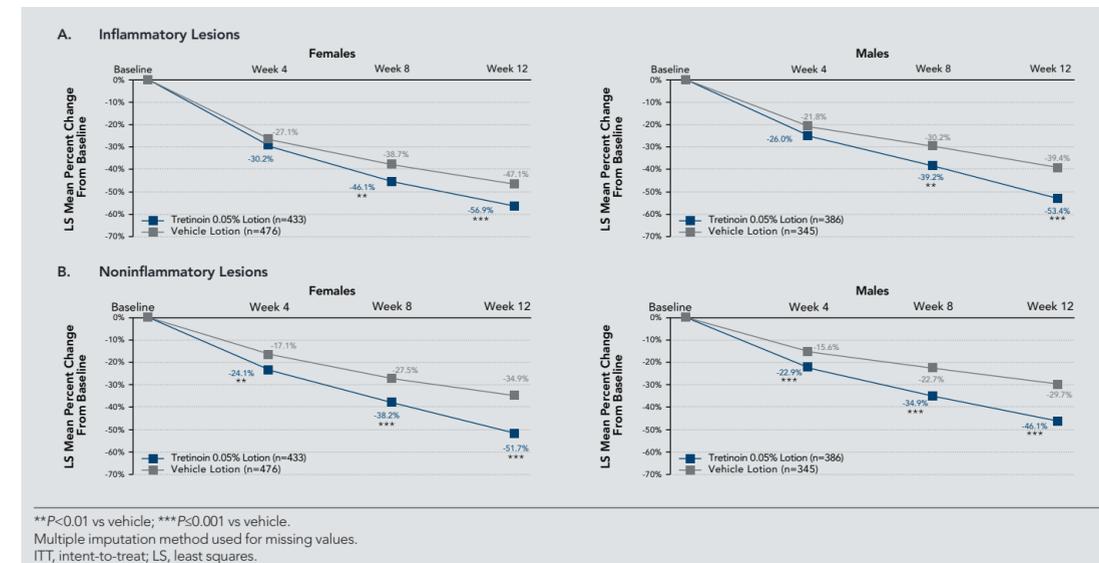


FIGURE 2. Percentage of Participants Achieving Treatment Success<sup>a</sup> at Week 12 by Gender and Race (ITT Population, Pooled)

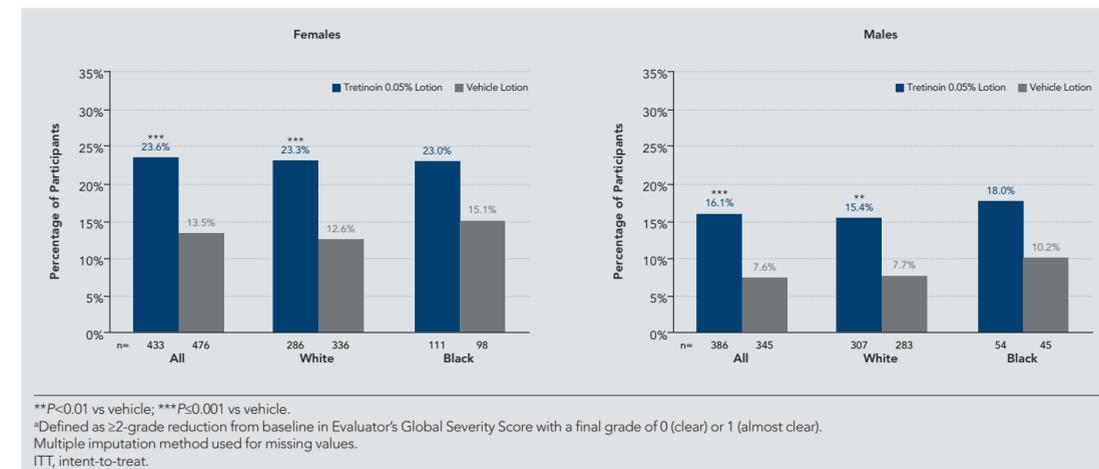
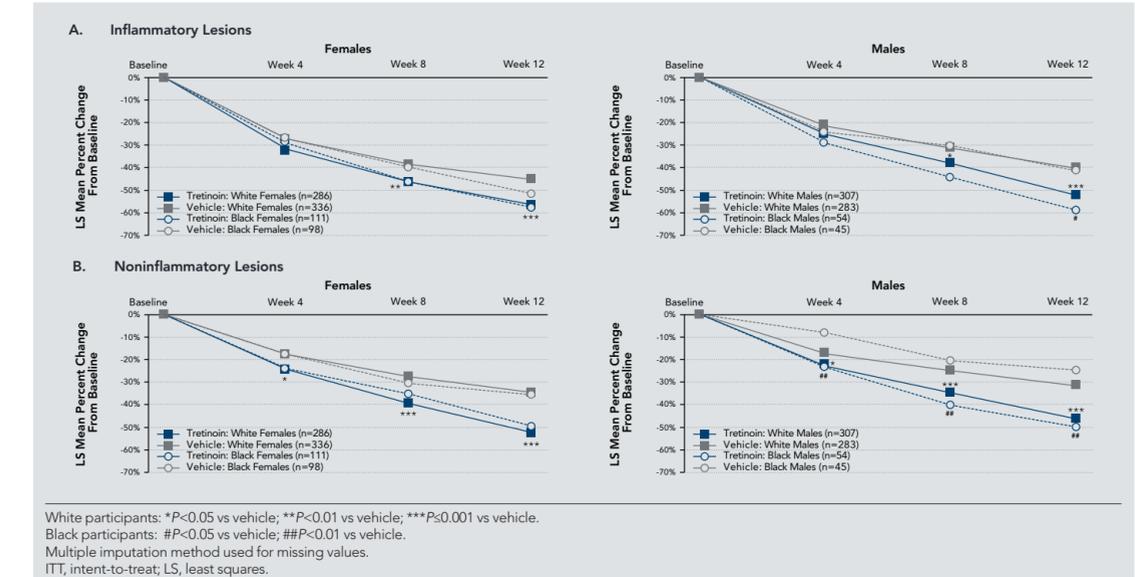


FIGURE 3. Mean Percent Reduction from Baseline in Inflammatory (A) and Noninflammatory (B) Lesion Counts by Gender, Race, and Visit (ITT Population, Pooled)



## CONCLUSIONS

- Tretinoin 0.05% lotion was significantly more effective than vehicle in reducing inflammatory and noninflammatory acne lesions and producing treatment success in males and females with moderate-to-severe acne
- Tretinoin 0.05% lotion was also significantly more effective than vehicle in reducing inflammatory and noninflammatory acne lesions in white males and females and black males
- In black females, there were improvements in lesion count reductions and a greater percentage achieved treatment success with tretinoin 0.05% lotion, but no efficacy endpoints reached statistical significance versus vehicle; this may be due in part to the small sample size and/or the greater response to vehicle

## REFERENCES

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## AUTHOR DISCLOSURES

Dr. Edward Lain has nothing to disclose. Dr. Doris Day has participated in speaker programs for Bausch Health. Dr. Julie Harper has received honoraria from Aclaris, Almirall, BioPharmX, Cassiopea, Cutanea, Dermira, Foamix, Galderma, LaRoche-Posay, Ortho Dermatologics, and Sun. Dr. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.