

# Novel Tretinoin 0.05% Lotion for the Once-Daily Treatment of Moderate-to-Severe Acne Vulgaris in an Asian Population

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## SYNOPSIS

- Acne is a common problem among Asian adolescents and adults<sup>1,2</sup>
- Generally, Asian skin is more pigmented, with a higher risk of acne sequelae<sup>3,4</sup>
- Potential for skin irritation and dryness, along with pigmentary changes, are key concerns that can significantly affect compliance and quality of life (QoL)<sup>1,5</sup>
- The first lotion formulation of tretinoin (Altreno<sup>®</sup> Ortho Dermatologics, Bridgewater, NJ) was developed by utilizing novel polymeric emulsion technology to provide an important alternative option to treat acne patients who may be sensitive to the irritant effects of other tretinoin formulations<sup>6</sup>

## OBJECTIVE

- Data from two phase 3 studies (NCT02932306, NCT02965456) were analyzed post hoc to evaluate the efficacy, tolerability, and safety of tretinoin 0.05% lotion in Asian patients with moderate-to-severe acne

## METHODS

- Data from Asian participants in two phase 3 studies were pooled and analyzed
- Participants in both studies were randomized (1:1) to tretinoin 0.05% lotion or vehicle, 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
- Efficacy assessments included:
  - Percent changes from baseline in inflammatory and noninflammatory lesions
  - Treatment success, defined as a  $\geq 2$ -grade reduction from baseline in Evaluator's Global Severity Score (EGSS) with a final grade of 0 (clear) or 1 (almost clear)
- QoL was assessed using the validated Acne-specific Quality of Life (Acne-QoL) scale
- Safety, adverse events (AEs), cutaneous tolerability and hyper- or hypo-pigmentation (range, 0 [none] to 3 [severe]) were also evaluated

## RESULTS

### Participants

- The pooled intent-to-treat analysis included 69 Asian participants, 42 (60.9%) of whom were female (Table 1)
- Ages in this subpopulation ranged from 12 to 48 years
- Based on EGSS scores, all participants had moderate or severe acne before treatment; the proportion of severe in Asian participants (18.8%) was higher than in the general study population (11.0%)<sup>6</sup>

TABLE 1. Demographics and Baseline Characteristics

	Tretinoin 0.05% (n=36)	Vehicle (n=33)	Total (N=69)
<b>Age, years</b>			
Mean (SD)	20.7 (7.9)	21.1 (6.9)	20.9 (7.4)
Range	12-38	12-48	12-48
<b>Sex, n (%)</b>			
Female	18 (50.0)	24 (72.7)	42 (60.9)
<b>EGSS score, n (%)</b>			
3 - Moderate	28 (77.8)	28 (84.8)	56 (81.2)
4 - Severe	8 (22.2)	5 (15.2)	13 (18.8)
<b>Lesion count, mean (SD)</b>			
Inflammatory	28.4 (6.4)	26.0 (4.8)	27.2 (5.8)
Noninflammatory	44.9 (21.3)	43.7 (20.8)	44.4 (20.4)

EGSS, Evaluator's Global Severity Score; SD, standard deviation.

### Efficacy

- At Week 12, mean percent reductions in inflammatory and noninflammatory lesion counts were greater with tretinoin 0.05% vs vehicle (Figure 1)
- Treatment success at Week 12 was also greater with tretinoin 0.05% vs vehicle (Figure 2)
- For each Acne-QoL domain, mean score improvements from baseline were significantly greater with tretinoin 0.05% compared to vehicle (Figure 3)

FIGURE 1. Percent Reduction in Lesion Counts

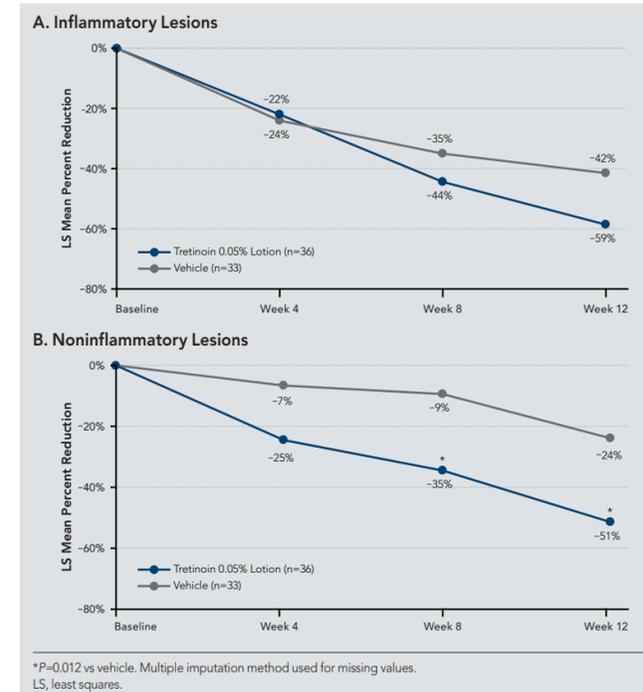


FIGURE 2. Treatment Success<sup>a</sup>

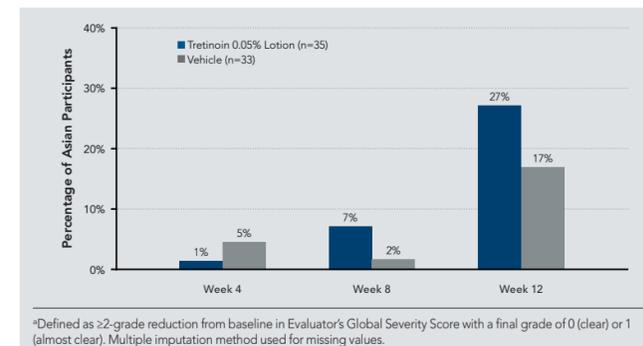
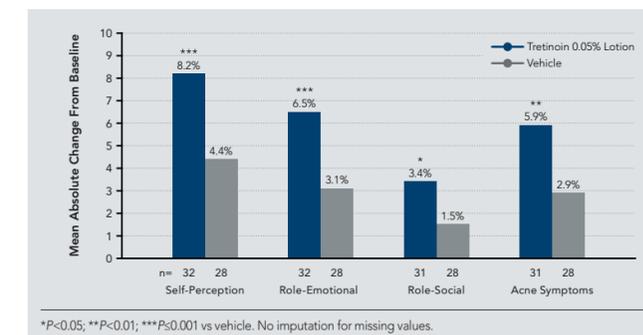


FIGURE 3. Quality of Life



## Safety

- Only five Asian participants in the pooled population reported any AEs with tretinoin 0.05% lotion (Table 2)
- All of these AEs with tretinoin 0.05% were mild or moderate and transient, and none were considered serious or related to treatment
- There were slight transient increases in scaling and burning over the first 4-8 weeks (Figure 4)
- Mild hyperpigmentation was reported at baseline (mean score 0.8) and remained mild throughout the study

FIGURE 4. Cutaneous Safety and Tolerability Assessments

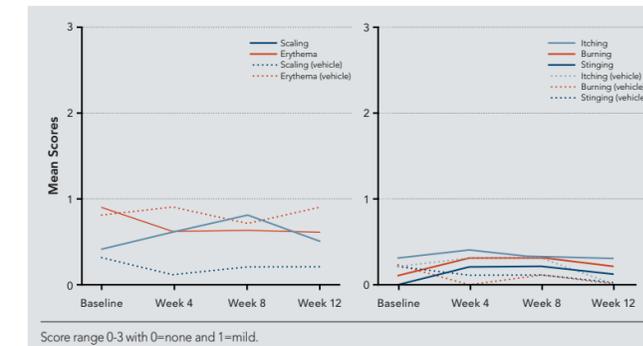


TABLE 2. Adverse Events

Summary of AEs, n (%)	Tretinoin 0.05% (n=34)	Vehicle (n=31)
Any AEs	5 (14.7)	6 (19.4)
Any serious AEs	0	0
Any AEs leading to discontinuation	0	0
Deaths	0	0
<b>Severity of AEs, n (%)</b>		
Mild	3 (8.8)	5 (16.1)
Moderate	2 (5.9)	1 (3.2)
Severe	0	0
<b>Relationship to study drug, n (%)</b>		
Related	0	1 (3.2)
Unrelated	5 (14.7)	5 (16.1)
<b>Treatment-Related AEs<sup>a</sup></b>		
Application site exfoliation	0	1 (3.2)

<sup>a</sup>Reported in any participants in either treatment arm.

## CONCLUSIONS

- Data pooled from two phase 3 studies showed that in Asian participants (n=69), tretinoin 0.05% lotion was significantly more effective than vehicle in reducing noninflammatory acne lesions and improving QoL
- This novel lotion formulation was well-tolerated, with no treatment-related AEs and no concerns with skin dryness, irritation or hyperpigmentation

## REFERENCES

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## AUTHOR DISCLOSURES

Dr. George Han has nothing to disclose.  
 Dr. April Armstrong has served as a research investigator and/or consultant for AbbVie, Janssen, Leo, Novartis, UCB, Ortho Dermatologics, Dermira, Sanofi, Regeneron, BMS, Dermavant, and Modernizing Medicine.  
 Dr. Seemal Desai has served as a research investigator and/or consultant for Skinmedica, Ortho Dermatologics, Galderma, Pfizer, Dermavant, Almirall, Dermira, and Watson.  
 Dr. Eric Guenin is an employee of Ortho Dermatologics.