A New Tazarotene 0.045% Lotion Formulation for Moderate-to-Severe Acne: Efficacy and Safety in Phase 2 and Phase 3 Clinical Trials

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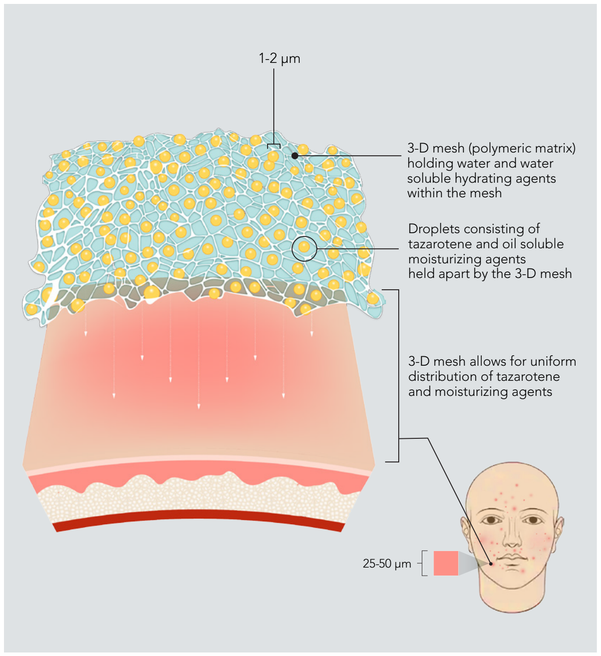
SYNOPSIS

- Topical tazarotene 0.1% is approved for the treatment of acne vulgaris, though skin irritation and other skin reactions may limit use of some gel, foam, and cream formulations[1]
- A recently-approved, lower-dose tazarotene 0.045% lotion was developed utilizing polymeric emulsion technology, allowing for rapid and uniform distribution of tazarotene, humectants, and moisturizers on the skin **(Figure 1)**[2]
- This highly spreadable lotion formulation was developed to allow for more efficient delivery of tazarotene into dermal layers while reducing the potential for skin irritation[2]

FIGURE 1. **Polymeric Emulsion Technology for Tazarotene 0.045% Lotion**

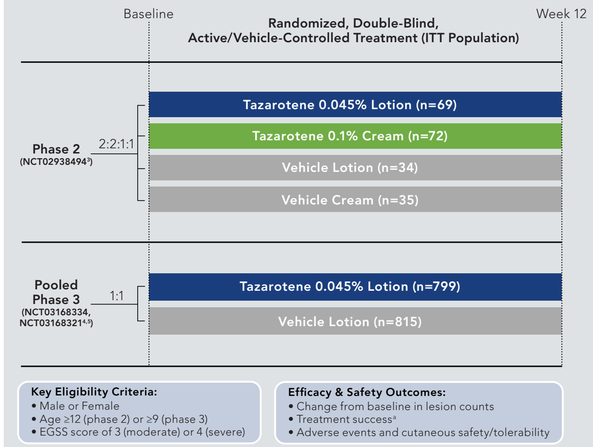


OBJECTIVE

- Data from a phase 2 study and two phase 3 studies were summarized to provide an overview of the efficacy and safety of tazarotene 0.045% lotion in participants with moderate-to-severe acne

METHODS

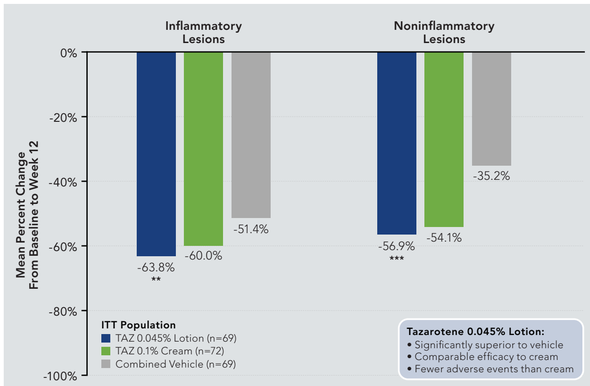
FIGURE 2. **Randomized, Double-Blind, 12-Week Studies of Tazarotene 0.045% Lotion**



[a]Defined as percentage of participants achieving ≥2-grade reduction from baseline in EGSS and a score of clear (0) or almost clear (1).
For this presentation, cream and lotion vehicles were combined (phase 2 study) and phase 3 study data were pooled. In these studies, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin.
EGSS, Evaluator's Global Severity Score; ITT, intent to treat.

RESULTS: PHASE 2 STUDY

FIGURE 3. **Phase 2 Study: Overview of Week 12 Results**

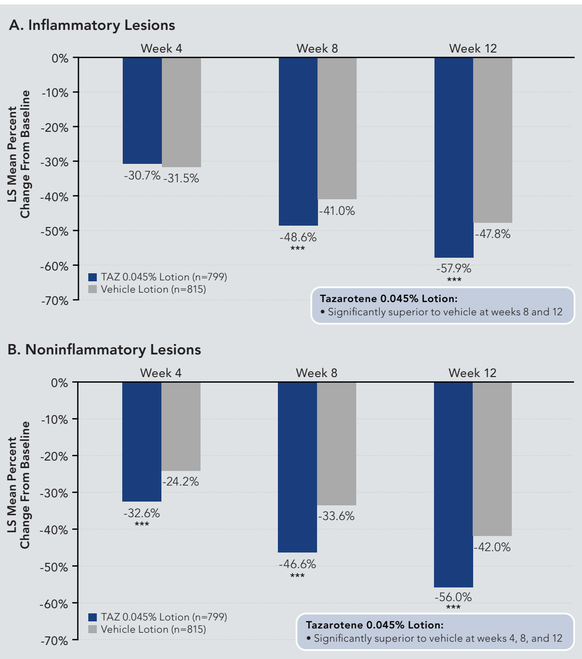


TEAE Summary, Safety Population	TAZ 0.045% Lotion (n=68)	TAZ 0.1% Cream (n=71)	Combined Vehicle (n=67)
Any TEAE	14.7%	26.8%	13.4%
Any SAE	0%	0%	0%
Any TEAE leading to discontinuation	0%	1.4%	0%
Any TEAE related to treatment	2.9%	5.6%	0%

**P<0.01, ***P<0.001 vs combined vehicle.
Statistical comparison between TAZ 0.1% cream and combined vehicle was not conducted. At week 12, a greater percentage of tazarotene 0.045%-treated participants achieved treatment success versus combined vehicle (18.8% vs 10.1%), though this difference did not reach statistical significance.
ITT, intent to treat; SAE, serious adverse event; TAZ, tazarotene; TEAE, treatment-emergent adverse event.

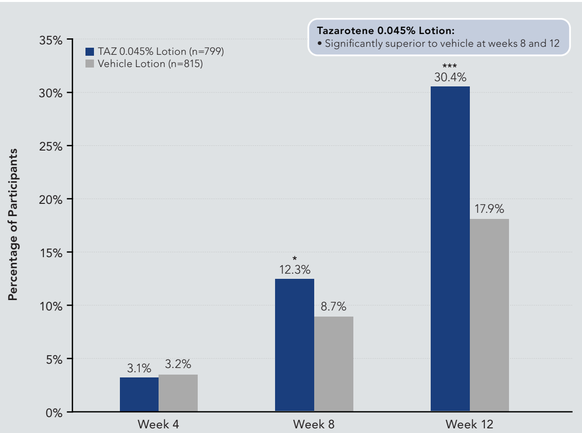
RESULTS: POOLED PHASE 3 STUDIES

FIGURE 4. **Change in Lesion Counts by Study Visit (ITT Population, Pooled Phase 3)**



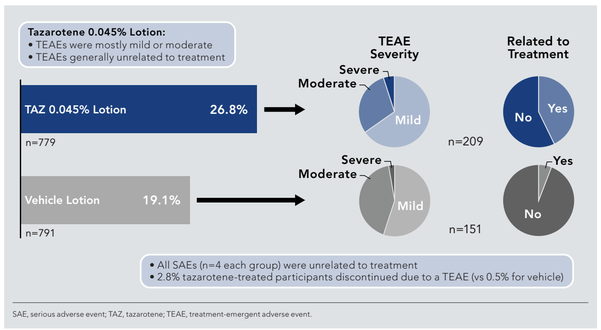
***P<0.001 vs vehicle.
ITT, intent to treat; LS, least squares; TAZ, tazarotene.

FIGURE 5. **Treatment Success[a] by Study Visit (ITT Population, Pooled Phase 3)**



*P<0.05, ***P<0.001 vs vehicle.
[a]Defined as percentage of participants achieving ≥2-grade reduction from baseline in EGSS and a score of clear (0) or almost clear (1).
EGSS, Evaluator's Global Severity Score; ITT, intent to treat; TAZ, tazarotene.

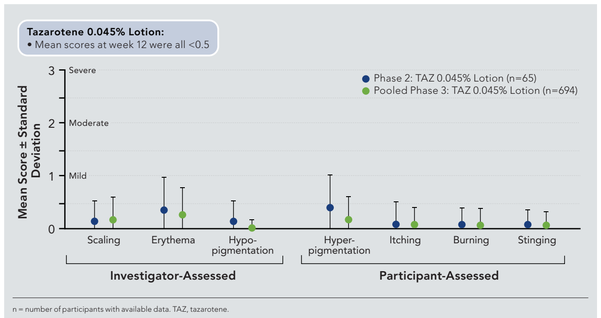
FIGURE 6. **Participants Reporting Any Treatment-Emergent Adverse Event (Safety Population, Pooled Phase 3)**



SAE, serious adverse event; TAZ, tazarotene; TEAE, treatment-emergent adverse event.

RESULTS: CUTANEOUS SAFETY/TOLERABILITY (PHASE 2 AND POOLED PHASE 3)

FIGURE 7. **Mean Cutaneous Safety and Tolerability With Tazarotene 0.045% Lotion at Week 12 (Safety Population, Phase 2 and Pooled Phase 3)**



n = number of participants with available data. TAZ, tazarotene.

CONCLUSIONS

- In a phase 2 and two pooled phase 3 studies, lower-dose tazarotene 0.045% lotion was more effective versus vehicle in the treatment of moderate-to-severe acne
- In the phase 2 study, tazarotene 0.045% lotion had comparable efficacy but fewer TEAEs than tazarotene 0.1% cream
- Overall, this new lotion formulation is a viable treatment option, particularly for patients who have tolerability issues with other tazarotene formulations

REFERENCES

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AUTHOR DISCLOSURES

EAT has served as speaker for Novartis, Ortho Dermatologics, Sun, Lilly, Galderma, AbbVie, and Dermira; served as a consultant/clinical studies for Hologic, Ortho Dermatologics, and Galderma; and is a stockholder for Accure. WPW has served as an investigator for Ortho Dermatologics. EL has nothing to disclose. AMC has nothing to disclose. EG is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company. SH, AL, and RP are employees of Bausch Health US, LLC and may hold stock and/or stock options in its parent company.

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