Safety and Tolerability of Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel for Truncal Acne

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SYNOPSIS

- Truncal acne—lesions on the shoulders, chest, upper extremities, and/or back—is underdiagnosed and under-treated[1,2]
- Untreated truncal acne can lead to scarring and postinflammatory hyperpigmentation and can negatively impact quality of life[2-4]
- Applying topical treatments to a larger skin surface area than the face introduces additional safety/tolerability concerns
- Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (CAB) gel is the only fixed-dose, triple-combination topical for acne and has demonstrated favorable efficacy, safety, and tolerability in participants with moderate to severe facial acne[5-7]
- The 3 active ingredients in CAB gel are delivered in a pH-balanced, spreadable polymeric mesh gel designed to break apart upon skin contact[6,8]; this may more evenly distribute the active ingredients, with the goal of minimizing cutaneous adverse effects

OBJECTIVE

- To evaluate the cutaneous safety and tolerability of CAB gel for the treatment of mild to severe truncal acne

METHODS

- Data were pooled from one phase 2 (NCT04892706) and two phase 3 (NCT04214639, NCT04214652[6,7]), double-blind, 12-week studies
- Participants aged ≥9 years (≥12 years, phase 2 study) with moderate to severe facial acne (Evaluator's Global Severity Score [EGSS] score of 3 or 4) were randomized to CAB or vehicle gel
- Treatment was applied to the face once daily for 12 weeks, with a subset of participants also applying treatment to the truncal area (neck, upper back, upper chest, and shoulders)
  - Truncal acne treatment was optional and no additional inclusion criteria were required for those treating truncal acne
  - CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed to all participants for optimal moisturization/cleaning of the skin
- Only participants treating both the face and trunk were included in this post hoc analysis
- Truncal acne severity was assessed via Truncal Severity Score (TSS); truncal acne lesion counts were not performed, and truncal efficacy was not the main outcome
- Truncal treatment-emergent adverse events (TEAEs; truncal or truncal and facial) were evaluated through week 12
- Truncal cutaneous safety/tolerability assessments were also evaluated at each visit

RESULTS

- In the 3 pooled clinical studies, 219 participants in the safety populations treated both truncal and facial acne (n=118 CAB; n=101 vehicle gel; **Table 1**)
  - Approximately half of participants were female, and most participants were White and non-Hispanic
  - The majority had moderate facial acne (EGSS=3) and mild to moderate truncal acne (TSS=2-3) at baseline

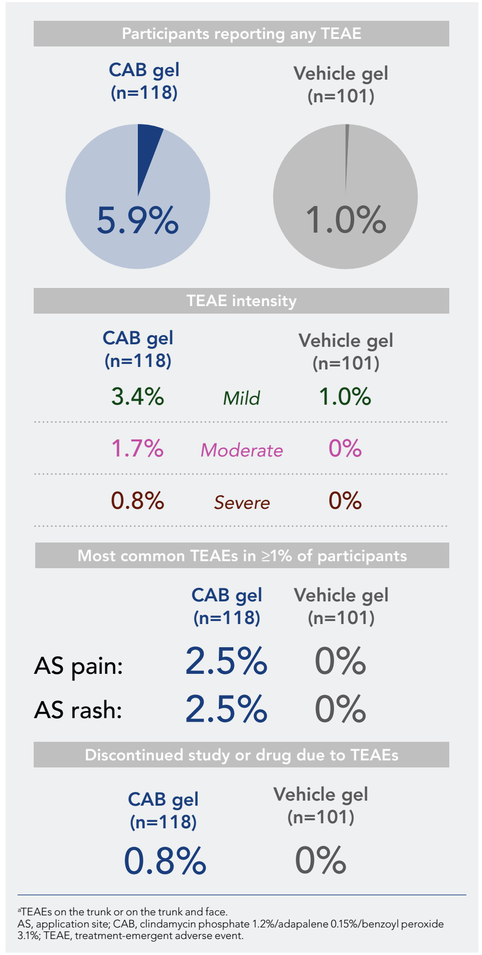
TABLE 1. Demographics and Baseline Characteristics of Participants Treating Truncal Acne (Safety Population, Pooled)

	CAB gel (n=118)	Vehicle gel (n=101)
Age, mean (SD), y	18.9 (6.6)	17.9 (5.7)
Sex, female, n (%)	63 (53.4)	51 (50.5)
Race, n (%)		
White	92 (78.0)	81 (80.2)
Black or African American	11 (9.3)	9 (8.9)
Asian	8 (6.8)	8 (7.9)
Other[a]	7 (5.9)	3 (3.0)
Ethnicity, not Hispanic/Latino, n (%)	91 (77.1)	71 (70.3)
Facial inflammatory lesion count, mean (SD)[b]	39.8 (12.2)	39.6 (12.0)
Facial noninflammatory lesion count, mean (SD)[b]	55.8 (22.7)	52.3 (19.7)
Facial Evaluator's Global Severity Score, n (%)		
3-Moderate	98 (83.1)	89 (88.1)
4-Severe	20 (16.9)	12 (11.9)
Truncal Severity Score, n (%)		
0-Clear	0	0
1-Almost clear	8 (6.8)	4 (4.0)
2-Mild	54 (45.8)	48 (47.5)
3-Moderate	49 (41.5)	46 (45.5)
4-Severe	7 (5.9)	3 (3.0)

[a]American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and multiple/other/not reported/unknown.
[b]Lesion counts were not assessed in truncal areas.
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; SD, standard deviation

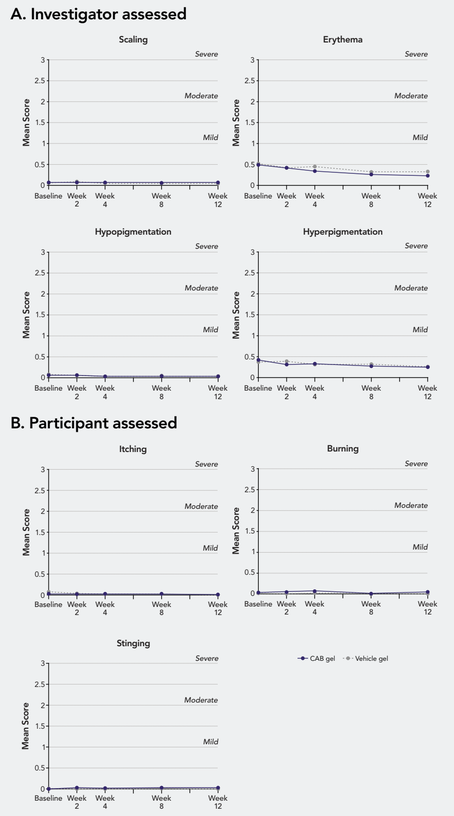
- TEAE rates on the trunk were higher in the CAB vs vehicle group; most TEAEs were mild, none were serious, and only 1 CAB-treated participant discontinued due to TEAEs (**Figure 1**)

FIGURE 1. Truncal TEAEs Through Week 12 (Safety Population, Pooled)[a]



[a]TEAEs on the trunk or on the trunk and face.
AS, application site; CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; TEAE, treatment-emergent adverse event.

FIGURE 2. Truncal Cutaneous Safety and Tolerability by Visit (Safety Population, Pooled)



Assessments were scored using a 4-point scale (0=none, 1=mild, 2=moderate, 3=severe).
N values: CAB: baseline, n=118; week 12, n=101; vehicle: baseline, n=101; week 12, n=81.
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%.

- Severe (grade 3) ratings postbaseline occurred in <1% of CAB-treated participants for truncal erythema, hyperpigmentation, and burning (**Table 2**)

TABLE 2. Grade 3 (Severe) Truncal Cutaneous Safety and Tolerability Assessments Postbaseline Through Week 12 (Safety Population, Pooled)

Participants, n (%)	CAB gel (n=112)	Vehicle gel (n=90)
Investigator evaluations of safety		
Scaling	0	0
Erythema	1 (0.9)	0
Hypopigmentation	0	0
Hyperpigmentation	1 (0.9)	3 (3.3)
Participant evaluations of tolerability		
Itching	0	0
Burning	1 (0.9)	0
Stinging	0	0

CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%.

- Mean scores on truncal cutaneous safety/tolerability evaluations with CAB were <0.5 (1=mild) at all visits (**Figure 2**)
  - As expected, slight increases occurred with CAB treatment at weeks 2-4 in burning and stinging; scores resolved back to near baseline levels by week 8
  - Erythema, hypopigmentation, hyperpigmentation, and itching scores decreased from baseline to week 12
- Greater than 92% of CAB-treated participants had a score of 0 (none) on scaling, hypopigmentation, itching, burning, and stinging at any visit (data not shown)

CONCLUSIONS

- Fixed-dose, triple-combination CAB gel demonstrated favorable safety and tolerability over 12 weeks in a subset of participants with truncal acne and moderate to severe facial acne
- The lack of safety signals combined with the favorable safety/tolerability profile of CAB shows that it is a safe treatment option for both truncal and facial acne

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AUTHOR DISCLOSURES

Leon H. Kircik has served as a consultant, speaker, advisor, or an investigator for Allergan, Almirall, EPI Health, Galderma, Novartis, Ortho Dermatologics, and Sun Pharma. Julie C. Harper has received honoraria from Almirall, Cutera, Galderma, LaRoche-Posay, Ortho Dermatologics, and Sun Pharma. Michael Gold has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Linda Stein Gold has served as investigator, consultant, or speaker for Ortho Dermatologics, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, Pfizer, Sun Pharma, UCB, Arcutis, and Lilly. Zoe D. Draelos received funding from Ortho Dermatologics. Eric Guenin and Su Yong Choi are employees of Ortho Dermatologics and may hold stock and/or stock options in its parent company. Karol Wroblewski has nothing to disclose. Hilary Baldwin has served as advisor and investigator and on speakers bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. Valerie D. Callender has served as an investigator, consultant, or speaker for Acne Store, Almirall, Aerolase, AbbVie, Allergan Aesthetics, Avava, Avita Medical, Beiersdorf, Cutera, Dermavant, Eirion Therapeutics, Eli Lilly, Galderma, Janssen, Jeune Aesthetics, L'Oréal, Ortho Dermatologics, Pfizer, Prollineum, Regeneron, Scientis, Sente, SkinBetter Science, SkinCeuticals, Symatese, Teoxane, and UpToDate. Adelaide A. Hebert has received honoraria from Galderma, LEO Pharma, Almirall, Cassiopea, Ortho Dermatologics, Cutanea, Ferrer, Pfizer, and Demira and the UTHealth McGovern Medical School has received research grants from Cassiopea, Demira, and Ortho Dermatologics. Jonathan S. Weiss has acted as an investigator, advisor and/or speaker for Almirall, Bausch Health Sciences, Dr Reddy's, EPI Health, Foamix, Galderma, Novartis, Sanofi, and Ortho Dermatologics.

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