Efficacy of clascoterone cream 1% through up to 12 months from a long-term extension study in patients ≥9 years of age with acne vulgaris

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INTRODUCTION

- 1% clascoterone cream is an androgen receptor inhibitor approved for the topical treatment of acne vulgaris in patients ages 12 years and older[1]
- In 2 identical, multicenter, randomized, vehicle-controlled, double-blind, Phase 3 studies (CB-03-01/25 and CB-03-01/26) in patients with moderate-to-severe facial acne vulgaris, twice-daily treatment with 1% clascoterone cream for 12 weeks resulted in significantly higher treatment success rates and greater reduction in lesion counts compared with vehicle treatment[2]
  - Clascoterone was well tolerated, with a safety profile similar to that of vehicle
- Patients from the Phase 3 studies could enter an optional long-term, open-label safety study; the safety results from that study are published[3]

OBJECTIVE

- To evaluate the long-term efficacy of twice-daily 1% clascoterone cream in patients who completed the long-term extension study per protocol

METHODS

- A multicenter, open-label, long-term extension study (CB-03-01/27) enrolled patients who completed 1 of the 12-week Phase 3 clinical trials (CB-03-01/25 and CB-03-01/26)
- Male or nonpregnant female patients ≥9 years of age who completed 1 of the 12-week Phase 3 pivotal clinical trials (CB-03-01/25 and CB-03-01/26) and enrolled within 3 days of the final pivotal trial visit were eligible
  - Patients with any skin pathology or condition that could interfere with the study or who planned to use other topical or systemic anti-acne preparations or undergo procedures on the face (or trunk, if applicable) were excluded
- Patients applied 1% clascoterone cream twice daily to the entire face and, if designated by the investigator and desired by the patient, to truncal acne, for 9 additional months of treatment
  - Total time on clascoterone including the Phase 3 studies could be up to 12 months for patients originally randomized to clascoterone treatment
  - Clascoterone treatment could be discontinued if the Investigator Global Assessment (IGA) score was 0 or 1 (clear/almost clear) and reinstated if/when acne worsened
- Efficacy was evaluated from the IGA severity score for each treatment area, as applicable
  - Assessed at every in-clinic study visit (baseline and Days 29, 85, 183, and 274) using a 5-point IGA (0, clear; 4, severe)
  - Efficacy analyses were performed on the per-protocol (PP) set, which included all patients who completed the study without significant protocol violations and remained on the trial at that time

RESULTS

Patient demographics

- The PP population included 324 patients, of whom 324 (100.0%), 324 (100.0%), 274 (84.6%), and 119 (36.7%) were on clascoterone for a total of 3, 6, 9, and 12 months, respectively
  - During the Phase 3 studies, 169 and 155 PP patients had received 1% clascoterone cream and vehicle, respectively
  - In the extension study, 126 PP patients also treated truncal acne, including 68 and 58 who received 1% clascoterone cream and vehicle, respectively, during the Phase 3 studies
- The majority of patients were female and White; mean age was 19.7 years (**Table 1**)
- Baseline IGA scores for the face and trunk were mild or moderate in the majority of patients
  - A higher proportion of patients who originally received 1% clascoterone cream during the Phase 3 studies had mild truncal acne at baseline relative to those who had been applying vehicle cream (**Table 1**)

Efficacy

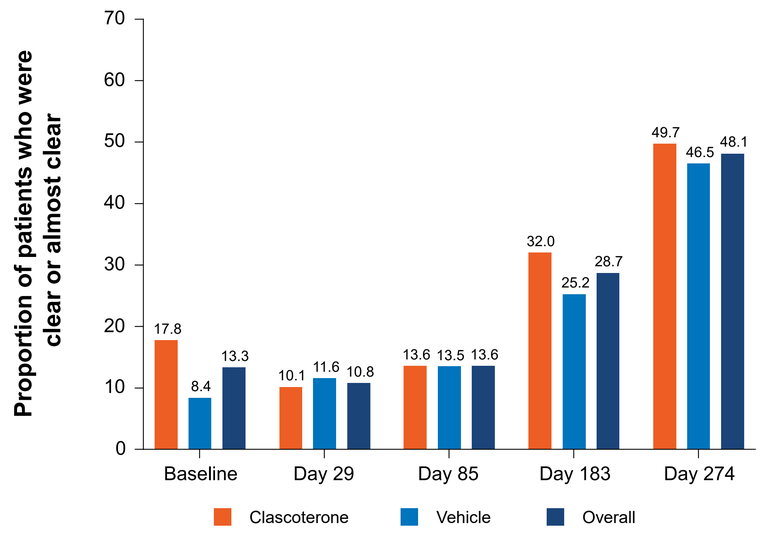
- Among patients who completed the study without major protocol violations, the proportion with clear or almost clear facial acne (IGA score 0/1) increased over time during treatment with 1% clascoterone cream, with almost half of all patients (48.1%) having a facial IGA score of 0/1 at the end of the study (Day 274; **Figure 1**)
  - Similar proportions of patients who originally received 1% clascoterone cream or vehicle in the Phase 3 studies were clear or almost clear at the end of the study
- The overall proportion of PP patients with clear or almost clear truncal acne increased over time with 1% clascoterone cream treatment (**Figure 2**)
  - At the end of the study, the proportion of patients with a truncal IGA score of 0/1 was higher among those originally assigned to treatment with 1% clascoterone cream vs vehicle (61.8% vs 41.3%)
- Consistent with IGA results at each study visit, the overall proportions of PP patients who were clear or almost clear on the face and trunk increased with time on 1% clascoterone cream treatment, with the greatest proportion of patients who were clear or almost clear observed after 12 and 9 months, respectively, of treatment with 1% clascoterone cream (**Figures 3–4**)

Table 1. Baseline demographics and clinical characteristics (per-protocol population)

	Clascoterone n = 169	Vehicle n = 155	Overall N = 324
Sex, female	99 (58.6)	100 (64.5)	199 (61.4)
Age, years, mean ± SD	19.6 ± 6.2	19.7 ± 7.1	19.7 ± 6.6
Race			
White	158 (93.5)	135 (87.1)	293 (90.4)
Black or African American	6 (3.6)	11 (7.1)	17 (5.2)
Asian	2 (1.2)	5 (3.2)	7 (2.2)
Native Hawaiian or other Pacific Islander	1 (0.6)	1 (0.6)	2 (0.6)
American Indian or Alaska Native	1 (0.6)	0	1 (0.3)
Other	1 (0.6)	1 (0.6)	2 (0.6)
Multiple	0	2 (1.3)	2 (0.6)
Ethnicity			
Non-Hispanic or Latino	159 (94.1)	148 (95.5)	307 (94.8)
Height, cm, mean ± SD	170.2 ± 10.0	169.1 ± 8.9	169.7 ± 9.5
Weight, kg, mean ± SD	66.3 ± 16.2	66.2 ± 16.9	66.2 ± 16.5
Body mass index, kg/m^2, mean ± SD	22.8 ± 4.9	23.1 ± 5.4	22.9 ± 5.2
Facial IGA			
0 (clear)	0	0	0
1 (almost clear)	30 (17.8)	13 (8.4)	43 (13.3)
2 (mild)	72 (42.6)	59 (38.1)	131 (40.4)
3 (moderate)	60 (35.5)	73 (47.1)	133 (41.0)
4 (severe)	7 (4.1)	10 (6.5)	17 (5.2)
Truncal IGA[a]			
0 (clear)	1 (1.5)	0	1 (0.8)
1 (almost clear)	1 (1.5)	3 (5.2)	4 (3.2)
2 (mild)	47 (69.1)	25 (43.1)	72 (57.1)
3 (moderate)	15 (22.1)	27 (46.6)	42 (33.3)
4 (severe)	3 (4.4)	1 (1.7)	4 (3.2)
Not done	1 (1.5)	2 (3.4)	3 (2.4)

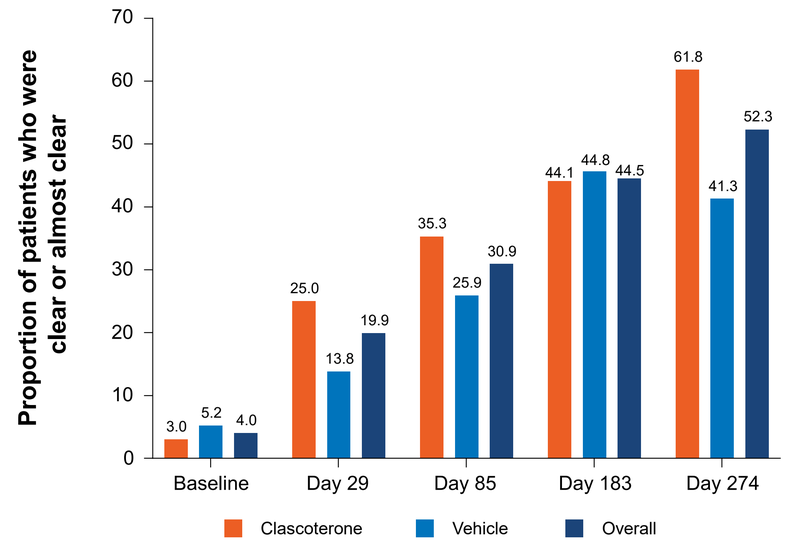
Data shown as n (%) unless otherwise noted.
[a]n = 68 clascoterone, n = 58 vehicle, N = 126 overall.
IGA, Investigator Global Assessment; SD, standard deviation.

Figure 1. Proportion of patients with IGA of 0 or 1 (clear or almost clear) for the face at all visits (PP set)



Patients are summarized overall and according to the original test article they received in the Phase 3 pivotal studies (CB-03-01/25 and CB-03-01/26).
IGA, Investigator Global Assessment; PP, per-protocol.

Figure 2. Proportion of patients with IGA of 0 or 1 (clear or almost clear) for the trunk at all visits (PP set)



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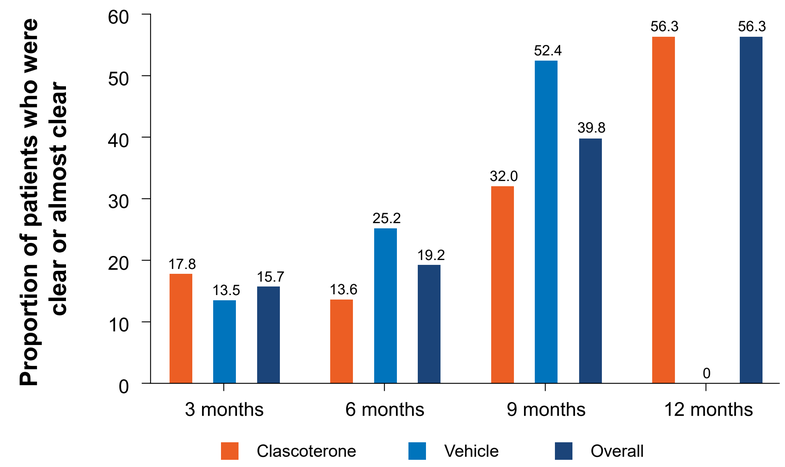
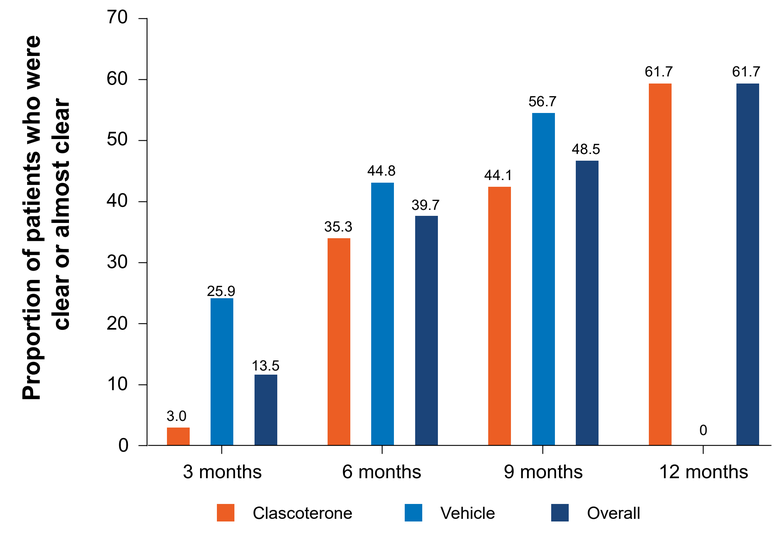
IGA, Investigator Global Assessment; PP, per-protocol.

Figure 3. Proportion of patients with IGA of 0 or 1 (clear or almost clear) for the face of patients on clascoterone for 3, 6, 9, and 12 months (PP set)[a]



Patients are summarized overall and according to the original test article they received in the Phase 3 pivotal studies (CB-03-01/25 and CB-03-01/26).
[a]This was a 9-month, open-label study of treatment with 1% clascoterone cream; thus, subjects who received vehicle for 3 months in the Phase 3 pivotal study could only receive up to 9 months of treatment with 1% clascoterone cream in this open-label study.
IGA, Investigator Global Assessment; PP, per-protocol.

Figure 4. Proportion of patients with IGA of 0 or 1 (clear or almost clear) for the trunk of patients on clascoterone for 3, 6, 9, and 12 months (PP set)[a]



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CONCLUSIONS

- Efficacy and safety[3] of 1% clascoterone cream for the treatment of acne vulgaris are maintained for up to 12 months
- Among patients who completed the study without major protocol violations, the proportion achieving clear or almost clear skin on the face and trunk increased with duration of 1% clascoterone cream treatment and was highest for patients on clascoterone for 12 months

REFERENCES

1) WINLEVI® (1% clascoterone cream). Full prescribing information. Sun Pharmaceutical Industries, Inc. 2021; **2)** Hebert A, et al. *JAMA Dermatol.* 2020;156(6):621–30; **3)** Eichenfield L, et al. *J Am Acad Dermatol.* 2020;83(2):477–85.

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DISCLOSURES

LE has served as an investigator, advisor, or consultant for Allergan, Almirall, Foamix Pharmaceuticals, Galderma Laboratories, L'Oreal, and Ortho Dermatologics. **AAH** is an employee of the McGovern Medical School of The University of Texas Health Science Center in Houston, which received compensation from Cassiopea S.p.A. for study participation; she also received an honorarium for serving on the Cassiopea advisory board. **LSG** is an employee of the Henry Ford Health System in Detroit, MI, which received compensation from Cassiopea S.p.A. for study participation; she has also received personal fees for advisory, speaking, consulting, research, and/or other ties with Almirall; Foamix; Galderma Laboratories; Novartis; Sol-Gel; and Sun Pharma. **MC** was employed as the senior director of medical affairs for Cassiopea, Inc., at the time the work was conducted; receives personal fees as a consultant from Cassiopea S.p.A.; receives personal fees as an adjunct faculty member from the University of Arizona; holds stock options in Cassiopea S.p.A.; and is a consultant to Abbott Nutrition. **LM** is an employee of Cassiopea S.p.A. and holds stock options in the company. **JH** is an employee of Pharmapace Inc. **NS** is an employee of Sun Pharmaceutical Industries, Inc. **AM** is employed as the chief medical officer for Cassiopea S.p.A., and holds stock options in the company; is a board member of Cassiopea S.p.A; and has served as the chief medical officer of Cosmo Pharmaceuticals.