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

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INTRODUCTION

- Clascoterone cream 1% is an androgen receptor inhibitor approved for the topical treatment of acne vulgaris in patients ≥12 years of age[1]
- Clascoterone efficacy and safety were evaluated 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[2]
  - — Twice-daily treatment with clascoterone cream 1% for 12 weeks resulted in significantly higher treatment success rates and greater reduction in lesion counts compared with vehicle treatment
  - — 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 clascoterone cream 1% in patients who enrolled in the long-term extension study

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 clascoterone cream 1% 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's 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 intention-to-treat (ITT) set, which included all enrolled patients

RESULTS

Patient demographics

- The ITT population included 609 patients, of whom 539 (88.5%), 417 (68.5%), 304 (49.9%), and 123 (20.2%) were on clascoterone for a total of 3, 6, 9, and 12 months, respectively
  - — During the Phase 3 studies, 317 and 292 ITT patients had received clascoterone cream 1% and vehicle, respectively
  - — In the extension study, 251 ITT patients were designated to treat truncal acne, including 130 and 121 who received clascoterone cream 1% and vehicle, respectively, during the Phase 3 studies
- The majority of patients were female and White; mean age was 19.2 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 clascoterone cream 1% during the Phase 3 studies had mild truncal acne at baseline relative to those who had been applying vehicle cream (**Table 1**)

Efficacy

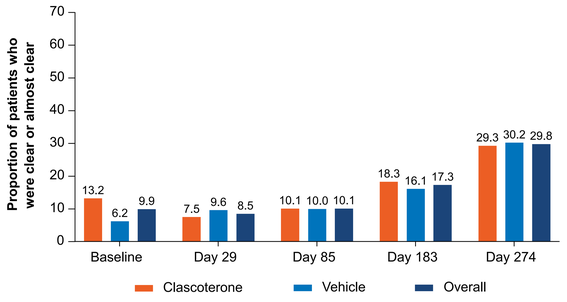
- The proportion of ITT patients with clear or almost clear facial acne (IGA score 0/1) increased over time during treatment with clascoterone cream 1%, with 29.8% achieving a facial IGA score of 0/1 at the end of the study (Day 274; **Figure 1**)
  - — Similar proportions of patients who originally received clascoterone cream 1% or vehicle in the Phase 3 studies were clear or almost clear at the end of the study
- The overall proportion of ITT patients with clear or almost clear truncal acne increased over time with clascoterone cream 1% 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 clascoterone cream 1% vs vehicle (36.1% vs 26.4%, respectively)
- Consistent with IGA results at each study visit, the overall proportions of ITT patients who were clear or almost clear on the face and trunk increased with time on clascoterone cream 1% treatment, with the greatest proportion of patients who were clear or almost clear observed after 12 months on treatment with clascoterone cream 1% (**Figures 3–4**)

Table 1. Baseline demographics and clinical characteristics (ITT population)

Characteristics	Clascoterone n = 317	Vehicle n = 292	Overall N = 609
Sex, female	198 (62.5)	183 (62.7)	381 (62.6)
Age, years, mean ± SD	19.2 ± 5.8	19.2 ± 6.7	19.2 ± 6.3
Race			
White	283 (89.3)	258 (88.4)	541 (88.8)
Black or African American	17 (5.4)	18 (6.2)	35 (5.7)
Asian	6 (1.9)	8 (2.7)	14 (2.3)
Native Hawaiian or other Pacific Islander	2 (0.6)	1 (0.3)	3 (0.5)
American Indian or Alaska Native	1 (0.3)	0	1 (0.2)
Other	4 (1.3)	1 (0.3)	5 (0.8)
Multiple	4 (1.3)	6 (2.1)	10 (1.6)
Ethnicity			
Not Hispanic or Latino	290 (91.5)	277 (94.9)	567 (93.1)
Height, cm, mean ± SD	169.4 ± 10.2	169.6 ± 9.4	169.5 ± 9.8
Weight, cm, mean ± SD	66.9 ± 18.0	66.6 ± 16.5	66.8 ± 17.3
Body mass index, kg/m^2, mean ± SD	23.2 ± 5.6	23.1 ± 5.2	23.2 ± 5.4
Facial IGA			
0 (clear)	0	0	0
1 (almost clear)	42 (13.2)	18 (6.2)	60 (9.9)
2 (mild)	124 (39.1)	120 (41.1)	244 (40.1)
3 (moderate)	130 (41.0)	132 (45.2)	262 (43.0)
4 (severe)	21 (6.6)	22 (7.5)	43 (7.1)
Truncal IGA[a]			
0 (clear)	2 (1.5)	0	2 (0.8)
1 (almost clear)	5 (3.8)	5 (4.1)	10 (4.0)
2 (mild)	76 (58.5)	60 (49.6)	136 (54.2)
3 (moderate)	41 (31.5)	52 (43.0)	93 (37.1)
4 (severe)	4 (3.1)	1 (0.8)	5 (2.0)

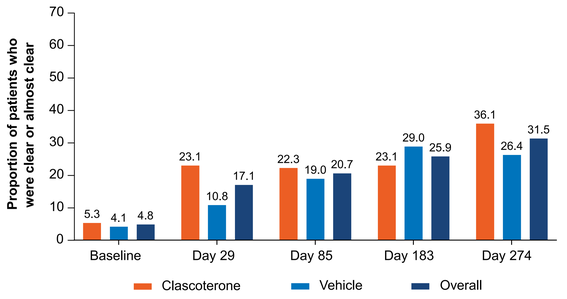
ITT population.
Data shown as n (%) unless otherwise noted.
[a]Clascoterone, n = 130; vehicle, n = 121; overall, N = 251.
IGA, Investigator's Global Assessment; ITT, intention-to-treat; SD, standard deviation.

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



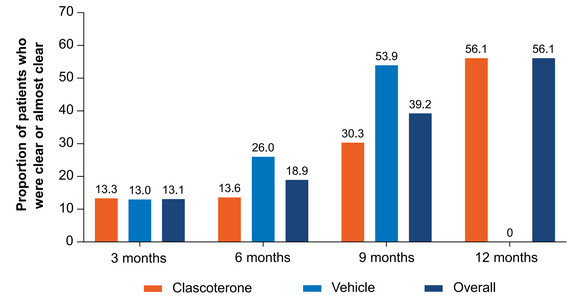
Patients are summarized overall and according to the original test article they received in the Phase 3 pivotal studies (CB-03-01/25 and CB-03-01/26).
IGA, Investigator's Global Assessment; ITT, intention-to-treat.

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



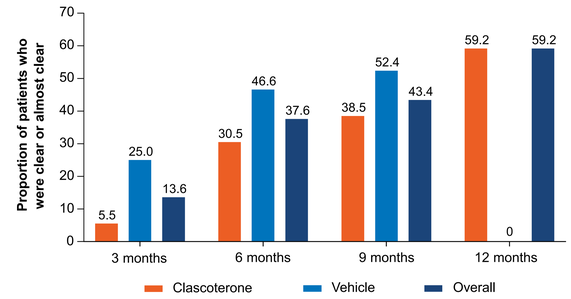
Patients are summarized overall and according to the original test article they received in the Phase 3 pivotal studies (CB-03-01/25 and CB-03-01/26).
IGA, Investigator's Global Assessment; ITT, intention-to-treat.

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 (ITT 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 clascoterone cream 1%; thus, patients who received vehicle for 3 months in the Phase 3 pivotal study could only receive up to 9 months of treatment with clascoterone cream 1% in this open-label study.
IGA, Investigator's Global Assessment; ITT, intention-to-treat.

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 (ITT set)[a]



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CONCLUSIONS

- Efficacy and safety[3] of clascoterone cream 1% for the treatment of acne vulgaris are maintained for up to 12 months
- The proportion of ITT patients achieving clear or almost clear skin on the face and trunk increased with duration of clascoterone cream 1% treatment and was highest for patients on clascoterone for 12 months

REFERENCES

1) WINLEVI® (clascoterone). Full prescribing information. Sun Pharmaceutical Industries, Inc. 2023. 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

LFE, AAH, and **LSG** were study investigators. **LFE, AAH,** and **LSG** were also compensated advisors to Cassiopea. **LFE** is an employee of the University of California San Diego, which received compensation from Cassiopea S.p.A. for study participation; he has also served as a consultant, investigator, or speaker for Almirall, Dermata, Galderma Laboratories, 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; all research grant funds were paid to her institution. She also received personal fees for advisory, speaking, and consulting roles from Pfizer, Sun Pharma, Galderma, Arcutis, Incyte, and LEO Pharma. **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** is employed as the Vice President, Medical Affairs at Novan, Inc.; was employed as the senior director of medical affairs for Cassiopea, Inc., at the time of the study; received personal fees as a consultant from Cassiopea S.p.A.; and receives personal fees as an adjunct faculty member from the University of Arizona. **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; and has served as the chief medical officer of Cosmo Pharmaceuticals.