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Integrated Short-Term and Long-Term Efficacy of Topical Clascoterone Cream 1% in Patients ≥12 years of Age With Acne Vulgaris

Lawrence F. Eichenfield MD,[a] Linda Stein Gold MD,[b] Jenny Han MS,[c] Adelaide A. Hebert MD,[d] Alessandro Mazzetti MD,[e] Luigi Moro PhD,[e] Nicholas Squittieri MD,[f] Diane Thiboutot MD[g]

[a]Departments of Dermatology and Pediatrics, University of California San Diego and Rady Children's Hospital-San Diego, San Diego, CA
[b]Department of Dermatology, Henry Ford Medical Center, Detroit, MI
[c]Pharmapace, Inc., San Diego, CA
[d]Department of Dermatology, UTHealth McGovern Medical School, Houston, TX
[e]Cassiopea S.P.A., Lainate, Italy
[f]Sun Pharmaceutical Industries, Inc., Princeton, NJ
[g]Department of Dermatology, The Pennsylvania State University College of Medicine, Hershey, PA

ABSTRACT

Background: Clascoterone cream 1% is approved for the treatment of acne vulgaris in patients aged ≥12 years based on results from two identical pivotal Phase 3 trials. Integrated efficacy of clascoterone in patients aged ≥12 years with acne vulgaris from the pivotal trials (NCT02608450 and NCT02608476) and long-term extension (LTE) study (NCT02682264) is reported.

Methods: In the pivotal trials, patients with moderate-to-severe acne vulgaris were randomized 1:1 to twice-daily application of clascoterone cream 1% or vehicle for 12 weeks; they could then enter the LTE study, where all patients applied clascoterone to the face and, if desired, trunk for up to 9 additional months. Efficacy was assessed from treatment success based on Investigator's Global Assessment scores (IGA 0/1) in patients aged ≥12 years in the intention-to-treat population; lesion counts were assessed through week 12. Missing data were handled using multiple imputation in the pivotal studies and were not imputed in the LTE study.

Results: Of 1421 patients enrolled, 1143 (clascoterone, 576; vehicle, 567) completed week 12; 600 entered and 343 completed the LTE study. The treatment success rate and most lesion count reductions following clascoterone vs placebo treatment reached statistical significance at week 12; the overall treatment success rate increased to 30.2% for facial acne after 12 months and 31.7% for truncal acne after 9 months of treatment.

Conclusions: The efficacy of clascoterone cream 1% for the treatment of acne vulgaris continued to increase over time for up to 12 months in patients aged ≥12 years with acne vulgaris.

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INTRODUCTION

Acne vulgaris is the eighth most prevalent disease worldwide, affecting approximately 85% of adolescents and young adults aged 12 to 25 years.[1,2] Androgen inhibition is an effective strategy for treating acne in female patients.[3] However, treatment with systemic androgen inhibitors such as combined oral contraceptives and spironolactone is associated with side effects that restrict their use in male patients, pregnancy, and other high-risk conditions.[4]

Clascoterone is a first-in-class molecule that competitively binds to androgen receptors with high affinity and inhibits the transcription of androgen-responsive genes, including sebum components and inflammatory cytokines.[5] Clascoterone cream 1% is approved in the US for the treatment of acne vulgaris in patients aged ≥12 years.[6] In two identical pivotal Phase 3 trials in patients with facial acne vulgaris, treatment with clascoterone cream 1% resulted in a marked clinical improvement after 12 weeks, with a favorable safety profile during up to 12 months of treatment in the extension study; efficacy was also maintained in patients who completed the extension study per protocol.[3,7-9] Here, we present the integrated efficacy of clascoterone cream 1% in the intention-to-treat (ITT) population of patients aged ≥12 years with acne vulgaris in the pivotal and extension studies.

MATERIALS AND METHODS

Study Design and Patients

The Phase 3 trial designs were described previously (Figure 1).[3,7-9] Briefly, patients ≥9 years of age with moderate-to-severe acne vulgaris were randomized to twice-daily treatment of the face with clascoterone cream 1% or vehicle for 12 weeks; patients completing either pivotal study could enter a long-term extension (LTE) study in which all patients applied clascoterone cream 1% twice daily to the face and, if designated by the investigator and desired by the patient, truncal acne for up to 9 additional months.[3,7] Patients who achieved an Investigator's Global Assessment (IGA) score of 0 or 1 (IGA 0/1) could stop treatment and resume if/when acne worsened (IGA ≥2), as assessed by the investigator for each respective treatment area. Only patients aged ≥12 years were included in the current analysis.

The institutional review board or ethics committee approved the study protocols at each participating site. The studies were conducted in accordance with the principles of the Declaration of Helsinki, the current Good Clinical Practice guidelines as defined by the International Conference on Harmonization, and all applicable regulatory requirements. All patients provided written informed consent before participation in the trials. Patients under 18 years of age were accompanied by a parent or legal guardian at the time of consent signing.[3,7]

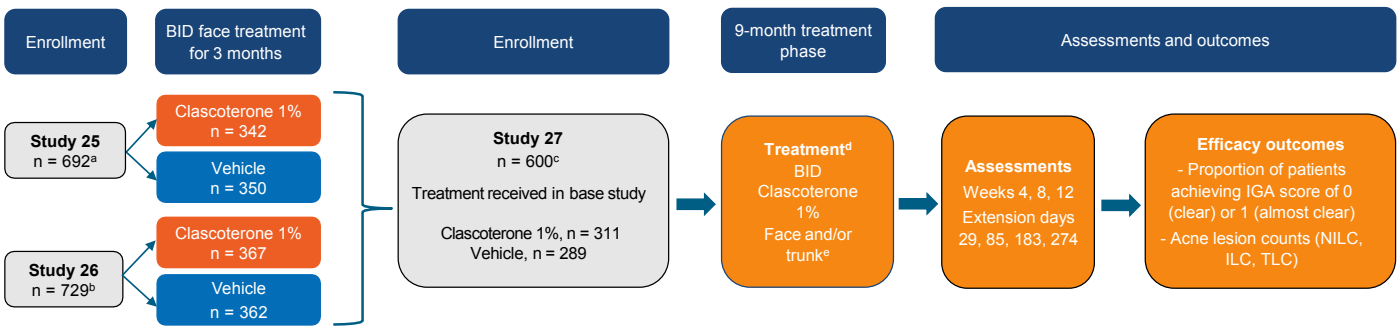
Assessments and Outcomes

The IGA was assessed at baseline and every 4 weeks in the pivotal studies and at extension days 0 (pivotal study week 12 visit), 29, 85, 183, and 274 in the LTE study using a 5-point scale (0 = clear to 4 = severe). Efficacy was assessed from the proportion of patients achieving treatment success (defined as IGA of 0 or 1 with a ≥2-point reduction in IGA score from baseline), assessed separately for the face and trunk in the long-term study. Noninflammatory (NILC), inflammatory (ILC), and total lesion counts (TLC) were obtained at each pivotal study visit, and the absolute and percent changes from baseline in NILC, ILC, and TLC were assessed through week 12.

Statistical Analysis

All statistical analyses were performed using SAS® for Windows, version 9.3 (SAS Institute, Cary, NC). The ITT patient population included all randomized individuals and was used for the analyses. For demographics, baseline characteristics, compliance, and efficacy analyses, continuous variables were described using descriptive statistics and categorical data by frequency counts and proportion of patients within each category. Efficacy comparisons between clascoterone and vehicle were performed using a logistic regression model as described previously.[3] Unadjusted and adjusted proportions and least squares means with associated 95% confidence intervals (CI) were analyzed, and two-sided *P*-values were reported. In the pivotal trials, missing data were handled using a multiple imputation method.[3] Missing data were not imputed in the LTE study.

FIGURE 1. Study design.



[a]Number of ITT patients ≥12 years of age enrolled in Study 25.
[b]Number of ITT patients ≥12 years of age enrolled in Study 26.
[c]Number of ITT patients ≥12 years of age enrolled in the long-term extension study (Study 27).
[d]Patients who achieved IGA score of ≤1 could stop treatment and resume if/when acne worsened.
[e]Total clascoterone treatment duration was up to 12 months for patients treated with clascoterone for 3 months in the pivotal studies.
BID, twice daily; IGA, Investigator's Global Assessment; ILC, inflammatory lesion count; ITT, intention-to-treat; NILC, noninflammatory lesion count; TLC, total lesion count.

TABLE 1.

Patient Disposition and Reasons for Discontinuation

Patients	Phase 3 pivotal studies						Long-term extension study		
	CB-03-01/25		CB-03-01/26		Total		CB-03-01/27		
	CLA (n = 342)	VEH (n = 350)	CLA (n = 367)	VEH (n = 362)	CLA (n = 709)	VEH (n = 712)	CLA (n = 311)	VEH-to-CLA (n = 289)	Total (N = 600)
Completed study	276 (80.7)	286 (81.7)	300 (81.7)	281 (77.6)	576 (81.2)	567 (79.6)	177 (56.9)	166 (57.4)	343 (57.2)
Discontinued	66 (19.3)	64 (18.3)	67 (18.3)	81 (22.4)	133 (18.8)	145 (20.4)	134 (43.1)	123 (42.6)	257 (42.8)
Reasons for discontinuation									
Adverse event	3 (0.9)	6 (1.7)	2 (0.5)	8 (2.2)	5 (0.7)	14 (2.0)	9 (2.9)	0 (0.0)	9 (1.5)
Lack of efficacy	0 (0.0)	3 (0.9)	3 (0.8)	1 (0.3)	3 (0.4)	4 (0.6)	12 (3.9)	16 (5.5)	28 (4.7)
Lost to follow-up	39 (11.4)	32 (9.1)	24 (6.5)	24 (6.6)	63 (8.9)	56 (7.9)	49 (15.8)	41 (14.2)	90 (15.0)
Noncompliance with study drug	0 (0.0)	2 (0.6)	1 (0.3)	5 (1.4)	1 (0.1)	7 (1.0)	1 (0.3)	4 (1.4)	5 (0.8)
Physician decision	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	1 (0.1)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Pregnancy	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	2 (0.3)	1 (0.3)	2 (0.7)	3 (0.5)
Progressive disease	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	2 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.2)
Recovery	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	2 (0.7)	3 (0.5)
Technical problems	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.2)
Withdrawal by patient	21 (6.1)	15 (4.3)	30 (8.2)	37 (10.2)	51 (7.2)	52 (7.3)	55 (17.7)	46 (15.9)	101 (16.8)
Withdrawal by parent/guardian	2 (0.6)	2 (0.6)	5 (1.4)	4 (1.1)	7 (1.0)	6 (0.8)	5 (1.6)	7 (2.4)	12 (2.0)
Other	0 (0.0)	2 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	3 (0.4)	0 (0.0)	4 (1.4)	4 (0.7)

ITT population.
Data shown as n (%) unless otherwise specified.
CLA, clascoterone; ITT, intention-to-treat; VEH, vehicle.

RESULTS

Patients

Overall, 1421 ITT patients ≥12 years of age enrolled in Phase 3 pivotal studies; 709 were randomized to apply clascoterone and 712 to vehicle (Figure 1). Baseline characteristics were previously reported.[9] Patient disposition in the pivotal and LTE studies is summarized in Table 1. The patients' baseline demographic characteristics were generally balanced between the treatment arms in the pivotal study and between patients originally randomized to clascoterone vs vehicle who continued into the LTE study. Patients' baseline characteristics were similar between the pivotal and LTE study populations, except that the proportion of non-Hispanic patients was higher in the LTE study relative to the combined pivotal studies (Table 2).

Short-Term Efficacy

The adjusted proportion of ITT patients achieving treatment success in the pivotal studies was higher among those receiving clascoterone vs vehicle beginning at week 8 (5.5% vs 3.7%, $P = 0.13$) and reached significance at week 12 (19.9% vs 7.7%,

TABLE 2.

Patient Demographics

Characteristic	Phase 3 pivotal studies						Long-term extension study		
	CB-03-01/25		CB-03-01/26		Total		CB-03-01/27		
	CLA (n = 342)	VEH (n = 350)	CLA (n = 367)	VEH (n = 362)	CLA (n = 709)	VEH (n = 712)	CLA (n = 311)	VEH-to-CLA (n = 289)	Total (N = 600)
Sex, female	211 (61.7)	210 (60.0)	242 (65.9)	220 (60.8)	453 (63.9)	430 (60.4)	193 (62.1)	180 (62.3)	373 (62.2)
Race									
Caucasian	290 (84.8)	296 (84.6)	355 (96.7)	347 (95.9)	645 (91.0)	643 (90.3)	279 (89.7)	257 (88.9)	536 (89.3)
Asian	8 (2.3)	10 (2.9)	0 (0.0)	4 (1.1)	8 (1.1)	14 (2.0)	5 (1.6)	8 (2.8)	13 (2.2)
Black or African American	30 (8.8)	34 (9.7)	7 (1.9)	6 (1.7)	37 (5.2)	40 (5.6)	16 (5.1)	16 (5.5)	32 (5.3)
Other	14 (4.1)	10 (2.9)	5 (1.4)	5 (1.4)	19 (2.7)	15 (2.1)	11 (3.5)	8 (2.8)	19 (3.2)
Ethnicity									
Not Hispanic	253 (74.0)	271 (77.4)	348 (94.8)	353 (97.5)	601 (84.8)	624 (87.6)	285 (91.6)	274 (94.8)	559 (93.2)
Age, years									
Mean	20.3	20.0	19.4	19.0	19.8	19.5	19.3	19.3	19.3
SD	6.54	6.71	5.61	5.38	6.09	6.09	5.77	6.68	6.22

ITT population.
Data shown as n (%) unless otherwise specified.
CLA, clascoterone; ITT, intention-to-treat; SD, standard deviation; VEH, vehicle.

TABLE 3.

Proportion of Patients Achieving Treatment Success in Pivotal Studies

Treatment success	CB-03-01/25			CB-03-01/26			Pooled		
	CLA (n = 342)	VEH (n = 350)	Point estimate (95% CI) *P*-value	CLA (n = 367)	VEH (n = 362)	Point estimate (95% CI) *P*-value	CLA (n = 709)	VEH (n = 712)	Point estimate (95% CI) *P*-value
Week 4, n (%)	3 (0.9)	5 (1.4)	0.6 (0.14 to 2.58)	8 (2.2)	7 (1.9)	1.0 (0.36 to 2.78)	11 (1.6)	12 (1.7)	0.9 (0.41 to 2.13)
Adjusted proportion	1.0	1.6	*P* = 0.50	2.3	2.3	*P* = 1.0	1.8	1.9	*P* = 0.87
Week 8, n (%)	13 (3.8)	9 (2.6)	1.4 (0.61 to 3.22)	21 (5.7)	12 (3.3)	1.6(0.79 to 3.18)	34 (4.8)	21 (2.9)	1.5 (0.89 to 2.60)
Adjusted proportion	4.6	3.3	*P* = 0.42	6.5	4.2	*P* = 0.20	5.5	3.7	*P* = 0.13
Week 12, n (%)	55 (16.1)	24 (6.9)	2.3 (1.41 to 3.89)	69 (18.8)	17 (4.7)	3.7 (2.16 to 6.27)	124 (17.5)	41 (5.8)	3.0 (2.07 to 4.27)
Adjusted proportion	18.8	8.7	*P* = 0.001	20.9	6.6	*P* <0.0001	19.9	7.7	*P* <0.0001

ITT population.
CI, confidence interval; CLA, clascoterone; ITT, intention-to-treat; VEH, vehicle.

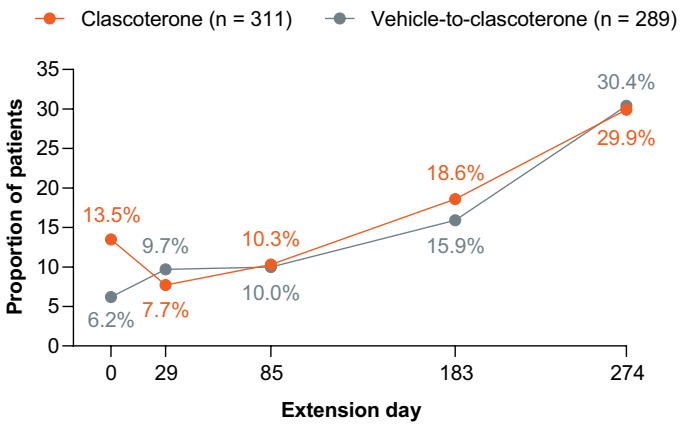
P<0.0001, Table 3), as previously reported.[9] Clascoterone treatment also resulted in significantly larger reductions in lesion counts compared with the vehicle at week 12 (Table 4), as previously reported.[9] The absolute and percent change from baseline in NILC reached statistical significance between patients treated with clascoterone vs vehicle at week 12. For ILC and TLC, the treatment difference for clascoterone vs placebo became significant starting at week 8 for absolute and percent change from baseline (Table 4).

Long-Term Efficacy

The unadjusted proportion of ITT patients previously treated with clascoterone who achieved facial IGA 0/1 increased from 42/311 (13.5%) at extension day 0 to 93/311 (29.9%) at extension day 274, with improvement observed at each visit from extension day 29. Similarly, the unadjusted proportion of ITT patients previously treated with vehicle and switched to clascoterone in the LTE study who achieved facial IGA 0/1 increased from 18/289 (6.2%) at extension day 0 to 88/289 (30.4%) at extension day 274, with improvement observed at each visit (Figure 2).

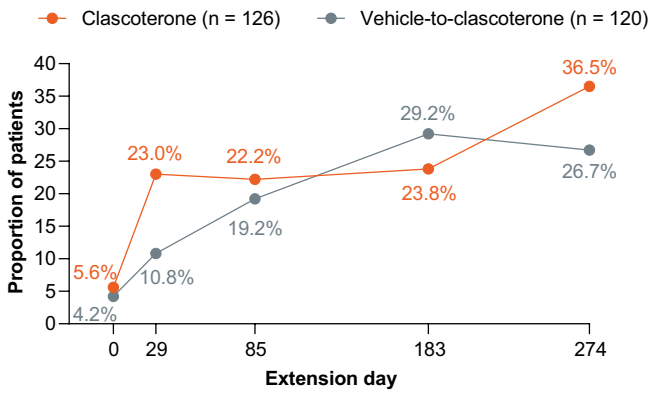
Among ITT patients who treated truncal acne, the unadjusted proportion with truncal IGA 0/1 increased from 12/246 (4.9%) at extension day 0 to 78/246 (31.7%) on extension day 274, with improvement observed at each visit beginning at extension day 29. Although patients were treated for truncal acne only in the LTE study, the unadjusted proportions achieving truncal IGA 0/1 were greater among patients previously treated with clascoterone vs vehicle in the pivotal studies at extension day 274 (46/126 [36.5%] vs 32/120 [26.7%], respectively; Figure 3).

FIGURE 2. Proportion of patients with facial IGA of 0/1 in the long-term extension study by visit.



ITT population.
IGA, Investigator's Global Assessment; ITT, intention-to-treat.

FIGURE 3. Proportion of patients with truncal IGA of 0/1 in the long-term extension study by visit.



ITT population.
IGA, Investigator's Global Assessment; ITT, intention-to-treat.

TABLE 4.

Absolute and Percent Changes From Baseline in Lesion Counts at Each Study Visit in Pivotal Studies

Change from baseline	CB–03–01/25			CB–03–01/26			Pooled		
	CLA (n = 342)	VEH (n = 350)	Point estimate (95% CI) *P*–value	CLA (n = 367)	VEH (n = 362)	Point estimate (95% CI) *P*–value	CLA (n = 709)	VEH (n = 712)	Point estimate (95% CI) *P*–value
NILC, absolute									
Week 4	–9.4	–9.2	–0.3 (–3.53 to 3.00) 0.87	–13.0	–11.5	–1.5 (–4.69 to 1.66) 0.35	–11.5	–10.2	–1.3 (–3.52 to 0.98) 0.27
Week 8	–15.8	–12.4	–3.4 (–6.95 to 0.23) 0.07	–15.3	–15.5	0.2 (–3.39 to 3.76) 0.92	–15.8	–14.0	–1.7 (–4.10 to 0.63) 0.15
Week 12	–20.4	–13.0	–7.3 (–11.10 to –3.50) 0.0001	–19.5	–10.8	–8.7 (–12.40 to –4.50) <0.0001	–19.8	–11.7	–8.1 (–10.78 to –5.44) <0.0001
NILC, percent									
Week 4	–14.7	–16.8	2.1 (–3.68 to 7.85) 0.48	–20.5	–17.4	–3.1 (–8.49 to 2.23) 0.25	–18.1	–16.8	–1.3 (–5.17 to 2.63) 0.52
Week 8	–24.7	–20.9	–3.9 (–10.13 to 2.38) 0.22	–23.7	–24.0	0.2 (–5.77 to 6.25) 0.94	–24.7	–22.5	–2.2 (–6.23 to 1.90) 0.30
Week 12	–32.6	–21.8	–10.8 (–17.60 to –3.90) 0.001	–29.6	–15.7	–13.8 (–20.10 to –7.50) <0.0001	–30.8	–18.3	–12.5 (–16.99 to –7.98) <0.0001
ILC, absolute									
Week 4	–12.5	–12.0	–0.5 (–2.53 to 1.56) 0.64	–14.6	–13.0	–1.6 (–3.66 to 0.53) 0.14	–13.8	–12.7	–1.1 (–2.53 to 0.33) 0.13
Week 8	–16.6	–15.0	–1.6 (–4.01 to 0.83) 0.20	–19.0	–16.3	–2.7 (–4.77 to –0.60) 0.01	–18.1	–15.6	–2.5 (–4.09 to –0.83) 0.003
Week 12	–19.3	–15.4	–3.9 (–6.50 to –1.30) 0.004	–20.1	–12.6	–7.5 (–9.90 to –5.20) <0.0001	–19.7	–13.8	–5.9 (–7.65 to –4.24) <0.0001
ILC, percent									
Week 4	–29.4	–28.5	–0.9 (–5.81 to 3.92) 0.70	–34.5	–30.7	–3.8 (–9.03 to 1.45) 0.16	–32.5	–29.9	–2.6 (–6.02 to –0.86) 0.14
Week 8	–38.9	–35.8	–3.1 (–8.81 to 2.61) 0.29	–45.0	–38.3	–6.6 (–11.77 to –1.52) 0.01	–42.6	–36.9	–5.7 (–9.60 to –1.90) 0.004
Week 12	–44.6	–36.3	–8.3 (–14.40 to –2.20) 0.007	–47.1	–29.8	–17.5 (–23.10 to –11.80) <0.0001	–46.2	–32.5	–13.7 (–17.62 to –9.69) <0.0001
TLC, absolute									
Week 4	–22.6	–21.4	–1.2 (–5.43 to 3.05) 0.58	–28.1	–24.8	–3.4 (–7.64 to 0.88) 0.12	–25.4	–23.2	–2.3 (–5.22 to 0.69) 0.13
Week 8	–33.3	–27.9	–5.4 (–10.16 to –0.63) 0.03	–34.8	–32.2	–2.7 (–7.50 to 2.18) 0.28	–34.2	–30.1	–4.1 (–7.52 to –0.75) 0.008
Week 12	–39.9	–28.5	–11.3 (–16.77 to –5.93) <0.0001	–40.2	–23.5	–16.7 (–22.20 to –11.29) <0.0001	–40.0	–26.1	–13.9 (–17.73 to –10.12) <0.0001
TLC, percent									
Week 4	–21.9	–21.5	–0.5 (–4.74 to 3.81) 0.83	–27.0	–23.2	–3.8 (–7.96 to 0.31) 0.07	–24.5	–22.4	–2.1 (–5.04 to 0.81) 0.15
Week 8	–31.9	–27.6	–4.3 (–9.04 to 0.44) 0.08	–33.3	–30.4	–2.9 (–7.72 to 1.92) 0.24	–32.8	–29.0	–3.8 (–7.14 to –0.50) 0.02
Week 12	–38.0	–28.3	–9.7 (–15.01 to –4.42) 0.0003	–37.6	–22.0	–15.5 (–20.84 to –10.23) <0.0001	–37.8	–25.1	–12.7 (–16.42 to –9.01) <0.0001

ITT population.
CI, confidence interval; CLA, clascoterone; ILC, inflammatory lesion count; ITT, intention–to–treat; NILC, noninflammatory lesion count; TLC, total lesion count; VEH, vehicle.

DISCUSSION

The present post hoc analysis was performed to assess the integrated efficacy of clascoterone in patients aged ≥12 years with moderate-to-severe facial and/or truncal acne vulgaris in the ITT populations across the pivotal and extension studies. The proportion of clascoterone-treated patients with facial IGA of 0/1 became significant at week 12 and continued to increase throughout the LTE study; the reductions in NILC, ILC, and TLC also reached significance at weeks 8 or 12. Efficacy also increased over time for patients reassigned from vehicle to clascoterone treatment and those who were treated for truncal acne.

Results from the current analysis align with the previously published results on the efficacy of clascoterone in patients with acne vulgaris.[3,8,9] This study expands the efficacy analyses to include time points before week 12 in the pivotal studies and the entire ITT population rather than the per-protocol population in the LTE study, allowing a comparison of success rates in the pivotal and extension studies. Although substantial numbers of patients did not complete the LTE study, as expected in a study of this duration, efficacy in the ITT population increased over time during treatment.

This analysis has some limitations. First, there was a high patient discontinuation rate before and during the LTE study, a common problem in studies with long-term follow-up. Therefore, the results of patients who entered and remained in the extension study may not be generalizable to the entire study population, which may further limit generalizability from the clinical studies to real-world patients. Second, the effect of clascoterone treatment on patients' quality of life was not assessed. Third, the majority of patients in the clinical trials were White (>84%) and not of Hispanic or Latino origin (>74%). Future studies should investigate the efficacy of clascoterone in a more diverse patient population.

CONCLUSION

The efficacy of clascoterone cream 1% for the treatment of acne vulgaris increased over time for up to 12 months in all treated patients aged ≥12 years with acne vulgaris. Clinicians may consider counseling patients that treatment persistence is required to maximize the efficacy of clascoterone treatment.

DISCLOSURES

LFE, AAH, and LSG were study investigators. LFE, AAH, and LSG were also compensated advisors to Cassiopea S.p.A. AAH is an employee of the McGovern Medical School of The University of Texas Health Science Center in Houston, Texas, 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. LFE is an employee of the University of California San Diego, which received compensation from Cassiopea S.p.A. for study participation; he also served as an investigator, advisor, or consultant for Almirall, Dermata, Galderma Laboratories, Ortho Dermatologics, and Pfizer. LSG is an employee of the Henry Ford Health System in Detroit, Michigan, which received compensation from Cassiopea S.p.A. for study participation; she also received personal fees for advisory, speaking, consulting, research, and/or other services from Almirall, Foamix, Galderma Laboratories, Novartis, Sol-Gel, and Sun Pharma. JH is an employee of Pharmapace, 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. LM is an employee of Cassiopea S.p.A. and holds stock options in the company. NS is an employee of Sun Pharmaceutical Industries, Inc. DT served in the past as a consultant to Cassiopea, Inc., and is an employee of the College of Medicine at The Pennsylvania State University in Hershey, which received compensation from Cassiopea S.p.A. for study participation; she also received honoraria from Galderma Laboratories and Novartis.

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AUTHOR CORRESPONDENCE

Lawrence F. Eichenfield MD

E-mail:..... leichenfield@rchsd.org