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Efficacy and Safety of Clascoterone Cream 1% for Acne Are Independent of Age and Sex

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ABSTRACT

Acne vulgaris is an inflammatory skin condition affecting adolescents and adults of both sexes. Clascoterone cream 1% is indicated for the topical treatment of acne vulgaris in patients ≥12 years of age based on the results of two Phase 3 trials (NCT02608450 and NCT02608476). This post hoc analysis evaluated the efficacy and safety of clascoterone cream 1% in patient subgroups defined by age (adolescent vs adult) and sex (male vs female). Patients ≥12 years of age with mild-to-moderate acne applied clascoterone cream 1% or vehicle twice daily for 12 weeks. Efficacy was assessed from Investigator's Global Assessment (IGA) treatment success and inflammatory, noninflammatory, and total lesion counts, and safety from frequency and severity of adverse events. Treatment with clascoterone cream 1% vs vehicle resulted in significantly greater IGA treatment success rates for all subgroups: at week 12, 47/287 (16.4%) vs 12/306 (3.9%) adolescent, 77/330 (23.3%) vs 29/309 (9.4%) adult, 32/226 (14.2%) vs 13/252 (5.2%) male, and 92/391 (23.5%) vs 28/363 (7.7%) female patients achieved IGA treatment success. Patients treated with clascoterone cream 1% vs vehicle in all subgroups also experienced significantly greater lesion count reductions. From baseline to week 12, clascoterone cream 1% treatment resulted in significantly larger reductions in lesion counts in adult vs adolescent patients; there were no statistically significant differences between male and female patients. Adverse events were similar across subgroups. These results further support the efficacy and tolerability of clascoterone cream 1% across the spectrum of patients ≥12 years of age with acne vulgaris.

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INTRODUCTION

Acne vulgaris is an inflammatory skin condition that affects 9.4% of the global population.[1] Acne is most common during adolescence but can also develop or persist into adulthood.[2] Both sexes are affected, although more women than men seek treatment for and are diagnosed with acne in adulthood.[3]

Acne pathogenesis is largely androgen driven. Testosterone and dihydrotestosterone regulate sebum production by binding to the androgen receptor in the sebaceous gland.[4,5] This sebum and excess keratinous material stimulate bacteria to colonize in pores, forming noninflammatory (closed or open comedones) and inflammatory (papules, pustules, nodules, and cysts) lesions.[6] Although the involvement of androgens explains the high incidence of acne in adolescents at the onset of puberty, acne pathogenesis is androgen driven regardless of age and sex.

Recommended treatments for acne include topical therapies (retinoids, antibiotics, benzoyl peroxide, salicylic acid, azelaic acid, and clascoterone), systemic antibiotics (doxycycline, minocycline, and sarecycline), hormonal agents (combined oral contraceptives [COCs], spironolactone, and intralesional corticosteroids), and isotretinoin[7]; however, some systemic treatments are not appropriate for all patients based on age and/or sex considerations.[7,8]

Clascoterone cream 1% is a first-in-class androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.[9,10] While the mechanism of action of clascoterone cream 1% for acne treatment is not known,[10] in vitro, clascoterone cream 1% is an androgen receptor antagonist that inhibits both lipogenic and pro-inflammatory signaling necessary for acne pathogenesis.[11,12] In two Phase 3 clinical trials, treatment with clascoterone cream 1% for 12 weeks demonstrated greater efficacy compared with vehicle cream for reducing acne severity and lesion counts in patients ≥9 years of age with moderate-to-severe facial acne, with a favorable safety profile during 9 months of treatment in an open-label extension study.[13,14] This post hoc pooled data analysis of the Phase 3 clinical trials was performed to evaluate the efficacy and safety of clascoterone cream 1% in patient subgroups defined by age (adolescent vs adult) and sex (male vs female).

MATERIALS AND METHODS

Study Design

The multicenter, randomized, double-blind, vehicle-controlled, parallel-group, Phase 3 trials (NCT02608450 and NCT02608476) evaluated the efficacy and safety of topical clascoterone cream 1% in patients with acne vulgaris.[13] Study approval was obtained for all study sites from the appropriate ethics committees, institutional review boards, and national central authorities, and protocols were approved by the US Food and Drug Administration (FDA). The studies were conducted according to the Declaration of Helsinki. Patients and/or parents or guardians provided informed consent/assent.

Patients

The Phase 3 studies enrolled male and nonpregnant female patients ≥9 years of age with moderate-to-severe facial acne vulgaris, defined as Grade 3 or 4 on the Investigator's Global Assessment (IGA) scale with 30 to 75 total inflammatory lesions and 30 to 100 total noninflammatory lesions[13]; only the approved population, patients ≥12 years of age, were included in this post hoc analysis. Patients were required to be on a consistent skin care regimen for at least 1 month prior to enrollment and continue the program for the duration of the study.[13] Exclusion criteria were previously described and included (1) more than 2 facial nodules; (2) use of any topical antiacne treatments or systemic antiacne medications; and (3) participation in a prior clascoterone clinical trial.[13]

Treatments and Assessments

Enrolled patients were randomized 1:1 to receive clascoterone cream 1% or matching vehicle cream. Patients applied approximately 1 gram of clascoterone cream 1% or vehicle cream to their entire face twice daily for 12 weeks.[13] Efficacy assessments were performed at all study visits (screening/baseline, week 4, week 8, and week 12) and included IGA, inflammatory lesion count (ILC), and noninflammatory lesion count (NILC). The IGA was rated on a 5-point scale from 0 (clear) to 4 (severe); lesions were counted manually.[13] The efficacy outcomes were the percentage of patients with treatment success at week 12, defined as an IGA score of clear (0) or almost clear (1) with at least a 2-point reduction compared to baseline (coprimary efficacy endpoint in the Phase 3 trials), and the absolute change from baseline in ILC, NILC (coprimary efficacy endpoints in the Phase 3 trials), and total lesion count (TLC; secondary efficacy endpoint in the Phase 3 trials). Safety assessments included the frequency and severity of adverse events, as previously described.[13]

Statistical Analysis

Sample size calculations were previously reported.[13] Data from patients ≥12 years of age were pooled from the two Phase 3 trials. Efficacy was analyzed in the intention-to-treat set, which included all randomized patients. Safety was analyzed in all patients who received ≥1 application of the study drug.[13] IGA success rates were analyzed using logistic regression, with study ID, age, sex, race, ethnicity, and baseline IGA scores as fixed effects. Changes in lesion counts were analyzed using analysis of covariance, with study ID, age, sex, race, ethnicity, and baseline IGA scores as fixed effects. Missing data were not imputed.

RESULTS

Patient Demographics and Baseline Characteristics

The two Phase 3 studies enrolled 1421 patients ≥12 years of age, of whom 709 were randomized to clascoterone cream 1% and 712 to vehicle cream. Mean age was 19.8 years for patients treated with clascoterone cream 1% and 19.5 years for vehicle-treated patients, and the majority of patients were female (clascoterone cream 1%, 63.9%; vehicle cream, 60.4%), White (clascoterone cream 1%, 91.0%; vehicle cream, 90.3%), and entered the study with moderate acne (IGA score of 3; clascoterone cream 1%, 82.5%; vehicle cream, 84.1%). Lesion counts were comparable between treatment arms (Table 1).

In the subgroup analysis by age, 316 adolescent and 393 adult patients received clascoterone cream 1%, and 325 adolescent and 387 adult patients received vehicle. In the subgroup analysis by sex, 256 male and 453 female patients were randomized to clascoterone cream 1%, and 282 male and 430 female patients were randomized to vehicle. Baseline lesion counts were comparable between adolescent and adult patients and between male and female patients (Table 2).

Efficacy

IGA treatment success

Acne severity, as assessed by IGA score, improved from baseline across the subgroups of adolescent, adult, male, and female patients using clascoterone cream 1% compared with

TABLE 1.

Demographics and Baseline Clinical Characteristics		
Characteristics	**Clascoterone n = 709**	**Vehicle n = 712**
Sex, n (%)		
Male	256 (36.1)	282 (39.6)
Female	453 (63.9)	430 (60.4)
Age, years		
12 to 17, n (%)	316 (44.6)	325 (45.6)
≥18, n (%)	393 (55.4)	387 (54.4)
Mean ± SD	19.8 ± 6.1	19.5 ± 6.1
Race, n (%)		
Asian	8 (1.1)	14 (2.0)
Black or African American	37 (5.2)	40 (5.6)
Other[a]	19 (2.6)	15 (2.1)
White	645 (91.0)	643 (90.3)
IGA score, n (%)		
3 (moderate)	585 (82.5)	599 (84.1)
4 (severe)	124 (17.5)	113 (15.9)
Lesion counts, mean ± SD		
NILC	60.9 ± 21.8	61.9 ± 21.3
ILC	42.6 ± 12.0	42.1 ± 11.7
TLC	103.5 ± 25.4	104 ± 25.1

Phase 3 pooled ITT population ≥12 years of age.
[a]Includes patients who identified as American Indian or Alaska Native, multiple races, Native Hawaiian or Other Pacific Islander, and other race.
IGA, Investigator's Global Assessment; ILC, inflammatory lesion count; ITT, intention-to-treat; NILC, noninflammatory lesion count; SD, standard deviation; TLC, total lesion count.

vehicle-treated patients. Treatment with clascoterone cream 1% vs vehicle led to significantly higher IGA treatment success rates at week 12 in both adolescent (16.4% vs 3.9%; odds ratio [OR; 95% confidence interval (CI)], 4.70 [2.48, 8.91]; *P*<0.001) and adult (23.3% vs 9.4%; OR [95% CI], 3.06 [1.93, 4.85]; *P*<0.001) patients (Figure 1). Similarly, male and female patients treated with clascoterone cream 1% had significantly higher rates of IGA treatment success compared with vehicle-treated patients at week 12 (male patients: 14.2% vs 5.2%; OR [95% CI], 2.99 [1.55, 5.77]; *P*=0.001; female patients: 23.5% vs 7.7%; OR [95% CI], 3.76 [2.40, 5.90]; *P*<0.001; Figure 1). Within the clascoterone cream 1% treatment arm, there were no statistically significant differences in week 12 IGA success rates between adolescent and adult patients (OR [95% CI], 0.77 [0.50, 1.17]; *P*>0.05; Figure 1) or between male and female patients (OR [95% CI], 0.63 [0.40, 1.00]; *P*>0.05; Figure 1).

Lesion counts

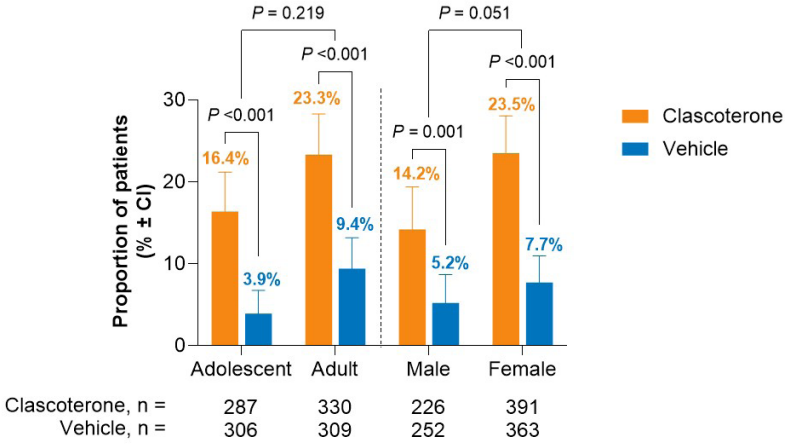
The ILC (Figure 2A), NILC (Figure 2B), and TLC (Figure 2C) decreased from baseline to week 12 across all subgroups of patients using clascoterone cream 1%. For adolescent patients treated with clascoterone cream 1%, the least square mean (LSM) difference (95% CI) compared with vehicle-treated patients was –6.11 (–8.93, –3.30; *P*<0.001) for ILC, –11.30 (–16.20, –6.39; *P*<0.001) for NILC, and –14.07 (–20.54, –7.59; *P*<0.001) for TLC. When comparing adult patients using clascoterone cream 1% with those using vehicle cream, LSM differences (95% CI) for ILC, NILC, and TLC were –6.88 (–9.17, –4.60; *P*<0.001), –9.30 (–13.03, –5.58; *P*<0.001), and –18.02 (–23.48, –12.55; *P*<0.001), respectively. The LSM difference (95% CI) for male patients treated with clascoterone cream 1% vs vehicle was –8.36 (–11.47, –5.26; *P*<0.001) for ILC, –11.00 (–16.00, –6.00; *P*<0.001) for NILC, and –18.11 (–25.17, –11.05; *P*<0.001) for TLC. Finally, for female patients treated with clascoterone cream 1%, the LSM difference (95% CI) vs vehicle for ILC was –6.12 (–8.33, –3.91; *P*<0.001), for NILC was –9.63 (–13.50, –5.76; *P*<0.001), and for TLC was –15.50 (–20.92, –10.08; *P*<0.001). Relative to adolescent patients, adults using clascoterone cream 1% had significantly larger mean reductions from baseline in ILC (LSM difference [95% CI], 3.62 [1.05, 6.19]; *P*=0.006; Figure 2A), NILC (LSM difference [95% CI], 9.06 [4.50, 13.62]; *P*<0.001; Figure 2B), and TLC (LSM difference [95% CI], 13.40 [7.16, 19.64]; *P*<0.001; Figure 2C) at week 12. No statistically significant differences in lesion count reductions from baseline at week 12 were observed between male and female patients using clascoterone cream 1% (ILC: LSM difference [95% CI], 0.85 [–1.85, 3.54]; *P*=0.537; Figure 2A; NILC: LSM difference [95% CI], 1.19 [–3.42, 5.80]; *P*=0.613; Figure 2B; TLC: LSM difference [95% CI], 5.15 [–1.28, 11.59]; *P*=0.116; Figure 2C).

TABLE 2.

Baseline Lesion Counts by Age and Sex								
Lesion Counts	**Adolescent**		**Adult**		**Male**		**Female**	
	Clascoterone n = 316	**Vehicle n = 325**	**Clascoterone n = 393**	**Vehicle n = 387**	**Clascoterone n = 256**	**Vehicle n = 282**	**Clascoterone n = 453**	**Vehicle n = 430**
NILC	65.2 ± 22.6	66.4 ± 20.8	57.4 ± 20.5	58.2 ± 21.0	61.1 ± 22.7	61.9 ± 21.0	60.7 ± 21.3	62.0 ± 21.5
ILC	42.8 ± 12.1	42.6 ± 11.6	42.5 ± 11.9	41.7 ± 11.7	44.2 ± 12.1	43.8 ± 11.7	41.7 ± 11.8	41.0 ± 11.5
TLC	108.0 ± 26.1	108.9 ± 24.6	99.9 ± 24.2	99.9 ± 24.7	105.3 ± 26.7	105.7 ± 24.3	102.5 ± 24.6	103.0 ± 25.5

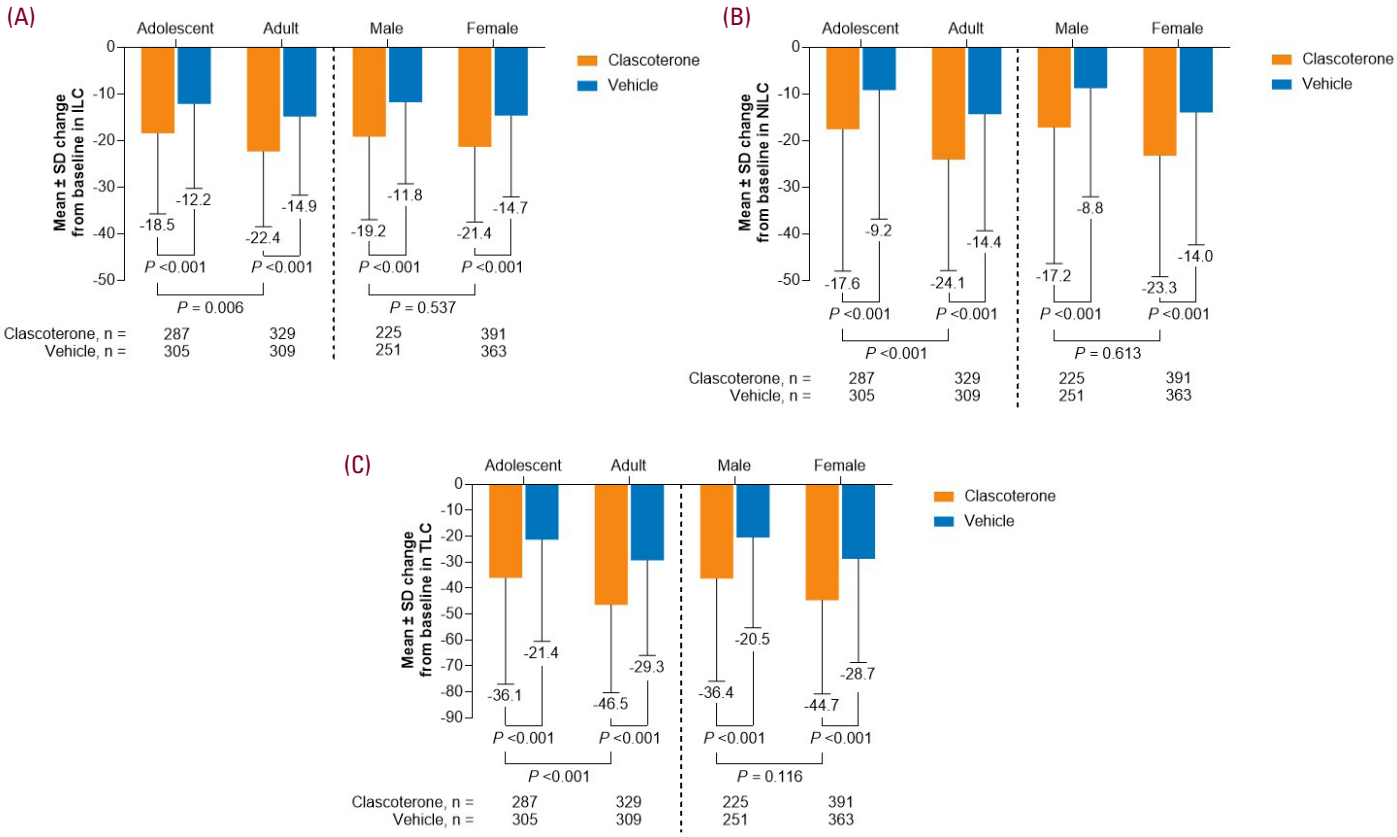
Data are shown as mean ± SD.
ILC, inflammatory lesion count; NILC, noninflammatory lesion count; SD, standard deviation; TLC, total lesion count.

FIGURE 1. Proportions of adolescent, adult, male, and female patients achieving IGA treatment success at week 12 in the Phase 3 clinical studies.



IGA success rates are presented at week 12 for the ITT population of patients ≥12 years of age. IGA success was defined as an IGA score of clear (0) or almost clear (1) and at least a 2-point reduction in IGA score compared to baseline.
CI, confidence interval; IGA, Investigator's Global Assessment; ITT, intention-to-treat.

FIGURE 2. Mean absolute change from baseline at week 12 stratified by age and sex in (A) inflammatory, (B) noninflammatory, and (C) total lesion counts.



The absolute changes from baseline in ILC, NILC, and TLC were evaluated at weeks 4, 8, and 12. Changes in ILC, NILC, and TLC at week 12 are presented.
ILC, inflammatory lesion count; NILC, noninflammatory lesion count; SD, standard deviation; TLC, total lesion count.

TABLE 3.

Summary of Treatment-Emergent Adverse Event by Age and Sex Through Week 12 of the Phase 3 Clinical Trials

Category, n (%)	Adolescent		Adult		Male		Female	
	Clascoterone n = 316	Vehicle n = 325	Clascoterone n = 393	Vehicle n = 387	Clascoterone n = 256	Vehicle n = 282	Clascoterone n = 453	Vehicle n = 430
Any TEAE	34 (10.8)	46 (14.2)	45 (11.5)	45 (11.6)	25 (9.8)	30 (10.6)	54 (11.9)	61 (14.2)
TEAE Severity								
Mild	26 (8.2)	35 (10.8)	38 (9.7)	28 (7.2)	20 (7.8)	22 (7.8)	44 (9.7)	41 (9.5)
Moderate	11 (3.5)	15 (4.6)	8 (2.0)	17 (4.4)	7 (2.7)	10 (3.5)	12 (2.6)	22 (5.1)
Severe	0	2 (0.6)	0	1 (0.3)	0	1 (0.4)	0	2 (0.5)
Treatment-Related TEAEs	5 (1.6)	6 (1.8)	7 (1.8)	16 (4.1)	4 (1.6)	6 (2.1)	8 (1.8)	16 (3.7)
Serious TEAEs	0	1 (0.3)	0	1 (0.3)	0	1 (0.4)	0	1 (0.2)

Safety and tolerability were assessed by monitoring TEAEs through week 12 of the study.
TEAE, treatment-emergent adverse event.

Safety

The frequency of treatment-emergent adverse events (TEAEs) was similar across subgroups and treatment arms (Table 3). Among patients treated with clascoterone cream 1% vs vehicle, TEAEs were observed in 10.8% vs 14.2% of adolescent patients, 11.5% vs 11.6% of adult patients, 9.8% vs 10.6% of male patients, and 11.9% vs 14.2% of female patients. The majority of TEAEs within both age and sex subgroups were mild or moderate in severity, and the frequency of TEAEs considered related to the study drug was similar across subgroups and treatment arms. No serious TEAEs were reported in patients treated with clascoterone cream 1% (Table 3). TEAEs leading to study discontinuation occurred in 2 (0.6%) and 5 (1.5%) adolescent patients, 3 (0.8%) and 9 (2.3%) adult patients, 2 (0.8%) and 5 (1.8%) male patients, and 3 (0.7%) and 9 (2.1%) female patients using clascoterone cream 1% and vehicle, respectively. The most common TEAEs among all subgroups were nasopharyngitis, oropharyngeal pain, and headache. No deaths were reported.

DISCUSSION

In this post hoc analysis of the Phase 3 clinical trials, the efficacy and safety of clascoterone cream 1% were evaluated in subgroups of patients defined by age (adolescent vs adult) and sex (male vs female). The efficacy of clascoterone cream 1% vs vehicle, based on improvements from baseline in IGA score and lesion counts at week 12 previously observed in the overall population,[13] was maintained regardless of patient age or sex. The IGA treatment success rates at week 12 were not significantly different between adolescent and adult or male and female patients treated with clascoterone cream 1%. Reductions in lesion counts from baseline to week 12 were larger in adult vs adolescent patients but not significantly different between male and female patients. The safety profile of clascoterone cream 1% remained similar to that of vehicle cream for all patient subgroups, consistent with results from the Phase 3 studies,[13] and was comparable between adolescent vs adult and male vs female patients. This safety profile supports the use of clascoterone cream 1% in patients ≥12 years of age without further age or sex restrictions.

The efficacy of clascoterone cream 1% in acne reduction is attributed to its inhibition of androgen-induced sebum production.[11] Systemic hormonal therapies that target this pathway include oral isotretinoin, COCs, and spironolactone; however, all of these treatments have age- and/or sex-related considerations that limit their use.[7,8] Isotretinoin requires strict contraceptive use for patients of childbearing potential due to the possibility of fetal congenital malformations,[7] while spironolactone may have effects such as gynecomastia that may not be acceptable to male patients.[8] COCs are only FDA approved for female patients ≥14 to 15 years of age and are contraindicated in patients ≥35 years of age who smoke or have other pre-existing health conditions due to increased risks of myocardial infarction and stroke[7]; thus, their use is restricted in adult female patients who make up the majority of adults seeking acne treatment.[3] In contrast, results from this study support the safe and effective use of clascoterone cream 1% in both male and female patients ≥12 years of age.

Topical therapies are considered the mainstay of acne treatment, but age- and sex-related differences in efficacy are observed for some of these agents.[7] In one study, combination therapy with the retinoid adapalene and benzoyl peroxide was equally safe and effective for reducing acne severity and lesion counts in adolescent vs adult and male vs female patients,[15] similar to our findings. In contrast, in male and female patient subgroups divided into 3 age categories (13–19, 20–29, and ≥30 years of age), tazarotene 0.045% lotion was significantly more effective vs vehicle at reducing acne severity and lesion counts only for younger patients; male and female patients ≥30 years of age did not experience statistically significant improvements compared with vehicle-treated patients.[16] In contrast, in the current study, adults using clascoterone cream 1% experienced significantly larger reductions from baseline to week 12 in lesion counts relative to adolescent patients. This observed difference may be due to Type I error; alternatively, the greater efficacy of clascoterone cream 1% in adult patients compared with adolescents may be due to poor treatment adherence[17] and/or higher androgen levels[18] in adolescents.

Strengths and Limitations of the Analysis

This analysis' strengths include using data from a large, prospective, randomized, placebo-controlled study. One limitation is that combinations of age and sex (eg, male adolescent patients vs female adolescent patients) could not be studied due to the limited number of patients in some subgroups. Thus, interpretations were limited to data stratified by age regardless of sex and by sex regardless of age, and potential interactions between the 2 variables could not be evaluated.

CONCLUSION

In conclusion, clascoterone cream 1% was significantly more effective relative to vehicle for treating acne regardless of patient age or sex. No significant differences in efficacy were observed between male and female patients, but adult patients experienced significantly larger reductions from baseline in lesion counts relative to adolescent patients. The safety profile of clascoterone cream 1% through week 12 was similar among all subgroups. These results provide further evidence supporting the use of clascoterone cream 1% for the treatment of acne vulgaris in patients 12 years of age and older, regardless of age or sex.

DISCLOSURES

JL received an honorarium and consulting fees from Sun Pharma. LFE, AAH, and LSG were study investigators. AAH and LSG were also compensated advisors to Cassiopea S.p.A. 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 an investigator, advisor, or consultant for Almirall, Dermata, Galderma, Ortho Dermatologics, and Pfizer. 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 has also received personal fees for advisory, speaking, consulting, and/or other services with Almirall, Aslan, Galderma, Incyte, Novartis, Pfizer, and Sun Pharma. 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 has also received personal fees for advisory, speaking, consulting, research, and/or other services with Almirall, Foamix, Galderma, Novartis, Sol-Gel, and Sun Pharma. MC is employed as the vice president of medical affairs at Novan, was employed as the senior director of medical affairs at 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. LM served as chief scientific officer of Cassiopea S.p.A. SS is an employee of Veranex. LL has received consulting fees from Arvelle Therapeutics, Celldex, Charite, Gamida Cell, Gossomer Bio, Halozyme Therapeutics, Kenjockety Biopharmaceuticals, mQOL, Noema Pharma, Regeneron Pharmaceuticals, Sun Pharma, UCARE, and the University of Berlin. DS was an employee of Sun Pharmaceutical Industries, Inc., at the time of study conduct. AM is employed as the chief medical officer for Cassiopea S.p.A., and has served as the chief medical officer of Cosmo Pharmaceuticals. NS and KK are employees of Sun Pharmaceutical Industries, Inc.

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