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Oral Sarecycline for Treatment of Papulopustular Rosacea: Results of a Pilot Study of Effectiveness and Safety

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ABSTRACT

Background: Cutaneous rosacea is a common inflammatory skin disorder that often presents with facial papulopustular lesions that are frequently bothersome to patients. Studies have shown oral sarecycline to be effective and safe for acne, with a low risk of side effects that are historically associated with other tetracycline-class drugs such as doxycycline and minocycline, in addition to offering a reduced risk of emergence of resistant bacteria due to its narrow-spectrum of antibiotic activity. Oral sarecycline is FDA-approved for the treatment of acne (2018).

Objective: A pilot study to evaluate the efficacy and safety of oral sarecycline in papulopustular rosacea.

Methods: A 12-week, prospective, parallel-group, investigator-blinded, controlled pilot study was completed evaluating once-daily sarecycline, using weight-based oral dosing as recommended for acne vs control (multivitamin tablet), for the treatment of moderate-to-severe papulopustular rosacea in adult subjects (n=102), aged ≥18 years. The primary efficacy endpoint was Investigator's Global score (IGA; clear or almost clear) and percent reduction in inflammatory lesion count at week 12. Safety and tolerability assessments were performed as well.

Results: A total of 102 subjects were randomized; 97 completed the study. At week 12, IGA improvement was significantly greater for oral sarecycline when compared to the control ($P<0.0001$). Furthermore, absolute and percent reductions in inflammatory lesion counts were significantly greater in the sarecycline group for all weeks (4, 8, and 12) when compared to the control ($P<0.001$). Significant improvement in facial burning, erythema, and pruritus was reported in the sarecycline group, when compared to the control ($P<0.05$). No serious AEs were reported.

Conclusion: Sarecycline was effective, safe, and well-tolerated for treating papulopustular rosacea in adults with marked superiority in efficacy compared to subjects in the control group. With its narrow-spectrum activity, oral sarecycline may be a good option for the treatment of papulopustular rosacea. Additional studies are warranted to confirm the positive results of this pilot study.

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INTRODUCTION

Cutaneous rosacea is a common inflammatory facial dermatosis characterized visibly by persistent central facial erythema, episodic dilation of facial vasculature (flushing), and telangiectasias, with or without inflammatory (papulopustular) lesions and phymatous changes.[1,2] Although prevalence rates vary among evaluated populations, and the disorder is reported to most commonly affect fair-skinned individuals, rosacea is an "equal opportunity disease" that can affect all races, colors, and creeds.[3-5] Beyond the signs and symptoms of rosacea, the disorder may be stigmatizing, can adversely influence workplace behavior and contribution, and has been associated with psychosocial sequelae including, anxiety, depression, embarrassment, and loss of self-esteem.[5] The presentation of patients with papulopustular rosacea is common in clinical practice, with flushing episodes and papulopustular lesions reported as the most bothersome manifestations of rosacea across all disease severities.[6]

Comprehensive management of rosacea requires the incorporation of multiple therapeutic approaches in order to fully address the signs and symptoms that are affecting any given patient with rosacea that we encounter in "real world" clinical practice.[7,8] With regard to use of pharmacologic therapies, the major emphasis to date has been with topical and oral agents that effectively reduce papulopustular lesions.[7,9,10] Among oral therapies, the second generation tetracycline agents, doxycycline and minocycline, have been the most commonly utilized for both acne and rosacea over the past several years, with greater emphasis in the literature on doxycycline for rosacea primarily due to approval by the United States (US) Food and Drug Administration (FDA) of a modified-release sub-antibiotic dose doxycycline capsule (40 mg daily) for papulopustular lesions of rosacea in adults.[11-13] In 2018, the third generation oral tetracycline, sarecycline, was approved by the US FDA for treatment of acne vulgaris in patients 9 years of age and older.[14] Reported potential advantages with sarecycline include a narrow spectrum of antibiotic activity with a lower risk of antibiotic selection pressure and emergence of resistant bacteria (including several gram-negative and anaerobic organisms that inhabit the gastrointestinal [GI] tract), and a low rate of adverse events historically associated with oral tetracyclines, such as photosensitivity, GI side effects, vertigo, and vaginal yeast infections.[15-18]

Due to the well-established role for oral tetracycline agents in rosacea treatment, and the desire to circumvent emergence of antibiotic resistant bacteria as much as possible, the authors have completed a pilot study evaluating the use of oral sarecycline in patients with rosacea. This article reviews the results of this study.

STUDY DESIGN

A prospective, parallel group, randomized, multicenter, investigator-blinded, clinical trial was designed with a target population of one hundred (100) adult subjects with moderate-to-severe papulopustular rosacea. Subjects were randomized to

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receive the brand tablet formulation of oral sarecycline (Seysara) once daily based on weight-based dosing as described in the approved product labeling for acne vulgaris (group A), or one tablet daily of Centrum Adult Multivitamin (group B) in a 3:1 ratio, respectively. The study duration was 12 weeks, with scheduled visits for screening, baseline, at week 4, at week 8, and at week 12 (end of study (EOS]). The study protocol was Institutional Review Board (IRB)-approved. All sites carried out the study in keeping with local legal and regulatory requirements, abided by principles defined in the recognized "Guideline for Good Clinical Practice", and strictly followed ethical principles described in the current version of the Declaration of Helsinki.

Inclusion Criteria

The study required enrollment of adult subjects (≥18 years of age) of either gender. Females of child-bearing potential were required to have a negative urine pregnancy test before enrollment and had to agree to use an effective method of contraception throughout the study. Importantly, a sterile sexual partner was not considered as an adequate form of birth control for entry into the study. All enrolled subjects agreed to minimize recognized or known external factors that might trigger rosacea flare-ups, such as spicy foods, thermally hot foods/drinks, hot ambient environmental temperature, prolonged sun exposure, and alcoholic beverages. Any subject utilizing facial makeup agreed to use the same brands/types of make-up and usage frequency for a minimum period of 14 days prior to study entry and throughout the study. The following inclusion criteria for facial papulopustular rosacea were required at baseline in order to be considered for randomization into the study:

1. Moderate or severe rosacea based on Investigator Global Assessment rating (Table 1)
2. At least 15 and <50 facial papules and pustules; no more than 2 facial nodules
3. Presence of or history of facial erythema and/or flushing

Exclusion Criteria

Subjects were excluded from enrollment in the study for any of the following reasons:

1. Women who are pregnant, lactating, or planning to become pregnant during the study period.
2. Presence of any facial skin condition that would interfere with the diagnosis or assessment of rosacea, including excessive facial hair.
3. Moderate or severe rhinophyma, dense telangiectasia, or plaque-like facial edema.
4. History of hypersensitivity or allergy to all tetracyclines, or to any component of the formulation, history of *C difficile*-associated colitis, or history of intracranial hypertension (pseudotumor cerebi).
5. Severe erythema, dryness, scaling, pruritus, stinging/burning, or edema.
6. Use within 6 months of oral retinoids or therapeutic vitamin A supplements of greater than 10,000 units/day (standard multivitamins are allowed).
7. Initiation of estrogens or oral contraceptives less than 3 months prior to baseline visit.
8. Use of systemic antibiotics with a known impact on the severity of facial rosacea and/or systemic corticosteroids within 1 month of baseline visit.
9. Use of topical agents including corticosteroids, antibiotics or rosacea medications, wax epilation or facial sauna/spa/cosmetic treatments within 2 weeks of baseline visit.
10. Active bacterial folliculitis.
11. Exposure to potential rosacea trigger factors such as excessive, prolonged exposure to sunlight, or weather extremes.
12. Presence of conditions that may compromise subject ability to comply with study requirements such as excessive alcohol use and/or abuse of licit or illicit drugs.
13. Presence of any condition that in the opinion of the Investigator would interfere with study evaluations or optimal participation in the study.
14. Participation in an investigational drug study within 30 days prior to baseline visit.
15. Prior laser therapy, electrodessication, or phototherapy to the facial area within 180 days prior to baseline visit.

A primary duty of the investigator is discontinuation of study participation if desired by a subject at any point in time or if the health or well-being of a subject is threatened by continuation in the study. If premature study discontinuation occurs, the primary reason should be determined as best as possible.

STUDY EVALUATIONS

At each visit, including screening, baseline, at week 4, at week 8, and at week 12 (EOS), informed consent and standard data collections were completed including inclusion/exclusion criteria, medical and surgical history, physical examination, vital signs, concomitant medications, tolerability and safety assessments, efficacy evaluations, and urine pregnancy testing (where applicable) following the *Schedule of Study Assessments and Procedures* mandated by the study protocol. Subject Global Assessment (SGA) ratings were also captured. Other than urinary pregnancy testing completed at all study visits in females of child-bearing potential, no other routine laboratory testing was completed during the study.

Efficacy Assessments

Primary Endpoints

The percent of subjects achieving clear or almost clear based on the protocol mandated IGA grading scale and the percent reduction of inflammatory lesions at week 12 are the primary endpoints. The IGA score was determined at each visit (Table 1).

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TABLE 1.

Investigator Global Assessment (IGA) Grading Scale	
Grade	**Description**
0 = Clear	*No inflammatory lesions present, no erythema*
1 = Almost Clear	*Very few small papules/pustules, very mild erythema present*
2 = Mild	*Few small or large papules/pustules, moderate erythema*
3 = Moderate	*Several small or large papules/pustules, moderate erythema*
4 = Severe	*Numerous small and/or large papules/pustules, severe erythema*

Secondary Endpoints

The percent of subjects achieving clear or almost clear based on the IGA rating and percent reduction of inflammatory lesions at week 4 and at week 8 are the secondary endpoints.

Lesion Counts (Papules/Pustules)

Counting of the number of papules/pustules at each study visit was completed by the investigator using only the face in the assessment (the whole face down from the hairline edge to the mandibular line).

Subject Global Assessment (SGA)

The Subject Global Assessment (SGA) was rated by all randomized subjects at each study visit using a 5-point comparative grading system (much worse, slightly worse, same, slightly better, much better).

Study Compliance

Compliance with the study treatment regimen was assessed at each visit by study site personnel. If the total amount of study medication used was less than half of the quantity of dispensed drug, those subjects were excluded from statistical analysis.

SAFETY AND TOLERABILITY EVALUATIONS

Local Signs and Symptoms (Facial Skin)

At each visit, the current severity of erythema, dryness, peeling, and oiliness using a 5-point scale for each parameter was rated as defined in the study protocol (0=absent, 1=trace, 2=mild, 3=moderate, 4=severe). The current severity of pruritus was documented from the subject through questioning by the investigator at each visit using a 6-point scale as defined in the study protocol (0=absent, 1=trace, 2=mild, 3=moderate, 4=marked, 5=severe).

Adverse Events

All subjects were monitored throughout the study for adverse events (AEs), irrespective of causality, including any illness, injury, toxicity, sensitivity, or sudden death. A reported AE must either not be present pre-study or must worsen in either intensity or frequency during the study. An unexpected AE was defined as any treatment-related AE that is not identified in nature, severity, or frequency in current literature as related to the study medication. Any serious or treatment-related unexpected AEs occurring during the study were promptly reported to the IRB as per protocol-mandated study guidelines.

Statistical Analysis

An estimated total of 100 subjects was the target sample size for this pilot study.

Statistical analyses were conducted on an intent-to-treat basis, with all tests two-sided and interpreted at a 5% significance level. Descriptive statistics (ie, mean, standard deviation, etc.) were provided for all continuous variables and frequencies and for all categorical variables, presented by treatment group. Comparisons between treatment groups will be performed using an ANCOVA technique; baseline values were used as the covariate providing necessary assumptions for parametric test satisfaction. The Wilcoxon Rank-Sum test was used if needed assumptions for parametric testing were not satisfied; comparative mean scores were also evaluated. Safety analyses were performed assessing incidence and severity of local tolerance signs and symptoms and adverse and/or unexpected events, including comparisons of mean scores. A complete listing of all reports of adverse and/or unexpected events was collected and tabulated.

STUDY OUTCOMES

Among the 102 subjects enrolled, 97 subjects completed the study, 72 in the sarecycline-treated group and 25 in the Centrum-treated group. Five subjects withdrew for varying reasons. All results throughout this report are based on the 97 subjects that completed the study. The majority of subjects were female (80; 82%) and white (95; 98%). The mean age was 52.4 years (SD = 14.5 years) and similar in both study groups, with an age range of 22 years to 81 years. Subjects were enrolled between 6/30/2019 through 7/1/2020, with a study period of 455 days. Times between study visits were consistent over all study sites and treatment groups.

Primary Endpoints

IGA Primary Endpoint

At baseline, IGA scores were evenly distributed between treatments at baseline (van Elteren test, P=.75). There were significant reductions in IGA scores from baseline to Week 12 for both study groups (sarecycline P<.001, Centrum P=.0008), with the sarecycline group exhibiting greater reductions (P<.0001). With regard to achieving clear or almost clear at week 12, sarecycline performed significantly better than Centrum (P<.0001), with 75 percent of sarecycline-treated subjects IGA-rated as clear or almost clear by EOS compared to 16 percent of Centrum-treated subjects. Data for the IGA primary endpoint are depicted in Table 2. *The percentage of subjects reaching the IGA primary endpoint was 75 percent (54/72 subjects) in the sarecycline group compared to 16 percent (4/25 subjects) in the Centrum group.*

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TABLE 2.

Primary Efficacy Endpoint Data Based on IGA Ratings at Each Study Visit

Treatment	Visit	Clear or Almost Clear	Clear	Almost Clear	Mild	Moderate	Severe	P-value IGA	P-value Almost Clear	P-value C vs. S
Centrum (C)	Baseline	0				24 (94%)	1 (6%)	-	-	-
	Week 4	2 (8%)		2 (8%)	4 (16%)	19 (76%)		.0177	.480	< .0001
	Week 8	3 (12%)		3 (12%)	9 (38%)	12 (50%)		.0009	.248	< .0001
	Week 12	4 (16%)	2 (8%)	2 (8%)	10 (40%)	11 (44%)		.0008	.134	< .0001
Sarecycline (S)	Baseline	0				67 (93%)	5 (7%)	-	-	-
	Week 4	15 (21%)	3 (4%)	12 (17%)	33 (46%)	24 (33%)		< .0001	.0003	-
	Week 8	32 (45%)	12 (17%)	20 (28%)	29 (40%)	11 (15%)		< .0001	< .0001	-
	Week 12	54 (75%)	18 (25%)	36 (50%)	10 (14%)	8 (11%)		< .0001	< .0001	-

TABLE 3.

Primary Efficacy Endpoint Data Based on Total Inflammatory Lesion Counts at Each Study Visit

		CENTRUM (C)			SARECYCLINE (S)			C vs. S
Visit	Statistics	Inflammatory Lesions	Change from Visit 1	P-value	Inflammatory Lesions	Change from Visit 1	P-value	P-value
Visit 1 (Baseline)	Mean (SD)	19 (7)			21 (9)			0.13
	Median	17 (16, 20)			18 (16, 23)			
	Min, Max	15, 42			14, 48			
Visit 2 (Week 4)	Mean (SD)	14 (10)	-5 (5)	.0003	11 (10)	-11 (6)	< .0001	< .0001
	Median	12 (9, 16)	-5 (-9, -2)		8 (4, 13)	-10 (-15, -7)		
	Min, Max	1, 49	-15, 7		0, 43	-28, 4		
	% Change from BL (SD)		-31 (30)	.0002		-56 (29)	< .0001	< .0001
Visit 3 (Week 8)	Mean (SD)	12 (11)	-8 (7)	.0005	7 (8)	-14 (6)	< .0001	< .0001
	Median	8 (5, 12)	-10 (-14, -5)		4 (1, 10)	-15 (-16, -11)		
	Min, Max	1, 47	-16, 15		0, 32	-28, 4		
	% Change from BL (SD)		-44 (42)	.0005		-71 (27)	< .0001	.0002
Visit 4 (Week 12)	Mean (SD)	9 (11)	-11 (7)	< .0001	5 (7)	-16 (6)	< .0001	< .0001
	Median	6 (4, 8)	-11 (-15, -7)		2 (0, 8)	-16, (-19, -13)		
	Min, Max	0, 45	-22, 4		0, 32	-31, 4		
	% Change from BL (SD)		-60 (32)	< .0001		-80 (24)	< .0001	< .0001

Key: BL, Baseline; SD, Standard Deviation

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Lesion Count Primary Endpoint

Total inflammatory lesion counts (papules, pustules) were evenly distributed at baseline (*P*=0.13). Both sarecycline and Centrum produced absolute and percent reductions in lesion counts at weeks 4, week 8, and week 12 (EOS) relative to baseline (*P*<.001 for all). Absolute and percent lesion count reductions were greater in the sarecycline group at all study visits (*P*<.001 for all). Summary data for total inflammatory lesion counts observed throughout the study are shown in Table 3. *These results demonstrate statistically superior total inflammatory lesion count reductions at week 12 (EOS) with sarecycline as compared to Centrum (P<.0001).* Then secondary endpoint evaluations of total inflammatory lesion count reductions at week 4 and week 8 in both study groups are also shown in Table 3.

Subject Global Assessment

There was a significant favorable change in Subject Global Assessment (SGA) scores in the sarecycline group (*P*<.001), but no significant change in the Centrum group (*P*=.68) from week 4 to week 12 (EOS). At week 12, 44 percent, 35 percent, and 21 percent of subjects reported "much better", "slightly better", or "same" in the sarecycline group, respectively, as compared to 16 percent, 16 percent, and 56 percent in the Centrum group, respectively. No sarecycline-treated subjects reported worsening of rosacea at any time point during the study, as compared to 12 percent of Centrum-treated subjects at week 8 and week 12.

Local Signs and Symptoms (Facial Skin)

Erythema, dryness, peeling, oiliness, and pruritus were evenly distributed between treatment groups at baseline; burning sensation was also not significantly different between both groups (*P*=.07). Absent or trace ratings for erythema at week 12, were significantly better in the sarecycline group (63 percent of subjects) as compared to the Centrum group (12% of subjects; *P*<.0001). From baseline to week 12, significant reductions in dryness were observed in the sarecycline group (*P*=.01). Absent or trace ratings for dryness at week 12 were reported in 98 percent in the sarecycline group and 84 percent in the Centrum group (*P*=.02). Significant reductions in peeling from baseline to week 12 were observed in the sarecycline group (*P*=.02) and not in the Centrum group (*P*=.77), with absent or trace peeling noted in 98 percent of sarecycline-treated subjects. Oiliness was not commonly observed among subjects in either treatment group. Sarecycline-treated subjects exhibited statistically significantly greater reduction in sensation of skin burning (*P*=.01), with absent or trace ratings documented in 96 percent of subjects receiving sarecycline versus 76 percent of those receiving Centrum (*P*=.038). Absent or trace ratings of pruritus at week 12 were significantly greater in the sarecycline group 94 percent of subjects) than in the Centrum group (76 percent of subjects; *P*=.023), with significant reductions also observed only in the sarecycline group from baseline to week 12 (*P*<.001).

Adverse Events

There were 26 AEs that occurred in 16 subjects in the sarecycline group at some time point during the study. Nine were considered "definitely related", 3 were "probably related", and 3 were "possibly related" to study drug as determined by the investigator. Seven AEs were rated as mild, 17 as moderate, and 2 as severe based on AE severity grading, with none determined to be serious AEs. Among the AEs of specific interest in patients treated with a tetracycline derivative, nausea occurred in 2 subjects, headache in 2 subjects, and facial sunburn in 2 subjects (1 mild case determined to be unrelated to study drug). Dosing was interrupted in 2 subjects for AEs determined to not be related to study drug (tinea versicolor, "unknown rash"). Sarecycline was discontinued in 3 subjects, with 2 AEs probably related to sarecycline (headache, gastroenteritis) and 1 AE unlikely related to sarecycline ("boil on leg"). In all other cases, no specific interventions occurred; all AEs resolved in cases where follow-up with subjects was possible, with the two exceptions of one case of mild nausea that was ongoing and one case of headache that was ongoing at EOS, neither of which underwent therapeutic intervention.

CONCLUDING REMARKS

Papulopustular rosacea is a common presentation of cutaneous rosacea which has been reported to be bothersome to affected patients. In this investigator-initiated, investigator-blinded, 12-week study, 97 subjects were enrolled. Seventy-two subjects received oral sarecycline once daily (daily dose based on patient weight) and 25 subjects received one Centrum oral multivitamin tablet daily. The results of the study demonstrate that oral sarecycline is efficacious for papulopustular rosacea in adults based on both IGA assessments and documentation of total inflammatory lesion reductions. Additionally, evaluation of local signs and symptoms of facial skin are typically included as part of the safety and tolerability evaluation. However, as this study assesses signs and symptoms at baseline and throughout the study, and is evaluating oral therapy only, the noted significant improvements in facial skin manifestations such erythema, dryness, peeling, burning, and pruritus are believed to be reflective of the therapeutic response of rosacea to oral sarecycline. The type, frequency, and severity of AEs reported in this study are consistent with what has been reported with oral sarecycline in the pivotal trials completed that support its US FDA approval for treatment of acne vulgaris. Additional studies are suggested to further evaluate the use of oral sarecycline for the treatment of rosacea.

DISCLOSURES

Dr. Del Rosso is a research investigator, consultant, and speaker for Almirall, Bausch Health, Galderma, Leo Pharma, and Vyne Therapeutics, and a consultant and speaker for EPI Health and Mayne Pharma.

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REFERENCES

1. Ahn CS, Huang WW. Rosacea pathogenesis. *Dermatol Clin.* 2018;36(2):81-86.
2. Wilkin J, Dahl M, Detmar M, et al. Standard classification of rosacea: report of the National Rosacea Society expert committee on the classification and staging of rosacea. *J Am Acad Dermatol.* 2002;46(4):584-587.
3. Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus recommendations from the American Acne & Rosacea Society on the management of rosacea, part 1: a status report on the disease state, general measures, and adjunctive skin care. *Cutis.* 2013;92(5):234-40.
4. Alexis AF, Callender VD, Baldwin HE, et al. Global epidemiology and clinical spectrum of rosacea, highlighting skin of color: review and clinical practice experience. *J Am Acad Dermatol.* 2019 ;80(6):1722-1729.
5. Oussedik E, Boucier M, Tan J. Psychosocial burden and other impacts of rosacea on patient's quality of life. *Dermatol Clin.* 2018;36(2):103-113.
6. Harper J, Del Rosso JQ, Ferrusi IL. Cross-sectional survey of the burden of illness of rosacea by erythema severity. *J Drugs Dermatol.* 2018;17(2):150-158.
7. Schaller M, Almeida LMC, Bewley A, et al. Recommendations for rosacea diagnosis, classification and management: update from the global ROSacea COnsensus 2019 panel. *Br J Dermatol.* 2020;182(5):1269-1276.
8. Del Rosso JQ, Thiboutot D, Gallo R. Consensus recommendations from the American Acne & Rosacea Society on the management of rosacea, part 5: a guide on the management of rosacea. *Cutis.* 2014;93(3):134-138.
9. Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus recommendations from the American Acne & Rosacea Society on the management of rosacea, part 3: a status report on systemic therapies. *Cutis.* 2014;93:18-28.
10. Del Rosso J, Tanghetti E, Webster G, et al. Update on the management of rosacea from the American Acne & Rosacea Society (AARS). *J Clin Aesthet Dermatol.* 2019;12(6):17-24.
11. McGregor SP, Alinia H, Snyder A, et al. A review of the current modalities for the treatment of papulopustular rosacea. *Dermatol Clin.* 2018;36(2):135-150.
12. Del Rosso JQ, Sachsman SM. Oral antibiotics in dermatology: a practical overview with clinically relevant correlations and management suggestions. In: Yamauchi PS, Ed. Biologic and systemic agents in dermatology. Springer International Publishing, Cham, Switzerland, 2018:531-539.
13. ORACEA PI
14. SEYSARA PI
15. Moore AY, Charles JEM, Moore S. Sarecycline: a narrow spectrum tetracycline for the treatment of moderate-to-severe acne vulgaris. *Future Microbiol.* 2019;14(14):1235-1242.
16. Moore A, Green LJ, Bruce S, et al. Once-daily oral sarecycline 1.5 mg/kg/day Is effective for moderate to severe acne vulgaris: results from two identically designed, phase 3, randomized, double-blind clinical trials. *J Drugs Dermatol.* 2018;17(9):987-996
17. Zhanel G, Critchley I, Lin LY. Microbiological profile of sarecycline, a novel targeted spectrum tetracycline for the treatment of acne vulgaris. *Antimicrob Agents Chemother.* 2018;63(1):e01297-e1318.
18. Moore AY, Del Rosso J, Johnson JL, et al. Sarecycline: A review of preclinical and clinical evidence. *Clin Cosmet Investig Dermatol.* 2020;13:553-560.

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