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

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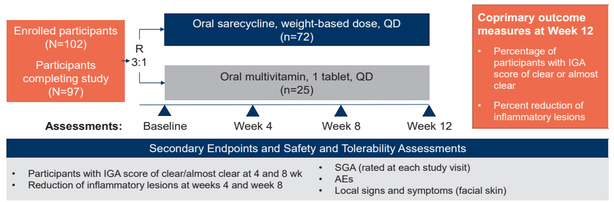
INTRODUCTION

- Papulopustular rosacea is a phenotype of rosacea characterized by papules and pustules located centrally on the face[1]
- Oral antibiotics such as tetracyclines are first-line treatments for patients whose disease does not respond to topical therapies or for patients with multiple papules and pustules[2]
- Sarecycline is a narrow-spectrum antibiotic approved by the US Food and Drug Administration in 2018 for treatment of moderate to severe acne vulgaris[3]
- Because of the well-established role for oral tetracyclines in rosacea and to limit emergence of antibiotic-resistant bacteria, a pilot study was conducted to assess oral sarecycline in adults with papulopustular rosacea (Clinicaltrials.gov identifier: NCT04555525)

METHODS

- This was a prospective, parallel-group, 12-week, randomized, investigator-blinded, pilot study of oral sarecycline treatment for adults with moderate to severe papulopustular rosacea (Figure 1)
- Eligible participants were adults (aged ≥18 years) with moderate or severe rosacea based on Investigator Global Assessment (IGA) rating with ≥15 and ≤50 facial papules/pustules and ≤2 facial nodules
- Statistical analyses were conducted on an intention-to-treat basis; all tests were 2-sided and interpreted at a 5% significance level

Figure 1. Study Design



AE, adverse event; IGA, Investigator Global Assessment; QD, once daily; R, randomization; SGA, Subject Global Assessment.

RESULTS

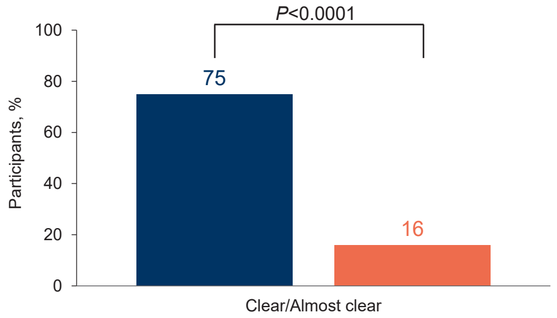
Disposition and Baseline Characteristics

- 102 adults with moderate-to-severe papulopustular rosacea were enrolled; 97 completed the study (sarecycline [n=72]; multivitamin [n=25])
- Most participants were female (n=80 [82%]) and white (n=95 [98%]), with mean (standard deviation) age of 52.4 (14.5) years

Efficacy

- Sarecycline was associated with significantly greater percentage of participants achieving IGA endpoint at week 12 vs multivitamin (coprimary endpoint; *P*<0.0001; Figure 2)
  - Significant differences in IGA score in favor of sarecycline vs multivitamin were observed as early as week 4 (21% vs 8%; *P*<0.0001)

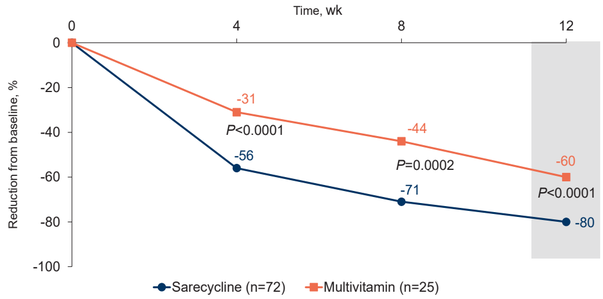
Figure 2. Participants Achieving IGA Scores of Clear/Almost Clear at Week 12 (Coprimary Endpoint)



IGA, Investigator Global Assessment.

- Sarecycline treatment was associated with statistically significantly greater reduction in inflammatory lesion count at week 12 vs multivitamin (coprimary endpoint; *P*<0.0001; Figure 3)
  - Rapid reduction in inflammatory lesion count was observed with sarecycline vs multivitamin as early as week 4 (Figure 3)

Figure 3. Percent Change From Baseline in Inflammatory Lesion Counts

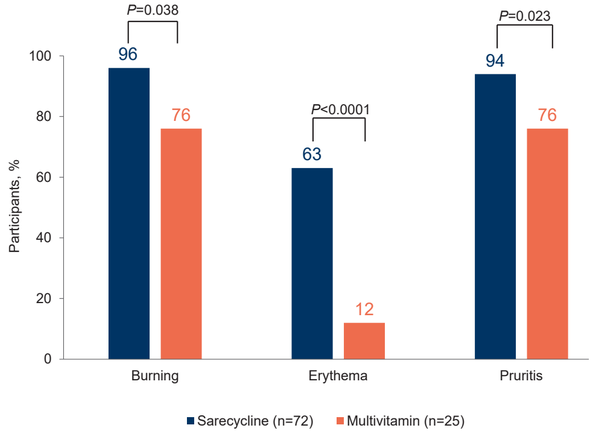


Grey shading indicates coprimary endpoint at week 12.

Secondary Endpoints and Skin Symptoms

- At week 12, absent or trace ratings were significantly better in the sarecycline vs multivitamin group for facial symptoms of burning (*P*=0.038), erythema (*P*<0.0001), and pruritus (*P*=0.023; Figure 4); significant differences were also observed for absent or trace dryness (*P*=0.02) and oiliness (*P*=0.039)

Figure 4. Participants With Absent/Trace in Facial Symptoms at Week 12



Safety

- 26 adverse events (AEs) occurred in 16 participants in the sarecycline group
  - 7 rated as mild, 17 as moderate, 2 as severe
  - No serious AEs reported
- Sarecycline was discontinued in 3 participants, with 2 AEs (headache and gastroenteritis) considered probably related to sarecycline
- AEs of interest with a tetracycline derivative that occurred in the sarecycline group were nausea (n=2), headache (n=2), and facial sunburn (n=2)

CONCLUSIONS

- In this pilot study, oral sarecycline demonstrated effectiveness for treatment of papulopustular rosacea in adults as early as 4 weeks based on IGA scores and reductions in inflammatory lesion counts
- Sarecycline improved facial symptoms, including burning, erythema, and pruritis
- Sarecycline was associated with a favorable safety and tolerability profile, with AEs consistent with prior studies
- Additional studies are warranted to further evaluate oral sarecycline as treatment for papulopustular rosacea

Acknowledgments:

This study was supported by Almirall, LLC. Medical writing, editorial assistance, and graphical support were provided under the direction of the authors by MedThink SciCom.

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