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

INTRODUCTION
• Papulopustular rosacea is a phenotype of rosacea characterized by papules and pustules located centrally on the face.
• 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.
• Sarecycline is a narrow-spectrum antibiotic approved by the US Food and Drug Administration in 2018 for treatment of moderate to severe acne vulgaris.
• 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.

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.
• 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 52 facial nodules.
• Statistical analyses were conducted on an intention-to-treat basis; all tests were 2-sided and interpreted at a 5% significance level.

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<0.001; 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).

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<0.001), 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=0.019).

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 pruritus.
• 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.

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References: