ORAL SARECYCLINE FOR TREATMENT OF PAPULOPUSTULAR ROSacea: RESULTS OF A PILOT STUDY EVALUATION OF EFFECTIVENESS AND SAFETY

By James Q. Del Rosso, DOa; Leon H. Kirikc, MDc; Cheryl Effron, MDb; Zoe D. Draelos, MDb

a. JDR Dermatology Research; Thomas Dermatology, Las Vegas, NV. b. Clinical Professor of Dermatology, Latin School of Medicine at Mount Sinai, New York, NY; Indiana University Medical Center, Indianapolis, IN; Medical Director, Physicians Skin Care, PLLC; DermResearch, Skin Sciences, PLLC, Louisville, KY. c. Medical Director, Cosmetic Dermatology of Orange County, Huntington Beach, CA; d. Dermatology Consulting Services, PLLC, High Point, NC

Introduction
Cutaneous rosacea is a common inflammatory facial dermatosis characterized by persistent central facial erythema, episodic dilation of venules (flushing), and telangiectasias, with or without papulopustular lesions and phymas.1-2 Beyond the signs and symptoms of rosacea, the disorder may be stigmatizing, can negatively influence workplace behavior, and has been associated with several adverse psychological sequelae.3-4 Flushing episodes and papulopustular lesions have been reported by patients to be the most bothersome manifestations of rosacea across all severities.5-6

The second-generation broad spectrum tetracyclines—sarecycline and minocycline—have been commonly used as oral therapies for rosacea over the past several years.7-8 Sarecycline, a new extended-release formulation of doxycycline, was FDA approved for treatment of papulopustular rosacea in adults based on IGA assessments, total inflammatory lesion reductions, SGA outcomes, and safety evaluations.9

Study Design
This was a prospective, parallel group, randomized, multicenter, investigator-blinded, IRB-approved clinical trial.

Study duration: 12 weeks
Scheduled visits/assessments: Screening; Baseline, Week 4; Week 8, Week 12 (end of study (EOS))

Eligible subjects: Adults (≥18 years) of either gender with moderate or severe rosacea, based on Investigator Global Assessment rating with at least 15 and ≥20 facial papules and pustules but no more than 2 facial nodules.

Randomization: Subjects were randomized to 2 groups at a 3:1 ratio
Group A: Received the brand label formulation of oral sarecycline (Seysara®) once daily based on weight-based dosing as described in the approved product labeling for acne vulgaris
Group B: Received one tablet daily of Centrum Adult Multivitamin

Efficacy Endpoints: Primary: Percent of subjects achieving clear or almost clear based on IGA grading scale;
Percent reduction of inflammatory lesions at week 12
Secondary: Percent of subjects achieving clear or almost clear based on the IGA rating and percent reduction of inflammatory lesions at week 4 and week 8;
Subgroup Global Assessment (SGA);
Tolerability, as measured by severity of erythema, dryness, peeling, oiliness, and pruritus

Statistical Analysis: Conducted on an intent-to-treat basis; all tests two-sided and interpreted at a 5% significance level. Comparisons between treatment groups performed using an ANCOVA technique; baseline values used as the covariate providing necessary assumptions for parametric test satisfaction; The Wilcoxon Rank-Sum test used if needed assumptions for parametric testing were not satisfied; comparative mean scores were also evaluated.

Study Evaluations
IGA Grading Scale

Table 2. Primary Efficacy Endpoint Data Based on Total Inflammatory Lesion Counts at Each Study Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Lesion Type</th>
<th>Sarecycline</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 0</td>
<td>Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td>Baseline</td>
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Figure 1.

IGA Improvement: 12 Weeks

References