

PATIENT REPORTED OUTCOMES AND INVESTIGATOR GLOBAL ASSESSMENT OF ACNE VULGARIS AMONG PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS ADMINISTERED SARECYCLINE IN REAL-WORLD COMMUNITY PRACTICES ACROSS THE U.S. (PROSES STUDY)

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BACKGROUND

- Acne Vulgaris, hereinafter referred to as acne, affects up to 50 million Americans and is the most common skin condition in the United States (U.S.).
- Acne has been shown to negatively affect QoL, resulting in low self-esteem and increased social and emotional anxiety.^{2,3}
- Patients with acne report more effects of their skin condition on their functioning, emotions, and symptoms than do patients with isolated benign skin lesions or those in the normative sample.⁴
- Acne has also been associated with considerable negative psychosocial impact, causing significant negative effects on self-image.⁵
- Sarecycline is a newer oral tetracycline class of narrow spectrum antibiotic, a first line therapy treatment for moderate to severe acne patients. Sarecycline is a viable option for Acne patients to reduce disease burden, due to its safety profile and efficacy demonstrated in two identical Phase-III randomized, controlled trials.⁶
- Assessing patient reported outcomes (PROs) and clinical effectiveness (in terms of Investigator Global Assessment (IGA) of acne) among patients in real-world setting is important to inform HCPs and Payers to aid their clinical and reimbursement decisions, respectively.

OBJECTIVE

- To evaluate PROs in terms of self-perceived acne signs and impact of acne on emotional/social functioning, and evaluate IGA success at Week-12, among acne patients administered sarecycline, in community practices across the U.S.

METHODS

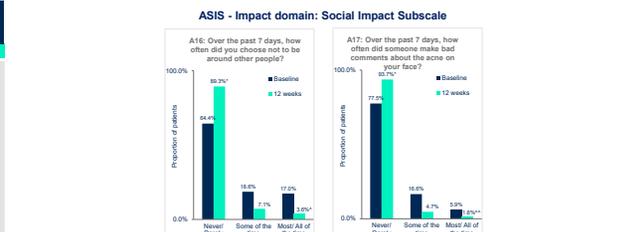
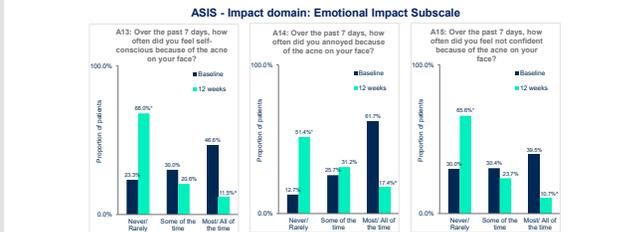
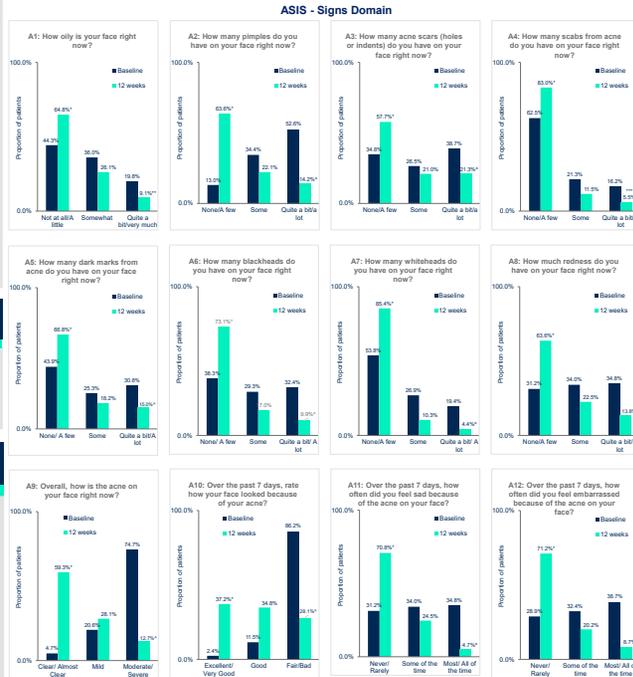
- Single-arm, prospective cohort study (PROSES) was conducted with moderate to severe non-nodular acne patients ≥9 years who were prescribed sarecycline in real-world community practices in the US.
- A total of 300 subjects were enrolled from 30 community practices across the U.S.
 - Primary outcome measures included validated Acne Symptom and Impact Scale (ASIS) questionnaire responses (from subjects ≥12 years) and caregivers (for subjects 9-11 years) at week-12 and corresponding change from baseline (CFB).
 - ASIS is a 17-item validated instrument that asks patients about the signs and impact of acne on emotional and social wellbeing and is a viable tool to assess disease burden and treatment outcomes.⁷
 - ASIS contains Signs domain (items 1-9) and Impact domain (emotional (items 10-15) & social (items 16-17)); all items are scored on a five-point adjectival response scale (score 0-4); higher scores indicate severe symptoms or negative impact of Acne.
 - Secondary outcome measure was physician-reported face IGA collected on a five-point adjectival response scale (score 0 (clear) - 4 (severe)). IGA success was assessed as ≥2-grade improvement in IGA and a score 0 [clear] or 1 [almost clear] at week-12.
 - Last observation carried forward (LOCF) imputation was considered for imputing missing data for the calculation of IGA success; however, there was no missing data at week-12, within the analytic population.
 - Physician satisfaction with sarecycline outcome at individual patient-level was also assessed at week-12.

RESULTS

- A total of 253 acne patients completed the study.
 - Pediatric (9-17 years): 39.92%; adults (>18 years): 60.08%.
 - Male: 33.60%; Female: 66.40%.
 - White: 68.39%; African-American: 9.88%; Asian: 7.11%.
- A statistically significant increase in patients with clear or almost clear acne at week-12 (baseline: 0%, week-12: 58.90%; p<0.0001). Correspondingly, IGA success was observed in majority (58.90%) of acne patients at week-12.
- A statistically significant reduction in patients with moderate/severe acne at week-12 (baseline: 100%, week-12: 11.10%; p<0.0001).

RESULTS

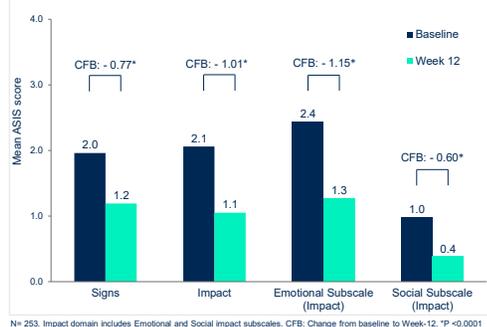
Patient's individual acne signs and social/emotional impact significantly improved over the 12-week sarecycline treatment period



N=253 for all items. In comparison to baseline: *p<0.0001; **p<0.001; ***p<0.0006; ****p<0.0001; *****p<0.0101.

RESULTS

Mean ASIS scores significantly decreased over the 12-week sarecycline treatment period

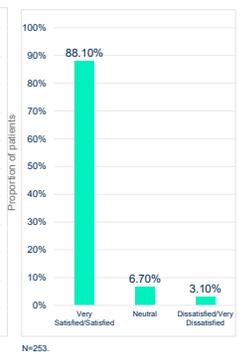


N=253. Impact domain includes Emotional and Social impact subscales. CFB: Change from baseline to Week-12. *p<0.0001

Acne severity (by IGA) decreased significantly over the 12-week sarecycline treatment period



For majority of acne patients, physicians were very satisfied or satisfied with sarecycline treatment outcomes at week-12



CONCLUSIONS

- Patients with moderate to severe acne using sarecycline reported a statistically significant improvement in acne symptoms, and social/emotional impact, as measured by validated ASIS questionnaire.
- Majority of acne patients had significant reduction in acne severity, and majority (58.9%) had IGA success at week-12.
- Overwhelming majority of physicians (88.1%) were satisfied/very satisfied with sarecycline outcomes.
- Assessing the impact of sarecycline treatment on acne patient outcomes, including patient QoL, in real-world community practice settings highlights the humanistic and clinical benefits associated with this narrow-spectrum antibiotic treatment option.

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