

CHANGES IN CLINICIAN REPORTED ACNE SEVERITY AND CLINICIAN SATISFACTION WITH TREATMENT OUTCOMES AMONG PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS ADMINISTERED SARECYCLINE IN COMMUNITY PRACTICES ACROSS THE U.S: ANALYSIS OF PROSES STUDY RESULTS

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BACKGROUND

- Acne Vulgaris (AV), hereinafter referred to as acne, affects up to 50 million Americans and is the most common skin condition in the United States (U.S).¹
- 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 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.
- Clinician satisfaction with sarecycline treatment outcomes (at individual patient-level) could complement clinical assessment of treatment effectiveness (in terms of Investigator Global Assessment (IGA) of AV) and could portray a full picture of value of AV treatments in the real-world.

OBJECTIVE

- The objective of this analysis was to evaluate changes in severity of AV and clinician satisfaction with treatment outcomes week-12, among AV patients administered sarecycline in community practices across the U.S.

METHODS

A single-arm, prospective cohort study (PROSES: NCT04820673) was conducted with moderate-to-severe non-nodular AV patients ≥9 years who were prescribed sarecycline in real-world community practices in the U.S.

- A total of 300 subjects were enrolled from 30 community practices across the U.S.
 - Patients and clinicians completed surveys and clinical assessments at baseline and weeks 4, 8 & 12.
 - Facial IGA of AV status was collected on a five-point adjectival response scale (0 (clear), 1 (almost-clear), 2 (mild), 3 (moderate), 4 (severe)).
 - Clinician satisfaction with sarecycline outcomes for individual patients was assessed at week-12 using a single question: "how satisfied are you with sarecycline treatment outcomes (for this patient)", with a five-point adjectival response scale (1 (very dissatisfied)-5 (very satisfied)).
- IGA results were analyzed for all study timepoints, clinician satisfaction was only collected and analyzed at week-12.

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RESULTS

A total of 253 AV patients completed the study at week-12.

- At baseline, 100% of patients had moderate and severe AV.
- Increase in proportion of patients with an IGA of clear/almost clear from baseline and decrease in proportion of patients with an IGA of moderate/severe from baseline were both statistically significant at p<0.0001

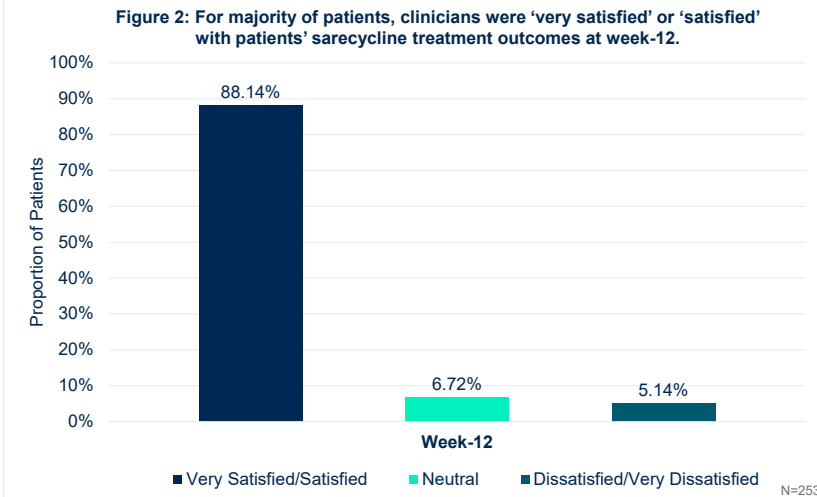
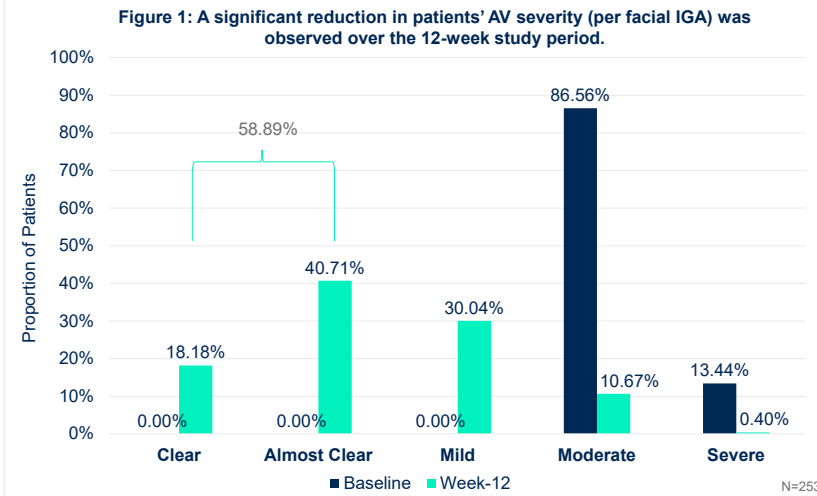


Table 1: Patient Baseline Characteristics

		N=253
Age Group, %	Pediatric (≤18 yrs)	39.92
	Adult (≥18 yrs)	60.08
Age Group, Mean yrs	Pediatric (≤18 yrs)	26.63
	Adult (≥18 yrs)	14.81
Gender, %	Male	33.60
	Female	66.40
Race, %	White	66.80
	Other	15.81
	Black/African American	9.88
	Asian	5.93
	Prefer not to answer	3.16
	American Indian or Alaskan	0.79
Ethnicity, % (Hispanic, Latino or of Spanish Origin)	Yes	33.99
	No	66.01
Baseline IGA, %	Moderate	86.56
	Severe	13.44

Table 2: Site Characteristics

	N=30
Current workplace, %	
Private, office-based practice	100.00
Hospital-based practice	0.00
Total number of board-certified dermatologists in the clinic/practice, Mean	3.10
Number of patients with AV managed by the clinic in a given month, Mean	86.90
Number of years practicing dermatology, Mean	19.30
How often do you prescribe broad-spectrum antibiotics (such as doxycycline and minocycline)?, %	
Never (0) / Rarely (1)	3.33
Some of the time (2)	36.67
Most of the time (3) / All of the Time	60.00

CONCLUSIONS

Patients administered 12-week course of sarecycline, a narrow-spectrum, tetracycline-derived antibiotic, had significant reduction in AV severity, and for an overwhelming majority of patients, clinicians were very satisfied/satisfied with sarecycline treatment outcomes at week-12.