

COMPARISON OF PATIENT AND CAREGIVER GLOBAL ASSESSMENT OF ACNE SEVERITY AMONG ADOLESCENT PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS (AV) 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. Around 85% of the affected population being adolescent and young adults. ²
- Acne has been shown to negatively affect QoL; resulting in low self-esteem and increased social and emotional anxiety. ^{3,4}
- 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. ⁵
- Acne has also been associated with considerable negative psychosocial impact, causing significant negative effects on self-image. ⁶
- Sarecycline is a novel oral tetracycline-derived 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. ⁷
- Assessing patient and caregiver reported outcomes as it relates to effectiveness of treatments in real-world setting is important to inform HCPs and Payers on the benefits adolescent AV patients derive from effective treatments and guide their clinical and reimbursement decisions, respectively.

OBJECTIVE

- The objective of this analysis was to compare patient and caregiver global assessment of severity of AV among adolescent patients (12-17yrs of age) 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.

- 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.
- 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. ⁸
 - ASIS contains Signs domain (items 1-9) and Impact domain (emotional (items 10-15) & social (items 16-17)).
 - Self-reported AV status/severity is part of Signs domain and is scored on a five-point adjectival response scale of 0 (clear), 1 (almost-clear), 2 (mild), 3 (moderate), 4 (severe) at baseline and weeks 4, 8 & 12.
 - For adolescent patients, both patients and their caregivers reported their perception of (patient) AV severity at all study timepoints.
- Patient and caregiver global assessment results were analyzed for all study timepoints.

REFERENCES

- Bickers DR, Lim HW, Margolis D, et al. J Am Acad Dermatol. 2006; 55:490-500.
- Bhate K, Williams HC. Br J Dermatol. 2013; 168(3):474-485.
- Timms RM. Psychol Health Med. 2013; 18(3):310-320.
- Revol O, Milozzi N, Gerard D. Br J Dermatol. 2015; 172(Suppl 1):52-58.
- Lasek RJ, Chen MM. Arch Dermatol. 1998; 134: 454-8.
- Gnieler U et al. J EADV. 2015; 29 (Suppl. 4):12-14.
- Moore A, Green LJ, Bruce S, et al. J Drugs Dermatol. 2018 Sep 1;17(9):987-996.
- Huddgens S, Harper JC, Daniels SR, et al. J Drugs Dermatol. 2015; 14(6):552-9.

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RESULTS

- Out of 101 pediatric AV patients, 97 patients aged 12-17 yrs completed the study at week-12 and included in the analyses.
- The caregivers of the pediatric patients in this study were 81.19% female with a mean age of 45.87 years.
- The proportion of adolescent patients with moderate/severe physician-reported facial IGA scores decreased from 100% at baseline to 13.40% at week-12.

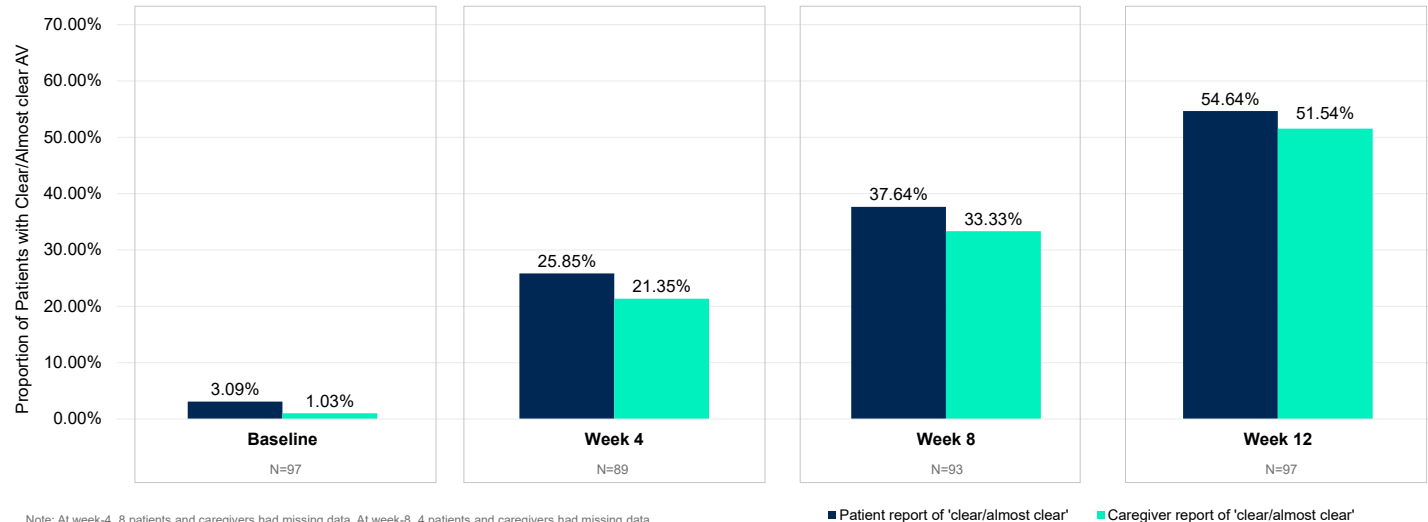
Table 1: Site Characteristics

	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

Table 2: Baseline Pediatric Patient Characteristics

		N=101
Age Groups, %	Age 9-11 years (n=4)	3.96
	Age 12-17 years (n=97)	96.04
Age, mean yrs		14.84
Gender, %	Male	49.14
	Female	50.86
Race, %	White	79.31
	Other	11.21
	Black / African American	6.90
	Asian	5.17
	Prefer not to answer	3.45
	Native Hawaiian / Pacific Islander	1.72
	American Indian / Alaskan	1.72
Hispanic, Latino, or of Spanish Origin, %		31.03

Figure 1: The proportion of adolescent patients with clear/almost clear facial AV (as reported by adolescent patients and their caregivers) increased during the 12-week study observation period.



CONCLUSIONS

- Within the study cohort of adolescent patients of age 12-17yrs administered sarecycline, a narrow-spectrum, tetracycline-derived antibiotic, for 12 weeks, there was high concordance in patient and caregiver reported of AV severity
- The proportion of patients with clear/almost clear facial AV (as reported by patients and their caregivers respectively) increased significantly, with more than half of the patients achieving clear/almost clear facial AV at week-12.