CHANGES IN PATIENT GLOBAL ASSESSMENT OF ACNE SEVERITY AND FACIAL APPEARANCE AMONG PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS ADMINISTERED SARECYCLINE IN COMMUNITY PRACTICES ACROSS THE U.S: ANALYSIS OF PROSES STUDY RESULT

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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 patient reported outcomes in real-world setting is important to inform HCPs and Payers on the benefits AV patients derive from effective treatments and guide their clinical and reimbursement decisions, respectively.

OBJECTIVE

The objective of this analysis was to evaluate changes from baseline in Patient's Global assessment (ptGA) of Acne Vulgaris (AV) on the face and patient's rating of facial appearance at 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.

- 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.[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).
  - Self-reported ptGA of AV status was collected as part of validated ASIS Signs domain, on a five-point adjectival response scale (0 (clear), 1 (almost-clear), 2 (mild), 3 (moderate), 4 (severe)) at baseline and weeks 4, 8 & 12.
  - Patient self-assessment of their facial appearance, via the question "how face looks because of AV' was also collected as part of validated ASIS questionnaire, on a five-point adjectival response scale (0 (excellent), 1 (very good), 2 (good), 3 (fair), 4 (bad)) at baseline and weeks 4, 8 & 12.
- ptGA and patient rating of 'how face looks because of AV' were analyzed for baseline and week-12.

REFERENCES

1. Bickers DR, Lim HW, Margolis D, et al. J Am Acad Dermatol. 2006; 55:490-500.
2. Timms RM. Psychol Health Med. 2013; 18(3):310–320.
3. Revol O, Milliez N, Gerard D. Br J Dermatol. 2015; 172(Suppl 1):52–58.
4. Lasek RJ, Chren MM. Arch Dermatol. 1998; 134: 454-8.
5. Gieler U et al. JEADV. 2015; 29 (Suppl. 4):12–14.
6. Moore A, Green LJ, Bruce S, et al. J Drugs Dermatol. 2018 Sep 1;17(9):987-996.
7. Hudgens S, Harper JC, Daniels SR, et al. J Drugs Dermatol. 2015; 14(6):552-9.

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RESULTS

A total of 253 AV patients completed the study surveys at week-12 and included in the analyses.

- Increase in proportion of patients reporting clear/almost clear AV and decrease in proportion of patients reporting moderate/severe AV at week-12 were both statistically significant at p<0.0001.
- Increase in proportion of patients reporting 'excellent/very good' and decrease in proportion of patients reporting 'fair/bad' at week-12 were both statistically significant at p<0.0001.

Figure 1: A significant improvement in patients' self-assessment of "How Face Looks" was observed over the 12-week study period.

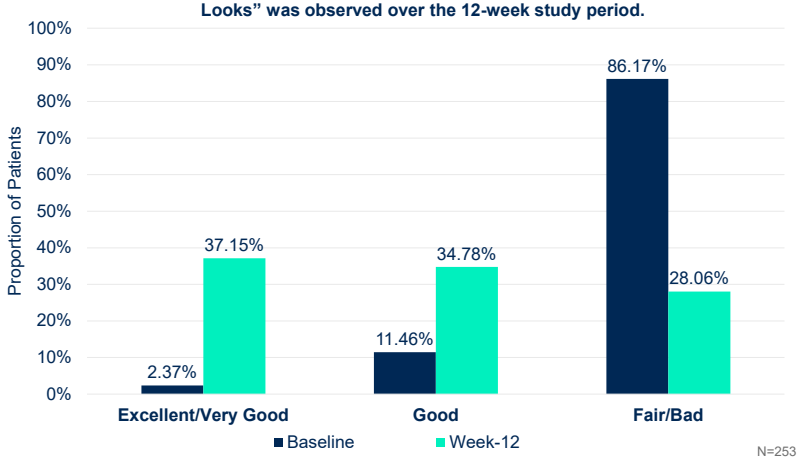

Figure 2: A significant reduction in patients' self-reported AV severity (per ptGA) was observed over the 12-week study period.

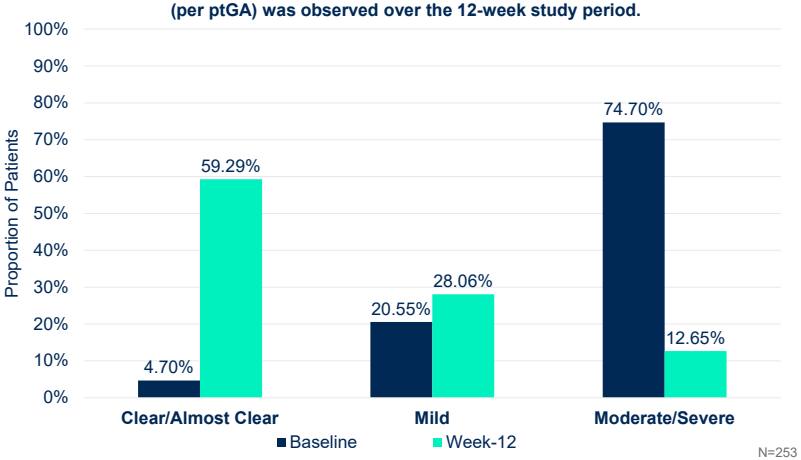

Table 1: Baseline Patient Characteristics

		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
	Native Hawaiian/Pacific Islander	0.40
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

CONCLUSIONS

Within the study cohort administered sarecycline, a narrow-spectrum, tetracycline-derived antibiotic, for 12 weeks, patients self-reported a significant decrease in AV severity and a significant improvement in facial appearance during the study observation period.