

# CHANGES IN SOCIAL FUNCTIONING, EMOTIONAL FUNCTIONING, AND ACTIVITIES OF DAILY LIVING (ADL) AMONG PEDIATRIC PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS (AV) 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 (US).<sup>1</sup>
- Acne has been shown to negatively affect QoL; resulting in low self-esteem and increased social and emotional anxiety.<sup>2,3</sup>
- 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.<sup>4</sup>
- Acne has been associated with considerable psychosocial impact, causing significant negative effects on self-image, leading to feelings of isolation and loneliness, and a significantly lower self-attitude, uselessness feeling, sense of pride and self-worth, and body satisfaction.<sup>5</sup>
- 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.<sup>6</sup>
- Understanding of the impact of acne AV on pediatric patient health-related quality of life is still evolving. Assessing PROs among patients in real-world setting is important to inform HCPs and patients to aid optimal disease management.

## OBJECTIVE

- The key objective of this analysis was to evaluate patient and caregiver perceived impact of AV on pediatric patient's emotional/social functioning and ADL through a novel Expert Panel Questionnaire (EPQ), among pediatric patients with AV administered sarecycline, in real-world community practices across the U.S.

## METHODS

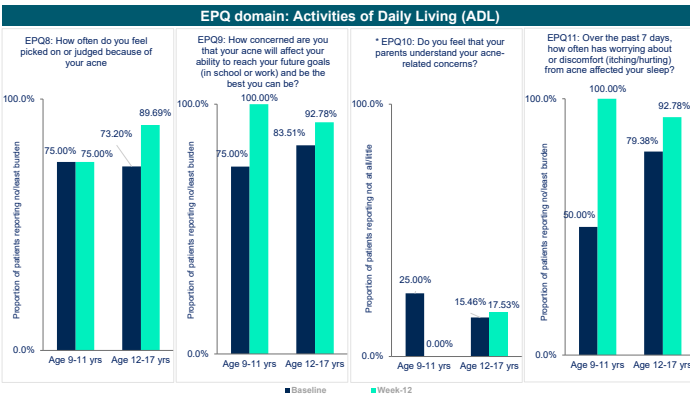
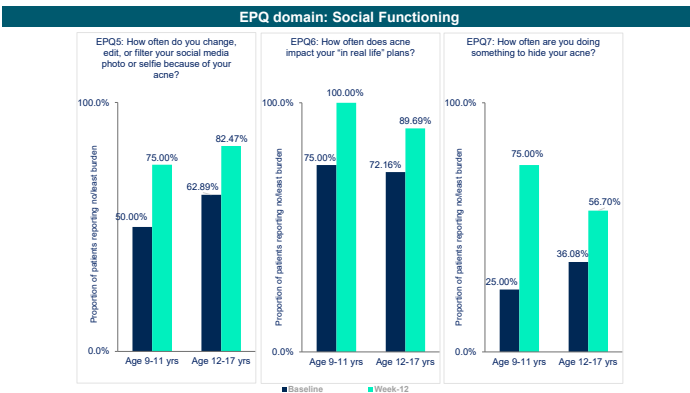
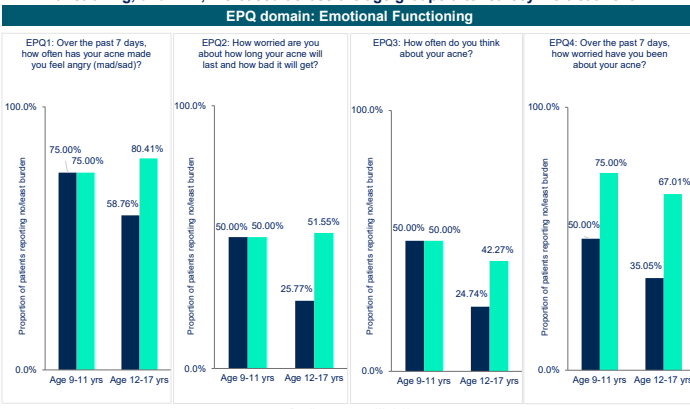
- Single-arm, prospective cohort study (PROSES: NCT04820673) was conducted with moderate-to-severe non-nodular AV patients ≥ 9yrs who were prescribed sarecycline in real-world U.S community practices.
- A total of 300 subjects were enrolled from 30 community practices across the U.S.
- A 10-person consensus panel of 8 dermatologists with expertise in the treatment of acne, including pediatric and skin of color focused expertise, one dermatologist/clinical psychologist, and one dermatologist/psychiatrist was virtually convened using a three-step modified Delphi method to establish consensus on an Expert Panel Questionnaire (EPQ) items that relate to how acne impacts the patient's emotional functioning, social functioning, activities of daily living.
- The EPQ covered emotional functioning (items 1-4), social functioning (items 5-7), and ADL (Items 8-11), and completed by patients (>12yrs) and caregivers (for patients 9-11yrs).
- EPQ items (1-9 & 11) were scored on five-point adjectival response scale (score: 0 (no burden/impact) – 4 (most burden/impact)); a higher EPQ score indicate severe symptoms or negative impact of AV.
- EPQ item 10 was scored on five-point adjectival response scale (score: 0 (not at all) – 4 (very much)); higher score indicate better understanding.
- Change from baseline (CFB) in proportion of patients reporting score=0/1 (no or least burden/impact) for individual EPQ items at week-12 for pediatric age strata (age 9-11yrs, age 12-17yrs) were analyzed, as observed.

## RESULTS

- 101 pediatric patients who completed the study at week-12 were included in the final analyses.
- All patients had answered all the EPQ items.

## RESULTS

### Proportion of patients reporting no/least AV burden associated with emotional and physical functioning, and ADL, increased across the age groups after sarecycline treatment



Note: Survey responses for pediatric patients 9-11 years old (N=4), were from caregivers of these patients. Survey responses for pediatric patients 12-17 years (N=97) were from patients themselves. CFB at Week-12 were significant at p<0.05 for ages 12-17 years, except for EPQ10. Never/Rarely (low) burden/impact refers to a score of 0/1 or the EPQ items, as follows:  
 • EPQ1, EP3, EPQ5, EPQ6, EPQ7, EPQ8, EPQ11: (0) Never (1) Rarely  
 • EPQ2, EPQ4, EPQ9, (0) Not at all, (1) Slightly  
 • EPQ10: (0) Not at all, (1) A little

## RESULTS

Table 1: Baseline Pediatric Patient Characteristics

|   |                                    | N=101 |
|---|------------------------------------|-------|
| Age, %                                    | 9 - 11 yrs                         | 3.96  |
|   | 12 - 17 yrs                        | 96.04 |
| 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 |

Table 2: Site Characteristics

|   | N=30  |
|---|-------|
| Current workplace:<br>Private, office-based practice, %                     | 100   |
| 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

- Patients reporting no/least AV burden in emotional functioning, social functioning, and ADL increased in majority of pediatric patients with moderate-to-severe AV who were administered sarecycline, a narrow-spectrum, tetracycline-derived antibiotic, for 12 weeks.
- The observed improvements in patient outcomes were more pronounced in 12-17yr old adolescent cohort.

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