

# IMPACT OF ACNE ON SOCIAL FUNCTIONING, EMOTIONAL FUNCTIONING, AND ACTIVITIES OF DAILY LIVING 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 (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-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.<sup>6</sup>
- Assessing PROs among patients in real-world setting is important to inform HCPs and patients to aid optimal disease management.

## OBJECTIVE

- To evaluate patient-perceived impact of AV on emotional functioning, social functioning and activities of daily living (ADL), using a novel Expert Panel Questionnaire (EPQ), among Acne patients administered sarecycline in real-world 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.
- Study primary outcome measures included responses to EPQ items (completed by subjects (≥12 years) and caregivers (for subjects 9-11 years) at Week-12 and corresponding change from baseline (CFB)).
- A 10-person consensus panel of eight dermatologists with expertise in the treatment of acne, one dermatologist/clinical psychologist and one dermatologist/psychiatrist was virtually convened using a three-step modified Delphi method to establish consensus on 11-item EPQ that relate to how acne impacts the patient's mood, social interactions, general thoughts/worries about acne and one's future goals, and impact on daily activities, including sleep. These recommendations were aligned with literature depicting the issues impacting acne patients.<sup>7,8</sup>
- EPQ consisted of three domains: emotional functioning (EPQ items 1-4), social functioning (EPQ items 5-7), and ADL (EPQ items 8-11).
- All EPQ items were scored on a five-point adjectival response scale (0: never, not at all; 1: slightly, rarely, a little; 2: some of the time, somewhat; 3: most of the time, moderately, quite a bit; 4: all of the time, extremely, very much).
- CFB in EPQ items was analyzed by evaluating the change in proportion of patients reporting score=0/1 (no/least impact) for EPQ items at Week-12, in comparison to baseline.

## REFERENCES

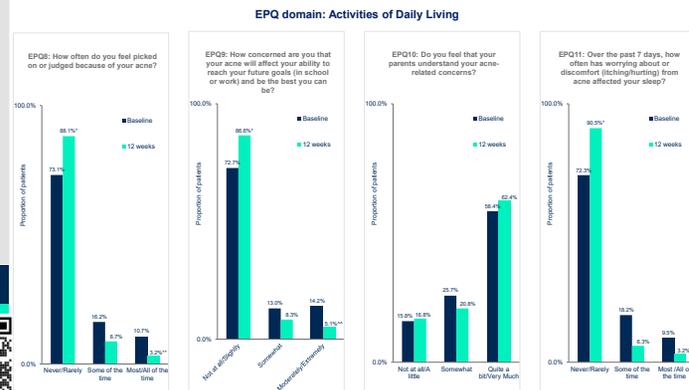
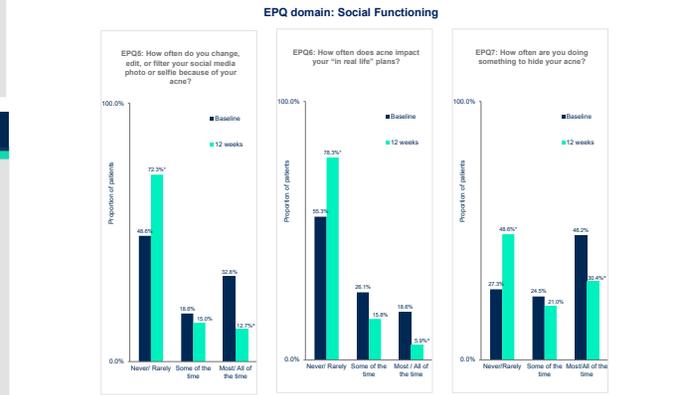
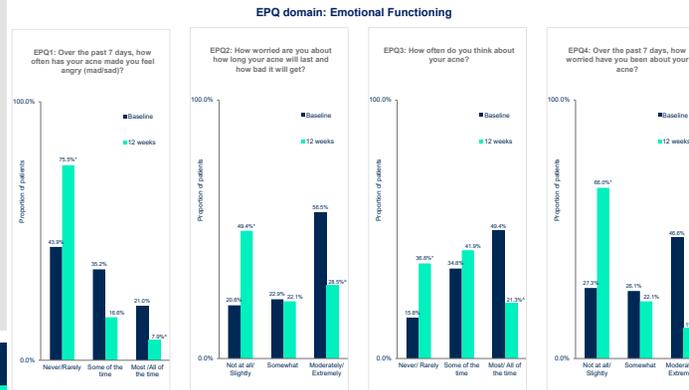
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## RESULTS

### Patient's Emotional and Physical Functioning and ADL significantly improved over the 12-week sarecycline treatment period



In comparison to baseline: \*p<0.0001; \*\*p<0.001; \*\*\*p<0.0009; \*\*\*\*p<0.0005; #p=0.0042. N=253 for all items, except for EPQ10 which corresponded to only caregivers of pediatric patients, with N=101.

## RESULTS

- 253 patients with data at week-12 were included in the final analyses.

Patient Demographics (N=253)		
Demographic	Group	Proportion of Patients
Age Group	Pediatric (≤18 yrs)	39.9%
	Adult (≥18 yrs)	60.1%
Gender	Male	33.6%
	Female	66.4%
Race	White	68.4%
	Other	15.4%
	Black/African American	9.9%
	Asian	7.1%
	Prefer not to answer	3.2%
	Native Hawaiian/Pacific Islander	1.2%
American Indian /Alaskan	0.8%	

### CFB in proportion of patients reporting (never/rarely, not at all/slightly/a little) for EPQ items significantly improved over the 12-week sarecycline treatment period

EPQ	CFB	p-value
EPQ1	31.6%	p<0.0001
EPQ2	28.9%	p<0.0001
EPQ3	20.9%	p<0.0001
EPQ4	38.7%	p<0.0001
EPQ5	23.7%	p<0.0001
EPQ6	22.9%	p<0.0001
EPQ7	21.3%	p<0.0001
EPQ8	15.0%	p<0.0001
EPQ9	13.8%	p=0.0005
EPQ10	1.0%	p=0.8491
EPQ11	18.2%	p<0.0001

- Proportion of patients reporting no/least acne burden (i.e., EPQ item scores of 0/1: (never/rarely; not at all/slightly) statistically significantly (p<0.001) increased at week-12 across all measures, except EPQ10.
- Proportion of patients reporting high acne burden (i.e., EPQ item scores of 3/4: most of the time/all of the time) statistically significantly (p<0.001) decreased at week-12 across all measures, except EPQ10.

## CONCLUSIONS

- Acne related burden was pronounced at baseline.
- Over the 12-week study period, patients reporting no/least acne burden increased significantly, while those reporting most/highest burden decreased significantly in emotional functioning, social functioning, and ADL domains among patients with moderate to severe acne who were administered sarecycline for 12 weeks.