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Spesolimab impact on health status among patients with generalized pustular psoriasis (GPP) measured by EQ-5D-5L: Results from the EFFISAYIL® 2 trial

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Introduction & Objectives: GPP is a serious, chronic, systemic neutrophilic disease with a heterogenous, unpredictable clinical course, causing systemic inflammation, increased risks of hospitalization and mortality, and poor quality of life (QoL). Spesolimab is a selective, humanized monoclonal antibody targeting the IL-36 receptor approved by the FDA and EMA for treatment of GPP in adults and adolescents aged ≥12 years. EFFISAYIL® 2 (NCT04399837) evaluated the use of spesolimab for GPP flare prevention. To determine the effects of spesolimab treatment on health state, we analyzed treatment responses using the EQ-5D-5L, focusing on flare-free patients receiving the approved spesolimab dose regimen, to aid decision making.

Materials & Methods: Eligible patients were randomized 1:1:1:1 to receive one of: 300 mg loading dose then 150 mg every (q) 12 weeks, 600 mg loading dose then 300 mg q12 weeks, 600 mg loading dose then 300 mg q4 weeks (approved dose) subcutaneous (sc) spesolimab, or sc placebo over 48 weeks.** EQ-5D-5L scores (range 0–1; higher scores indicate better health status) were collected at baseline, Weeks 4, 8, 12, 24, 36, and 48, and during a flare, and described descriptively. Mixed-effects regression analysis adjusted for covariates was used to estimate scores for flare-free patients in the 600 mg then 300 mg q4 weeks dose group, and for those experiencing flares (based on GPP Physician Global Assessment [GPPGA] scores).

Results: In total, 30 patients were randomized to spesolimab 600 mg then 300 mg q4 weeks and 31 to placebo. Mean ± standard deviation (SD) age of enrolled patients was 40.4±15.8 years, 62% were female, and ethnicity was 36% White, 64% Asian. Baseline characteristics were similar across all groups. Mean±SD EQ-5D-5L index score estimate in patients experiencing a flare was 0.35±0.36 (GPPGA score ≥2) and was worse for those with higher GPPGA scores: 0.43±0.43 (score=2) vs 0.31±0.33 (score=3 or 4), with a similar pattern for individual domains (Table 1). Among patients who did not experience a flare in the approved spesolimab 600 mg then 300 mg q4 weeks group (n=27; 90%), the mean EQ-5D-5L index score improved from 0.68±0.30 at baseline to 0.84±0.21 (placebo: 0.70±0.24 to 0.80±0.19) at Week 48 (mean change from baseline 0.16±0.34 vs placebo 0.10±0.12), while mean changes from baseline in EQ-5D-5L domain scores at Week 48 generally favored spesolimab vs placebo (Table 2).

Conclusion: These findings highlight the considerable QoL burden of GPP flares. Spesolimab limits these potential QoL impacts by reducing the incidence and occurrence of flares. Furthermore, for patients with GPP who did not experience a flare, spesolimab improved the overall QoL burden, with pain/discomfort, mental health, and the ability to perform daily activities all improving following treatment. Similar improvements in health-related QoL were observed with spesolimab based on the short form-36 (these data are reported in another EADV 2025 abstract).

Table 1: Individual EQ-5D-5L domain scores during a flare

	Mean±SD index score and individual EQ-5D-5L domain scores during a flare (n)		
	GPPGA score ≥2 (N=32)	**GPPGA score 2 (N=9)**	**GPPGA score 3 or 4 (N=23)**
EQ-5D-5L index score	0.35±0.36 (32)	0.43±0.43 (9)	0.31±0.33 (23)
EQ-5D-5L domain			
Mobility	2.47±1.11 (32)	2.22±1.09 (9)	2.57±1.12 (23)
Self-care	2.22±1.18 (32)	1.89±1.27 (9)	2.35±1.15 (23)
Usual activities	2.97±1.18 (32)	2.67±1.41 (9)	3.09±1.08 (23)
Pain/discomfort	3.47±1.11 (32)	3.22±1.39 (9)	3.57±0.99 (23)
Anxiety/depression	2.91±1.23 (32)	2.67±1.50 (9)	3.00±1.13 (23)

EQ-5D-5L index score: 0 to 1, higher score indicates improved health state; EQ-5D-5L domain scores: 1 (no issues) to 5 (extreme issues)
GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; SD, standard deviation

Table 2: Spesolimab (600 mg loading dose then 300 mg q4 weeks) improved individual EQ-5D-5L domain scores from baseline in flare-free patients by Week 48

	Mean±SD BL and Week 48 change from BL in EQ-5D-5L index and domain scores (n)	
	Spesolimab (N=27)	**Placebo (N=15)**
EQ-5D-5L index score (BL)	0.68±0.30 (27)	0.70±0.24 (15)
Week 48 change from BL	0.16±0.34 (25)	0.10±0.12 (15)
EQ-5D-5L domain		
Mobility (BL)	1.78±1.05 (27)	1.80±1.01 (15)
Week 48 change from BL	-0.32±1.18 (25)	-0.33±0.62 (15)
Self-care (BL)	1.52±0.94 (27)	1.67±0.98 (15)
Week 48 change from BL	-0.24±1.05 (25)	-0.33±0.62 (15)
Usual activities (BL)	1.93±1.04 (27)	1.67±0.90 (15)
Week 48 change from BL	-0.60±1.38 (25)	-0.20±0.56 (15)
Pain/discomfort (BL)	2.19±1.11 (27)	2.00±0.93 (15)
Week 48 change from BL	-0.56±1.12 (25)	-0.27±0.80 (15)
Anxiety/depression (BL)	1.89±1.09 (27)	2.00±0.65 (15)
Week 48 change from BL	-0.60±1.04 (25)	-0.40±0.63 (15)

EQ-5D-5L index score: 0 to 1, higher score indicates improved health utility; EQ-5D-5L domain scores: 1 (no issues) to 5 (extreme issues); negative changes vs baseline in EQ-5D-5L domain scores indicate improvement
BL, baseline; SD, standard deviation; q4, every 4