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The impact of spesolimab on health-related quality of life (HRQoL) measured by the short form-36 (SF-36) among patients with generalized pustular psoriasis (GPP): 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 has a persistent impact on physical health, emotional health, and HRQoL. Spesolimab, a selective, humanized anti-IL-36 receptor monoclonal antibody, is approved by the FDA and EMA for treating patients with GPP aged ≥12 years. In EFFISAYIL® 2 (NCT04399837), spesolimab significantly reduced the risk and occurrence of GPP flares. To determine the effects of spesolimab treatment on HRQoL, we analyzed SF-36 scores collected during EFFISAYIL® 2 in patients who received the approved spesolimab dose regimen.

Materials & Methods: In EFFISAYIL® 2, patients were randomized 1:1:1:1 to receive subcutaneous (sc) spesolimab as a 300 mg loading dose then 150 mg every (q)12 weeks, as a 600 mg loading dose then 300 mg q12 weeks, or as a 600 mg loading dose then 300 mg q4 weeks, or sc placebo over 48 weeks.** SF-36 domain scores (range 0–100; higher scores indicate better HRQoL) were collected at baseline and each subsequent 12-week timepoint through to Week 48 for patients without flares. Data for the placebo group and the spesolimab 600 mg then 300 mg q4 weeks (approved dose) group were summarized using descriptive statistics.

Results: Thirty patients were randomized to spesolimab 600 mg then 300 mg q4 weeks and 31 patients were randomized to placebo. At baseline, the mean ± standard deviation (SD) age of patients in the spesolimab group was 40.2±16.4 years, 60% were female, ethnicity was 30% White and 60% Asian, and 73% of patients had received systemic medications for GPP. Baseline characteristics were consistent across the treatment groups. Among patients in the spesolimab group who did not experience a flare (n=27; 90%), mean±SD SF-36 domain scores improved during treatment (Table 1). The mean changes from baseline at Week 48 for the physical and mental component summary scores were 5.83±12.78 and 4.45±10.36, respectively, versus 4.21±6.10 and 3.08±14.46 for placebo. In most cases, improvements at Week 48 in the individual SF-36 domains favored the spesolimab group compared with placebo (Table 1), including bodily pain (27.22±30.05 vs 7.20±20.12), physical functioning (12.17±38.34 vs 8.33±12.77), vitality (8.61±23.90 vs 3.75±19.02), and mental health (8.91±20.34 vs 4.00±26.54).

Conclusion: These findings, based on the analysis of patient HRQoL from the EFFISAYIL® 2 clinical trial, underscore the potential role of spesolimab in improving physical and social functioning, bodily pain, and mental

health, domains potentially impacted by chronic disease, resulting in improved overall HRQoL for patients with GPP. This improvement is observed in addition to the clinical benefits achieved with spesolimab. Similar improvements in health status were observed with spesolimab based on the EQ-5D-5L (these data are reported in another EADV 2025 abstract).

Table 1: Spesolimab (600 mg loading dose then 300 mg q4 weeks) improved SF-36 domain scores by Week 48

	Mean±SD BL scores and Week 48 change from BL (n) in SF-36 domain scores	
	Spesolimab (N=27)	**Placebo (N=15)**
SF-36 domain		
Physical component summary (BL)	46.93±9.75 (26)	46.75±9.90 (15)
Week 48 change from BL	5.83±12.78 (23)	4.21±6.10 (15)
Physical functioning (BL)	73.27±27.82 (26)	74.33±27.38 (15)
Week 48 change from BL	12.17±38.34 (23)	8.33±12.77 (15)
Role-physical (BL)	64.18±35.16 (26)	63.33±30.05 (15)
Week 48 change from BL	12.77±42.83 (23)	14.58±20.55 (15)
Bodily pain (BL)	56.00±29.94 (26)	68.60±29.31 (15)
Week 48 change from BL	27.22±30.05 (23)	7.20±20.12 (15)
General health (BL)	53.19±21.56 (26)	38.07±18.19 (15)
Week 48 change from BL	5.83±23.46 (23)	12.80±21.18 (15)
Mental component summary (BL)	41.74±11.15 (26)	41.49±10.18 (15)
Week 48 change from BL	4.45±10.36 (23)	3.08±14.46 (15)
Vitality (BL)	53.45±25.85 (26)	50.00±22.53 (15)
Week 48 change from BL	8.61±23.90 (23)	3.75±19.02 (15)
Social functioning (BL)	59.13±32.12 (26)	61.67±22.39 (15)
Week 48 change from BL	20.65±32.55 (23)	15.00±29.96 (15)
Role-emotional (BL)	67.31±27.28 (26)	68.89±26.25 (15)
Week 48 change from BL	9.78±29.80 (23)	9.44±31.95 (15)
Mental health (BL)	60.19±22.43 (26)	60.00±17.73 (15)
Week 48 change from BL	8.91±20.34 (23)	4.00±26.54 (15)

Positive changes in SF-36 domain scores indicate improvement; numbers in parentheses indicate the number of subjects

BL, baseline; SD, standard deviation; SF-36, short form-36; q4, every 4