

Spesolimab increases the percentage of generalized pustular psoriasis (GPP) patients with clear skin over time as measured by the Physician's Global Assessment for GPP (GPPGA):

Results from the EFFISAYIL[®] 2 trial

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Objective

- To evaluate the effect of spesolimab on GPPGA total score in patients with GPP over the duration of the 48-week EFFISAYIL[®] 2 study

Conclusions

- Continuous treatment with s.c. spesolimab improved skin symptoms in GPP, with 50% of patients achieving clear skin at Week 48
- These findings suggest a role of spesolimab in the complete resolution of GPP skin symptoms



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Introduction

- GPP is a chronic inflammatory, and potentially life-threatening skin disease characterized by episodic flares of widespread skin pustulation. Many patients experience chronic skin symptoms between flares, which can lead to significant disease burden¹
- Spesolimab, an anti-interleukin-36 receptor monoclonal antibody, is approved in the United States² as an i.v. or s.c. formulation to treat GPP in adults and pediatric patients ≥12 years of age and weighing at least 40 kg
- Here, we report the percentage of patients achieving clear skin over time using the GPPGA,³ among patients who were treated with the US FDA-approved spesolimab dosing regimen (300 mg s.c. q4w after a 600 mg s.c. loading dose) in EFFISAYIL[®] 2 (NCT04399837)

Methods

- For this subgroup analysis, total GPPGA scores were assessed in patients randomized to receive high-dose spesolimab over the duration of the EFFISAYIL[®] 2 study (Figure 1)
- Total GPPGA scores were calculated for each patient (Table 1, Figure 2) at 4 timepoints during the study (baseline, Week 4, Week 16, and Week 48)

Table 1. Components of the GPPGA score³

Score	Erythema	Pustules	Scaling
0 (clear)	Normal or post-inflammatory hyperpigmentation	No visible pustules	No scaling or crusting
1 (almost clear)	Faint, diffuse pink or slight red	Low-density occasional small discrete pustules (noncoalescent)	Superficial focal scaling or crusting restricted to periphery of lesions
2 (mild)	Light red	Moderate-density grouped discrete small pustules (noncoalescent)	Predominantly fine scaling or crusting
3 (moderate)	Bright red	High-density pustules with some coalescence	Moderate scaling or crusting covering most or all lesions
4 (severe)	Deep fiery red	Very high-density pustules with pustular lakes	Severe scaling or crusting covering most or all lesions

Figure 1. Patients in EFFISAYIL[®] 2

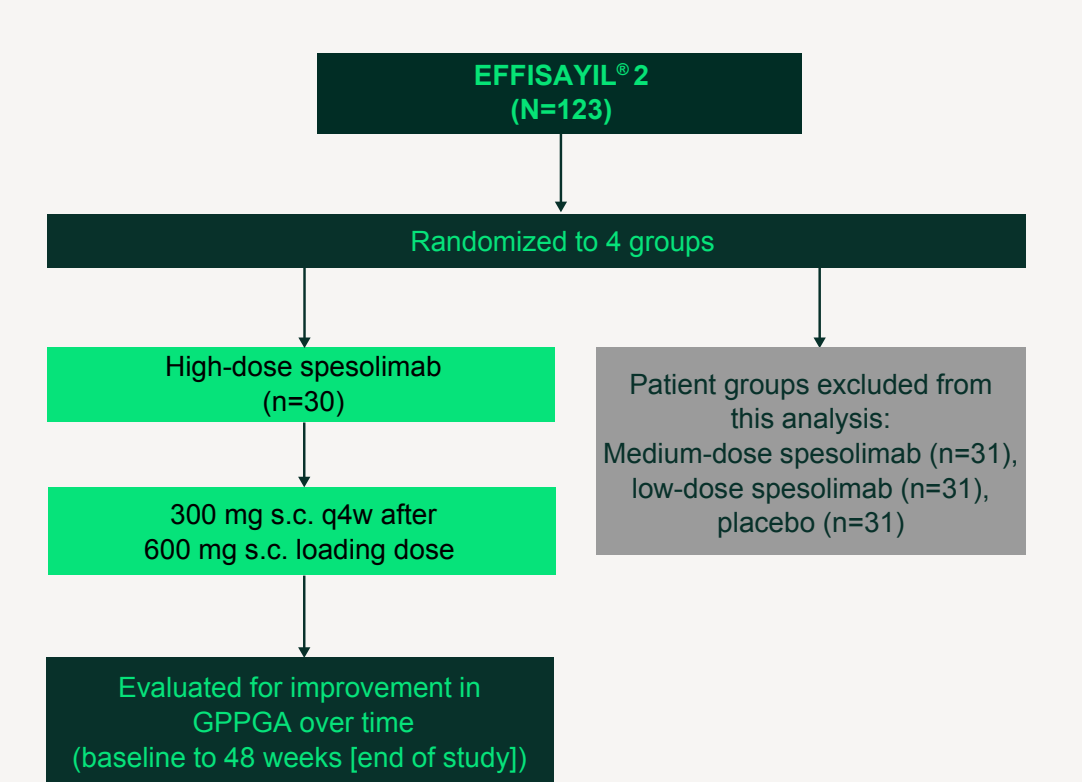
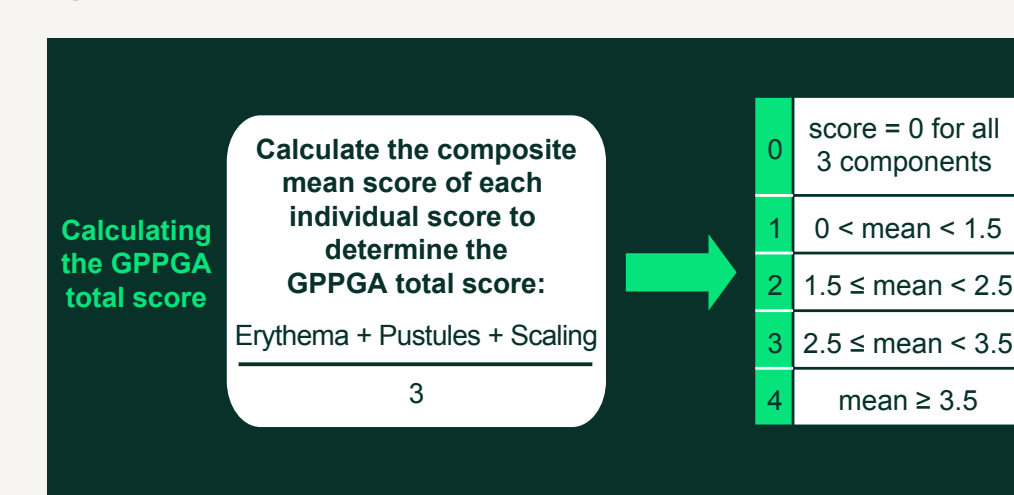


Figure 2. Assessment of GPPGA^{3*}



*Data collected closest to the given time points were used by including the effect of potential i.v. spesolimab treatment and subsequent open-label s.c. spesolimab treatment in patients who experienced a flare. The data were analyzed as observed and by NRI.

Abbreviations
BMI, body mass index; FDA, Food and Drug Administration; GPP, generalized pustular psoriasis; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; GPPASI, Generalized Pustular Psoriasis Area and Severity Index. i.v., intravenous; NRI, non-response imputation; PVO, psoriasis; PSS, Psoriasis Symptom Scale; q4w, every 4 weeks; q12w, every 12 weeks; s.c., subcutaneous

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Results

- The average age of patients in this group was 40 years, 60% were female, and all patients were Asian (70%) or White (30%) (Table 2)

Table 2. Baseline patient characteristics

	High-dose spesolimab (300 mg s.c. q4w*) n=30
Mean age (SD), years	40.2 (16.4)
Female, n (%)	18 (60)
Race, n (%)	
Asian	21 (70)
White	9 (30)
Mean BMI (SD), kg/m ²	25.6 (7.3)
Mean GPPASI total score (SD)	3.92 (4.4)
GPPGA total score, n (%)	
0	3 (10)
1	27 (90)
Mean PSS total score (SD)	5.3 (3.8)
Mean historical number of flares per year (SD)	2.4 (1.9)
Concurrent plaque PsO at baseline, n (%)	7 (23)

*Following a 600 mg s.c. loading dose

- The proportion of patients with a GPPGA total score of 0 increased over time with high-dose spesolimab treatment, from 10.0% (n=3/30) at baseline, to 27.6% (n=8/29) at Week 4, 48.1% (n=13/27) at Week 16, and 52.2% (n=12/23) at Week 48 (Figure 3)
- Data were also analyzed with NRI to account for missing values (i.e., for the 3 patients who had flare events, and those who discontinued the trial prematurely). Even after imputation, the proportion of patients with GPPGA total score of 0 increased from baseline to Week 48 (Figure 3, inset)

Figure 3. Proportion of patients treated with high-dose spesolimab who had a GPPGA score of 0 over time, as observed, and by NRI (inset)

