Spesolimab decreases generalized pustular psoriasis (GPP) body surface area (BSA) over time in patients with various lengths of disease history:

Results from the EFFISAYIL® 2 trial

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Objective

- To assess the efficacy of spesolimab on GPP BSA over time in patients with different durations of disease history

Conclusions

- Total BSA involvement decreased over the 48 weeks of the trial in spesolimab-treated patients regardless of whether they were early (≤5 years) or late (>5 years) in their disease course
- This finding demonstrates the efficacy of spesolimab in controlling GPP consistently for patients with various lengths of disease history

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Introduction

- GPP is a chronic inflammatory, and potentially life-threatening skin disease characterized by episodic flares of widespread skin pustulation. Most patients experience chronic skin symptoms between flares, which can lead to significant patient burden[1]
- Spesolimab is an anti-interleukin-36 receptor monoclonal antibody that has been approved in the United States 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[2]
- In EFFISAYIL® 2 (NCT04399837), efficacy and safety of subcutaneous spesolimab were evaluated in patients with GPP[1]
- Here, we report the effects on GPP BSA over time in patients diagnosed with GPP ≤5 years vs >5 years prior to enrollment when 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

Methods

- Patients from the high-dose spesolimab group of EFFISAYIL® 2 were evaluated in this subgroup analysis (**Figure 1**)
- The average total BSA involvement was determined for patients in this analysis, stratified by time since the patient's first GPP diagnosis: ≤5 years or >5 years prior to enrolment (**Figure 2**)

Figure 1. Patients in EFFISAYIL® 2 stratified by time since first GPP diagnosis

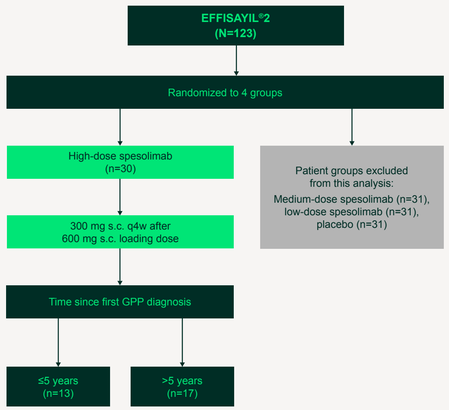
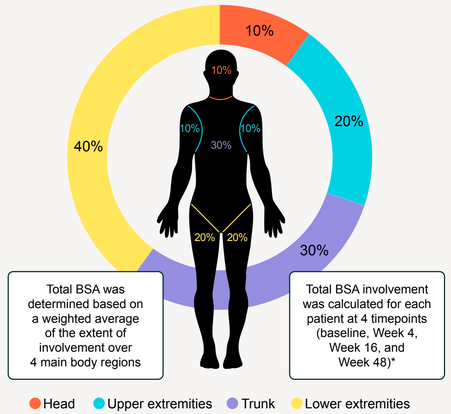


Figure 2. Assessment of body surface area



*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 LOCF.

Results

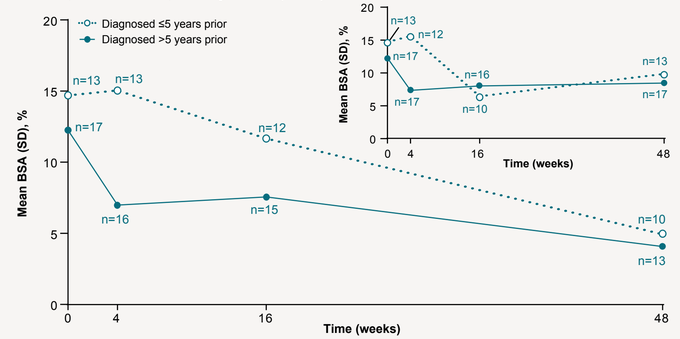
- The average age of patients in this group was 40 years, 60% were female, and all patients were Asian (70%) or White (30%) (**Table 1**)

	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/m²	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

- Within the US FDA-approved spesolimab regimen group, average BSA for patients diagnosed with GPP for ≤5 years (n=13) was 14.7 at baseline, 15.0 at Week 4, decreasing to 11.7 at Week 16, and 5.0 at Week 48 (**Figure 3**)
- For patients diagnosed with GPP for >5 years and treated with high-dose spesolimab (n=17), the average BSA was 12.3 at baseline, decreasing to 7.0 at Week 4, increasing slightly to 7.6 at Week 16, and decreasing to 4.1 at Week 48 (**Figure 3**)
- Data were also analyzed with LOCF 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, BSA improved by Week 48 compared with baseline (**Figure 3, inset**)

Figure 3. Mean BSA in patients receiving high-dose spesolimab, stratified by length of disease, as observed, and by LOCF (inset)



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Abbreviations
BMI, body mass index; BSA, body surface area; FDA, Food and Drug Administration; GPP, generalized pustular psoriasis; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; GPPASI, Generalized Pustular Psoriasis Area and Severity Index; ITT, intent-to-treat; i.v., intravenous; LOCF, last observation carried forward; PsO, psoriasis; PSS, Psoriasis Symptom Scale; q4w, every 4 weeks; q12w, every 12 weeks; s.c., subcutaneous; SD, standard deviation

References

1. Morita A. et al. *Lancet.* 2023;402:1541–51.
2. SPEVIGO® prescribing information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761244s003lbl.pdf (accessed Aug 8, 2024).

Disclosures
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