Spesolimab improves quality of life in generalized pustular psoriasis (GPP) as measured by proportion of patients with Dermatology Life Quality Index (DLQI) scores of 0 or 1 and reduction in pain severity over time

Results from the EFFISAYIL® 2 trial

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Objective

- To report the effects of continuous treatment with SC spesolimab on patient-reported outcomes on the DLQI and Pain VAS in patients with GPP

Conclusions

- After 48 weeks of SC spesolimab treatment, the proportion of patients with GPP exerting no effect on quality of life doubled and no patients reported severe pain due to GPP
- These findings suggest a role for spesolimab in improving quality of life in GPP according to DLQI score and pain severity

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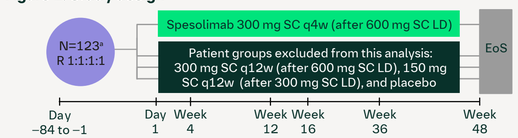
Introduction

- GPP is a rare, chronic, and potentially life-threatening skin disease characterized by widespread eruption of sterile pustules, often accompanied by systemic inflammation[1]
- Most patients with GPP experience long-term and persistent symptoms leading to significant burden on quality of life[2]
- Spesolimab is an anti-interleukin-36 receptor antagonist approved in the US to treat GPP in adults and pediatric patients aged ≥12 years and weighing ≥40 kg[3]
- We report the effects of the FDA-approved SC spesolimab dosing regimen (300 mg SC q4w after 600 mg SC LD) on PROs from the EFFISAYIL® 2 trial (NCT04399837)[4]

Methods

- Patients with a history of GPP were randomized (1:1:1:1) to 1 of 3 SC spesolimab regimens or placebo for 48 weeks (**Figure 1**)
- DLQI and pain VAS were assessed in patients receiving 600 mg SC loading dose followed by 300 mg SC q4w. Data were analyzed as observed
- DLQI was assessed at baseline and Weeks 4, 12, 36, and 48; chronic disease burden was assessed by the proportion of patients with a DLQI total score of 0 or 1 at each time point, indicating no effect at all on patient's life (**Figure 2**)
- Pain VAS was assessed at baseline and 4-week intervals; the severity of pain attributed to GPP was assessed by the proportion of patients with Pain VAS scores correlating with no pain, mild pain, moderate pain, and severe pain (**Figure 3**)

Figure 1. Study design

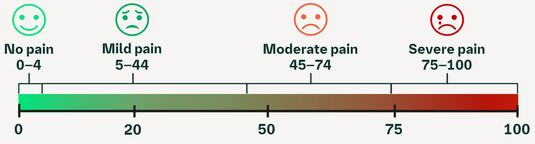


[a]Patients with GPP and a GPPGA total score of 0 or 1 at screening or randomization

Figure 2. DLQI scoring system

DLQI total score	Response category
0–1	No effect at all on patient's life
2–5	Small effect on patient's life
6–10	Moderate effect on patient's life
11–20	Very large effect on patient's life
21–30	Extremely large effect on patient's life

Figure 3. Pain VAS scale



Patients

- Of the 30 patients randomized to receive spesolimab SC 300 mg q4w after a 600 mg SC loading dose, the average age was 40 years, 60% of patients were female, and all patients were either Asian (70%) or White (30%) (**Table 1**)

Table 1. Baseline patient characteristics

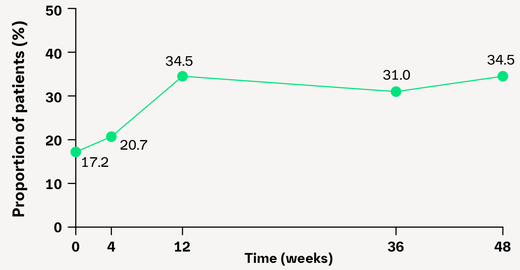
	Spesolimab (300 mg SC q4w[a]) n=30
Mean age (SD), years	40.2 (16.4)
Female, n (%)	18 (60)
Race, n (%)	
Asian	21 (70)
White	9 (30)
Mean BMI (SD), kg/m²	25.6 (7.3)
GPPGA total score, n (%)	
0	3 (10)
1	27 (90)
Mean Pain VAS score (SD)	29.1 (31.8)
Mean DLQI total score (SD)	11.1 (6.9)

[a]After a 600 mg SC LD

Results

- The proportion of patients with DLQI total scores of 0 or 1 increased with spesolimab treatment over the study duration (**Figure 4**)
- Notably, the proportion of patients with a DLQI total score of 0 or 1 doubled from baseline to week 48, increasing from 17.2% to 34.5%
- When missing data (i.e., early trial discontinuation) were excluded, the proportion of patients with DLQI 0 or 1 at week 48 increased to 50%

Figure 4. Proportion of patients with DLQI total score of 0 or 1 over the study period[a]

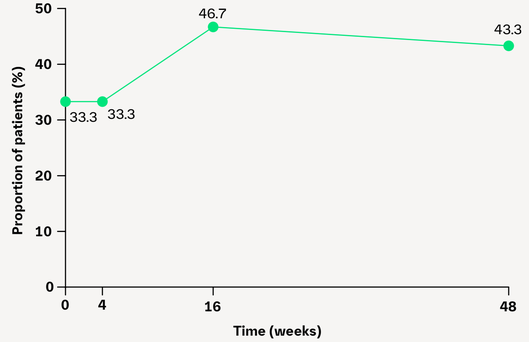


[a]Out of 29 patients at each time point

Results (continued)

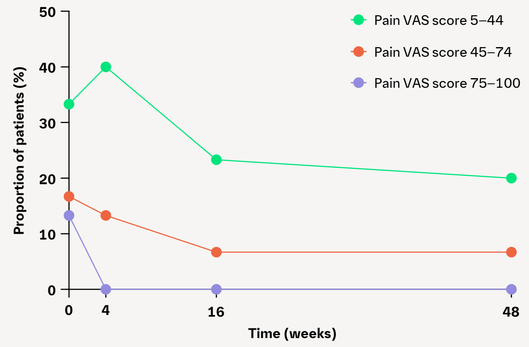
- The proportion of patients with a Pain VAS score indicating no pain related to GPP consistently increased with spesolimab treatment from baseline to Week 48, from 33.3% to 43.3% (**Figure 5**)
- The proportion of patients with Pain VAS scores corresponding with mild, moderate, and severe pain consistently decreased with spesolimab treatment (**Figure 6**)
  - From baseline to Week 48, the proportion of patients with mild pain decreased from 33.3% to 20.0%, the proportion of patients with moderate pain decreased from 16.7% to 6.7%, and the proportion of patients with severe pain decreased from 13.3% to 0%

Figure 5. Proportion of patients with Pain VAS score 0–4 indicating no pain over the study period[a]



[a]Out of 30 patients at each time point

Figure 6. Proportion of patients with Pain VAS score 5–44 indicating mild pain, 45–74 indicating moderate pain, and 75–100 indicating severe pain, over the study period[a]



[a]Out of 30 patients at each time point

Abbreviations
BMI, body mass index; DLQI, Dermatology Life Quality Index; EoS, end of study; FDA, Food and Drug Administration; GPP, generalized pustular psoriasis; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; LD, loading dose; PRO, patient-reported outcome; q4w, every 4 weeks; q12w, every 12 weeks; R, randomization; SC, subcutaneous; SD, standard deviation, VAS, visual analog scale.

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Disclosures
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