

# Spesolimab rapidly improves quality of life in patients with generalized pustular psoriasis, as per Dermatology Life Quality Index scores: Data from the Effisayil® 2 trial

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## Aim: To further analyze the effect of spesolimab 300 mg SC q4w (following a 600 mg SC loading dose) versus placebo on DLQI scores in Effisayil® 2

### Background

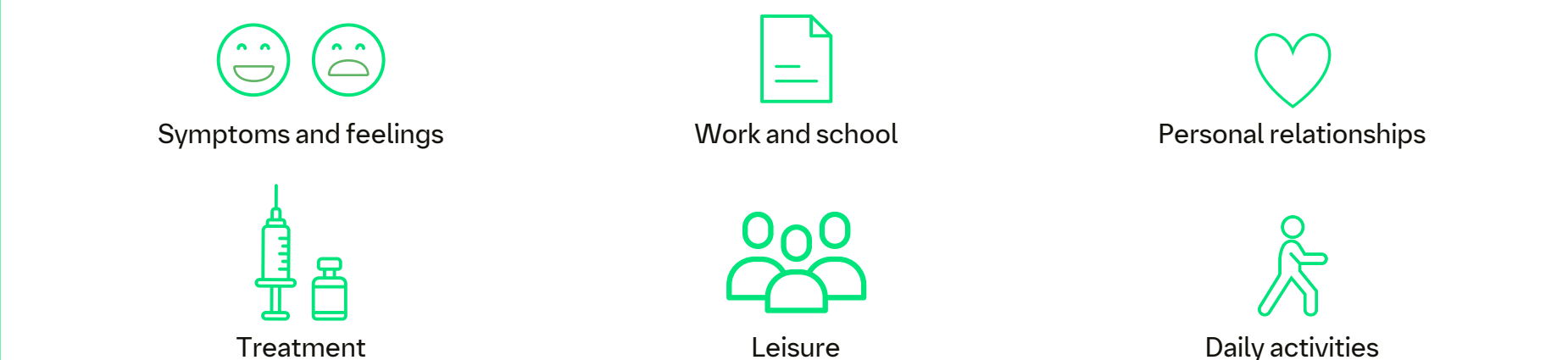
- GPP is a chronic and potentially life-threatening disease characterized by flares of widespread skin pustulation<sup>1</sup>
- In Effisayil® 2 (NCT04399837), spesolimab (300 mg SC q4w\*) was significantly superior to placebo for the prevention of GPP flares, reducing the risk of a GPP flare by 84%<sup>1</sup>
- Spesolimab (300 mg SC q4w\*) also numerically reduced the risk of DLQI worsening (≥4-point increase in total score from baseline; secondary endpoint) up to Week 48<sup>1</sup>

\*Following a 600 mg SC loading dose.

### Methods

- The DLQI is a 10-question, QoL questionnaire that covers six domains including symptoms and feelings, work and school, personal relationships, treatment, leisure, and daily activities.<sup>2</sup> The DLQI reports the impact on QoL, ranging from 0 (no effect on a patient's life) to 30 (extremely large effect)<sup>2,3</sup>
- DLQI was assessed in patients in the spesolimab (300 mg SC q4w\*) and placebo groups at Weeks 4, 8, 12, 24, 36, and 48 (EoS)<sup>1</sup>
- A 4-point change from baseline was considered a clinically important difference

Figure 1. DLQI domains and interpretation of scoring



| Score | Response category <sup>4</sup> |
|-------|--------------------------------|
| 0     | Not relevant/not at all        |
| 1     | A little                       |
| 2     | A lot                          |
| 3     | Very much                      |

\*Following a 600 mg SC loading dose.  
<sup>1</sup>DLQI questionnaire responses for subjects who were less than 16 years of age were censored at Day 1.  
<sup>2</sup>Question 7 is a 'yes'/'no' question where 'yes' is scored as 3; the magnitude of impact is assessed in a follow-up question.

### Results

- Baseline characteristics were generally similar, though the spesolimab (300 mg SC q4w\*) group had a higher DLQI score at baseline

Table 1. Baseline characteristics

|                                   | Spesolimab (300 mg SC q4w*)<br>N=30 | Placebo<br>N=31  |
|-----------------------------------|-------------------------------------|------------------|
| Mean age (SD), years              | 40.2 (16.4)                         | 39.5 (14.0)      |
| Female, n (%)                     | 18 (60)                             | 18 (58)          |
| Race, n (%)                       |                                     |                  |
| Asian                             | 21 (70)                             | 17 (55)          |
| White                             | 9 (30)                              | 14 (45)          |
| Mean BMI (SD), kg/m <sup>2</sup>  | 25.6 (7.3)                          | 26.9 (8.3)       |
| GPPASI total score (SD)           | 3.92 (4.42)                         | 3.11 (2.81)      |
| GPPGA total score, n (%)          |                                     |                  |
| 0                                 | 3 (10)                              | 4 (13)           |
| 1                                 | 27 (90)                             | 27 (87)          |
| PSS total score (SD)              | 5.3 (3.8)                           | 3.6 (2.9)        |
| <b>DLQI total score (SD)</b>      | <b>11.1 (6.9)</b>                   | <b>7.2 (5.6)</b> |
| Historical flares per year (SD)   | 2.4 (1.9)                           | 2.4 (1.2)        |
| Time since first diagnosis, n (%) |                                     |                  |
| ≤1 year                           | 4 (13)                              | 3 (10)           |
| >1 to ≤5 years                    | 9 (30)                              | 10 (32)          |
| >5 to ≤10 years                   | 8 (27)                              | 7 (23)           |
| >10 years                         | 9 (30)                              | 11 (35)          |

\*Following a 600 mg SC loading dose.

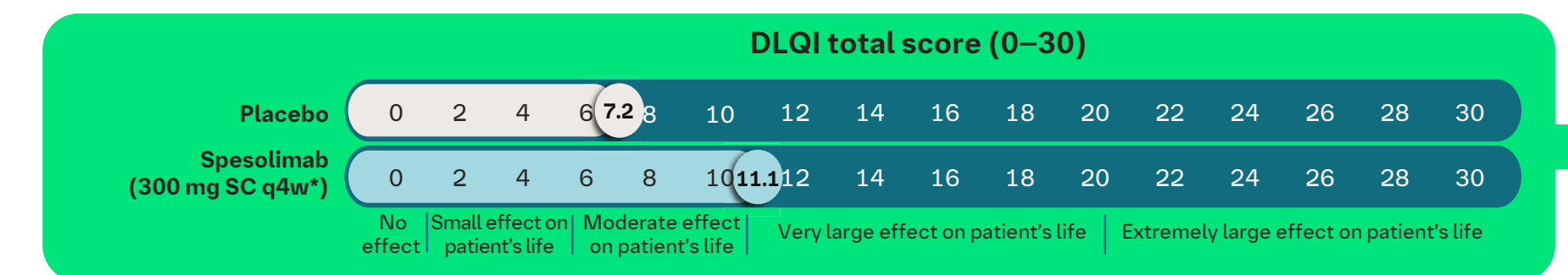


Figure 2. Proportion of patients without a flare with ≥4-point improvement in DLQI score up to Week 48

- A smaller proportion of patients (data not shown) in the spesolimab (300 mg SC q4w\*) group had a GPP flare (3/29) from Week 4 to 48 compared with placebo (16/31)
- In patients without a flare, a higher proportion of patients in the spesolimab (300 mg SC q4w group\*) had a ≥4-point improvement from baseline in DLQI scores from Week 4 to Week 48 compared with placebo

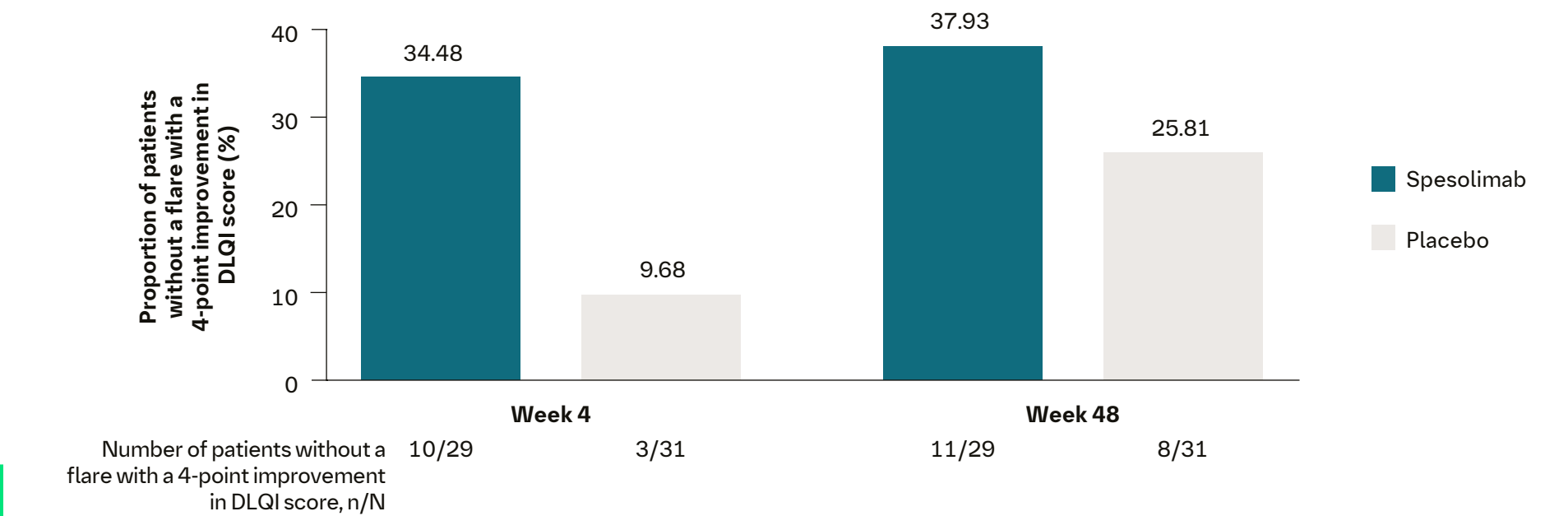
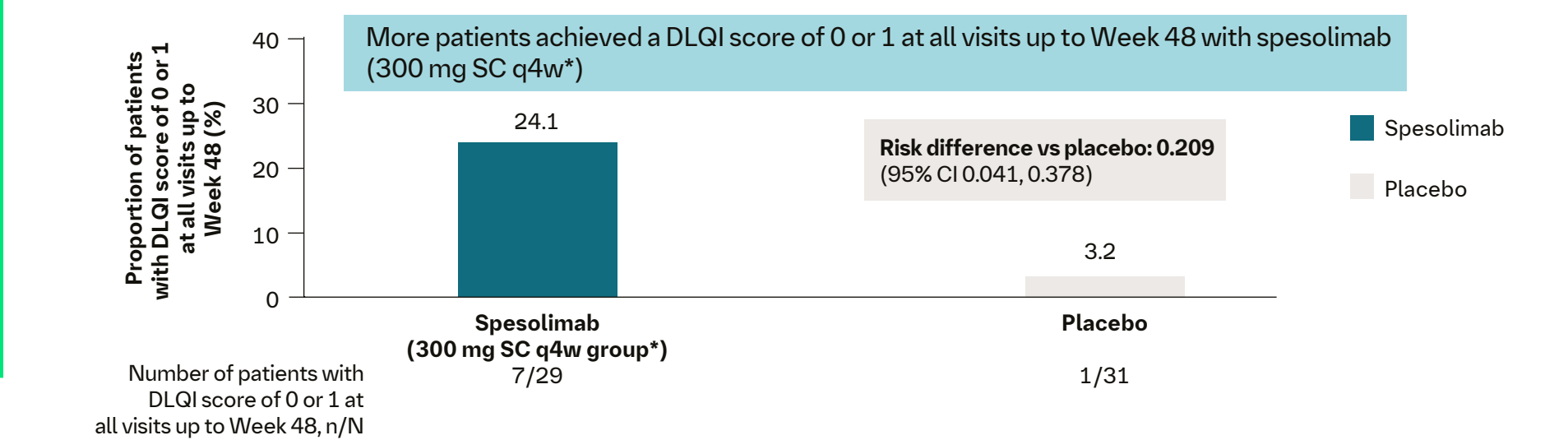


Figure 3. Proportion of patients with DLQI score of 0 or 1 at all visits up to Week 48



\*Following a 600 mg SC loading dose.

## Conclusions

- In the Effisayil® 2 trial, patients in the spesolimab (300 mg SC q4w\*) group had an 84% reduction in the risk of a GPP flare compared with placebo
- Patients treated with spesolimab (300 mg SC q4w\*) rapidly gained improvements in DLQI scores compared with placebo, which were sustained through to Week 48
- Even when examining only patients without a GPP flare, a higher proportion of patients treated with spesolimab (300 mg SC q4w\*) had a clinically meaningful ≥4-point improvement in DLQI scores compared with placebo at all visits up to Week 48
- More patients achieved a DLQI score of 0 or 1 at all visits up to Week 48 with spesolimab (300 mg SC q4w\*)

\*Following a 600 mg SC loading dose.

### References

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- Finlay AY & Khan G. *Clin Exp Dermatol*. 1994;19:210–6.
- Dermatology Quality of Life Index (DLQI). <https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questions/dermatology-life-quality-index> (accessed November 8, 2023).

### Abbreviations

BMI, body mass index; DLQI, Dermatology Life Quality Index; EoS, end of study; GPP, generalized pustular psoriasis; GPPASI, Generalized Pustular Psoriasis Area and Severity Index; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; PSS, Psoriasis Symptom Scale; QoL, quality of life; q4w, every 4 weeks; SC, subcutaneous; SD, standard deviation.

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