Spesolimab use for generalized pustular psoriasis flare prevention in patients with concomitant plaque psoriasis: Results from the Effisayil 2 trial

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The subpopulation of patients with GPP and concomitant PsO had low TPSS scores at baseline and they remained low in both the placebo and spesolimab-treatment groups throughout the trial

AIM

To report the effect of spesolimab vs placebo on mean changes in TPSS (target plaque severity score) from baseline in patients with GPP and concomitant PsO who participated in the Effisayil 2 study

INTRODUCTION

- GPP is a chronic, inflammatory, and potentially life-threatening skin disease characterized by episodic flares of widespread pustular eruptions and erythema
- Spesolimab, an anti-interleukin-36 receptor monoclonal antibody, is approved to treat GPP flares in adults in the US,[1] and many other countries
- Effisayil 2 (NCT04399837) was a pivotal, randomized, placebo-controlled trial that evaluated the efficacy and safety of spesolimab SC in preventing GPP flares[2]
- An estimated 31–78% of all patients with GPP have concomitant PsO[3,4]
- This subgroup analysis examines plaque severity in Effisayil 2 study participants with concomitant PsO

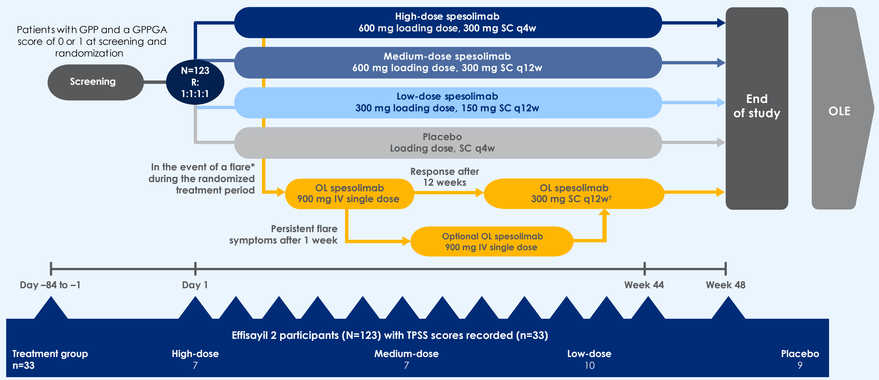
CONCLUSIONS

- Low baseline TPSS scores observed in this subpopulation of 33 GPP patients with concomitant PsO suggest that plaque characteristics in PsO are generally mild to moderate
- TPSS scores remained low and consistent throughout the trial in both dosing groups, and decreases in TPSS score by Week 16 (spesolimab-treated) and Week 48 (both groups) compared with baseline were observed

METHODS

- In Effisayil 2, eligible patients with a history of GPP were randomized (1:1:1:1) to receive 1 of 3 spesolimab SC regimens or placebo for 48 weeks (**Figure 1**)

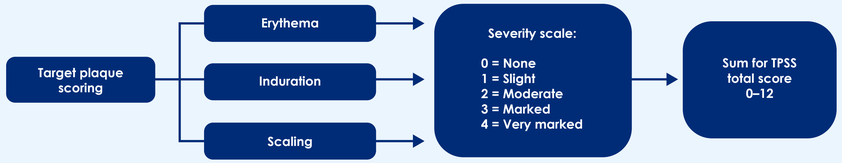
Figure 1. Study design



*GPP flare was defined as an increase in the GPPGA total score of ≥2 from baseline and GPPGA pustulation subscore of ≥2 from baseline. The use of medication with OL spesolimab IV or other investigator-prescribed medication was considered to be a GPP flare.
†Patients receiving OL spesolimab 300 mg SC q12w had the option to escalate to 300 mg SC q4w if they had an increase in the GPPGA pustulation subscore of ≥1 from any previous OL visit(s).

- In this exploratory analysis, a target PsO lesion ≥9 cm^2 with TPSS total score ≥5 and induration subscore ≥2 was selected by the investigator at baseline for each participant with PsO
- At subsequent study visits, the target plaque was scored for erythema, induration (plaque thickness), and scaling, with each category graded on a 5-point severity scale (**Figure 2**)
  - The summation of the 3 subscores yielded the TPSS total score, which ranged from 0 to 12, with higher scores representing greater severity of psoriasis

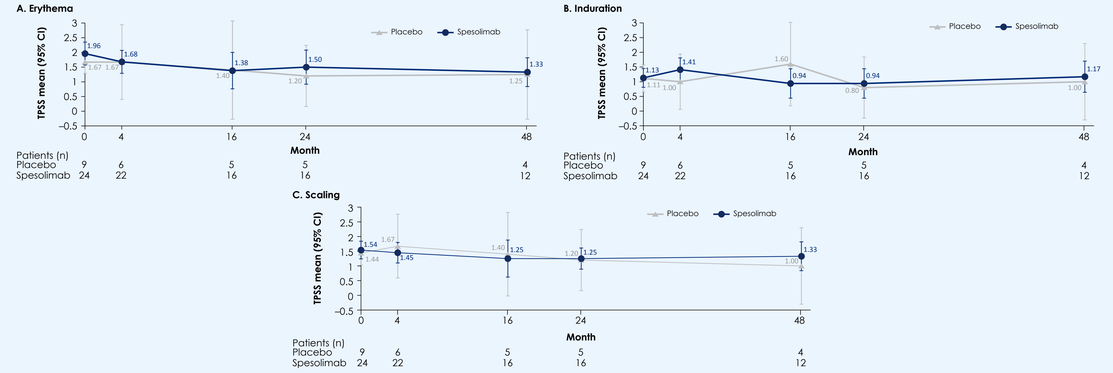
Figure 2. TPSS Scale on psoriasis severity



RESULTS

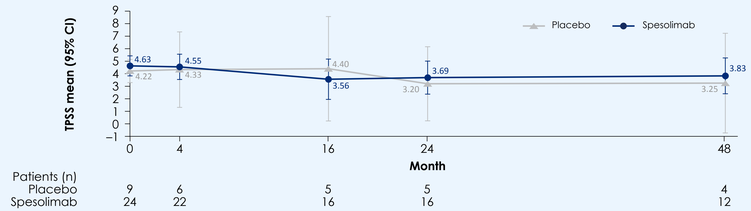
- TPSS was measured in 33 of 123 (27%) patients who presented with PsO in the trial (9 placebo, 10 low-dose, 7 medium-dose, 7 high-dose)
- The number of patients with TPSS data declined in both groups over time due to the study protocol, because of GPP flare or early discontinuation

Figure 3. Mean TPSS of (A) erythema, (B) induration, and (C) scaling with total SC spesolimab and placebo



Mean TPSS subscores for each category (erythema, induration, scaling) were low at baseline.
In both the spesolimab and placebo arms, TPSS subscores trended down and remained low across all categories over the course of the 48-week trial

Figure 4. Mean of absolute value of TPSS with total SC spesolimab and placebo



The mean TPSS total scores in placebo and in spesolimab-treated patients were low at baseline, with slight decreases observed for each group by Week 48

Abbreviations

GPP, generalized pustular psoriasis; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; IV, intravenous; OL, open-label; OLE, open-label extension; PsO, plaque psoriasis; q4w, once every 4 weeks; q12w, once every 12 weeks; R, randomized; SC, subcutaneous; TPSS, target plaque severity score

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