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Spesolimab treatment improves pain, symptoms of psoriasis, fatigue and quality of life in patients with generalized pustular psoriasis: Patient-reported outcomes from the Effisayil™ 1 study

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Patients with a generalized pustular psoriasis (GPP) flare who were treated with up to three doses of 900 mg of spesolimab intravenously showed clear improvements from baseline in the patient-reported outcomes (PROs) of pain, fatigue, overall quality of life (QoL) and skin symptoms

PURPOSE

To evaluate PROs of measures of pain, fatigue, impact on overall QoL and skin symptoms in patients treated with spesolimab, an anti-interleukin-36 receptor monoclonal antibody, in the Effisayil™ 1 study.

INTRODUCTION

- GPP is a rare, potentially life-threatening, neutrophilic skin disease characterised by widespread eruption of sterile, visible pustules, and can occur with or without systemic inflammation[1–3]
- In the multicentre, randomised, double-blind, placebo-controlled Effisayil™ 1 study (NCT03782792) in patients presenting with a GPP flare, spesolimab treatment led to rapid pustular and skin clearance within 1 week.[4] GPP flares are associated with a high clinical burden in PROs including symptoms such as pain, itching and fatigue, which all impact overall QoL[5,6]
- Here we explore PROs in patients with a GPP flare receiving spesolimab treatment

CONCLUSIONS

- In this study, patients who received 900 mg of intravenous spesolimab showed clinically significant improvements from baseline in the PROs of pain, fatigue, overall QoL and skin symptoms
- The clear separation of the spesolimab and placebo curve occurred early during the placebo-controlled period (Week 1). This suggests that spesolimab results in the rapid improvement of PROs, with considerable improvement in fatigue and pain
- PRO scores continued to improve up to Week 4 and were sustained through Week 12

METHODS

- Patients (N=53) were randomised (2:1) to receive placebo or 900 mg of spesolimab on Day 1 and were followed for 12 weeks
- If disease worsening occurred during Week 1, patients were able to receive escape treatment (any other treatment for GPP) any time after their first dose of spesolimab or placebo on Day 1 and before Day 8
- Patients who achieved qualifying clinical assessment scores (GPPGA total score ≥2 or GPPGA pustulation subscore ≥2) and did not receive escape treatment during Week 1 were eligible to receive open-label (OL) spesolimab on Day 8 and another dose of OL spesolimab between Day 8 and Week 12 to treat new flares
  - Spesolimab arm (n=35): One dose of spesolimab at Day 1 (n=23); optional second dose of OL spesolimab at Day 8 (n=12); optional third dose of OL spesolimab between Weeks 1 and 12 (n=2)
  - Placebo arm (n=18): optional first dose of OL spesolimab at Day 8 (n=15); optional second dose of OL spesolimab between Weeks 1 and 12 (n=1)
- All randomised patients were included in this analysis. The observed cases irrespective of any use of escape treatment, OL spesolimab on Day 8 or after Day 8 (representing the intention-to-treat principle) are summarised descriptively
- To monitor any changes in outcomes, patients completed the following PRO questionnaires throughout the study: Pain visual analogue scale (pain VAS), Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-Fatigue), Dermatology Life Quality Index (DLQI) and the Psoriasis Symptom Scale (PSS)
  - All four PROs were measured on Day 1, Day 8 and Weeks 2–4, 8 and 12. PSS scores were also measured on Day 2 and Day 3

RESULTS

PRO survey multiple-choice answers and their corresponding scores

Pain VAS
- Measures severity of pain
- Score is determined by measuring the distance (mm) on the 10 cm line between the 'no pain' anchor and the patient's mark

No pain — Very severe pain
0 — 10 cm — 100

DLQI
- 10-item scale
- Assesses six areas of quality of life: symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment
- Scores from each answer totalled; maximum 30

No effect | Small effect | Moderate effect | Very large effect | Extremely large effect
0 — 30
0–1 | 2–5 | 6–10 | 11–20 | 21–30

FACIT-Fatigue
- 13-item scale
- Measures self-reported fatigue and its impact on daily activities and function
- Scores from each answer totalled; maximum 52

High impact — Low impact
0 — 52

PSS
- 4-item scale
- Measures severity of pain, redness, itching and burning
- Scores from each answer totalled; maximum 16

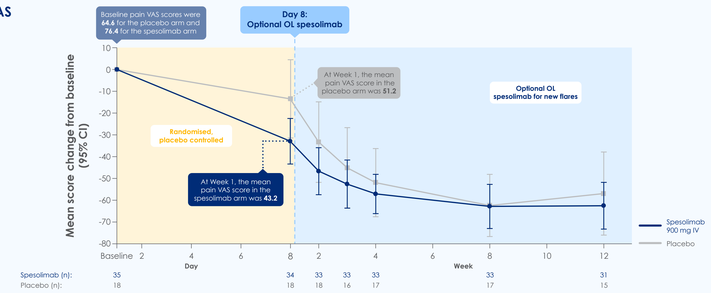
Less severe — More severe
0 — 16

DLQI, Dermatology Life Quality Index; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy–Fatigue; PRO, patient-reported outcome; PSS, Psoriasis Symptom Scale; VAS, visual analogue scale.

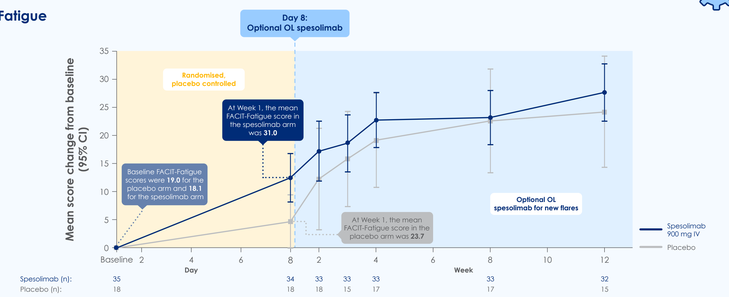
High total scores indicate a large impairment or intense severity, except for FACIT-Fatigue, for which higher scores represent less fatigue

Absolute change from baseline in PRO scores over time

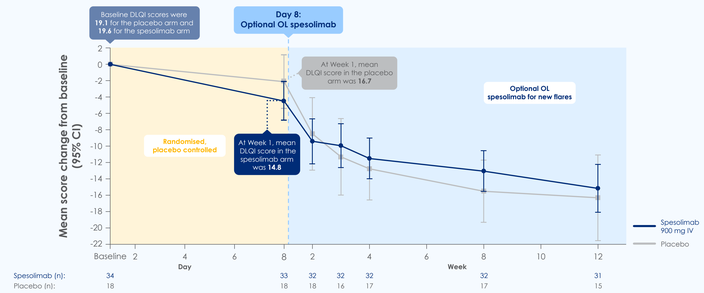
Pain VAS



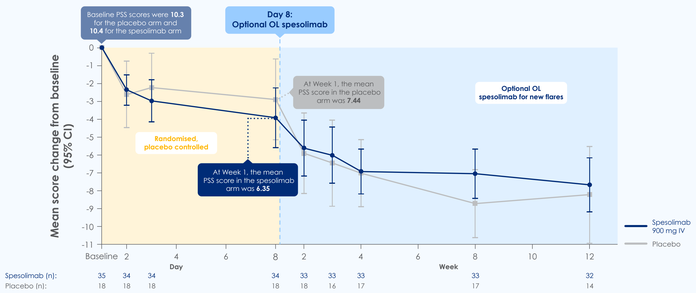
FACIT-Fatigue



DLQI



PSS



CI, confidence interval; DLQI, Dermatology Life Quality Index; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy–Fatigue; IV, intravenous; OL, open-label; PRO, patient-reported outcome; PSS, Psoriasis Symptom Scale; VAS, visual analogue scale.

Although the study was not designed to test a statistical difference for PROs between spesolimab and placebo earlier than week 4, there was a numerical trend of early separation between spesolimab and placebo within the first week which continued to improve over time with spesolimab. The placebo curve begins to converge with the spesolimab curve after administration of OL spesolimab at Day 8

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