

The effect of present or historical psoriasis on the efficacy of spesolimab in patients with a generalized pustular psoriasis (GPP) flare

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The efficacy and safety of spesolimab for the treatment of GPP flares are consistent between patients with and without present or historical psoriasis

PURPOSE

To evaluate the efficacy of spesolimab treatment in patients with a GPP flare with and without present or historical psoriasis.

INTRODUCTION

- GPP is a rare, potentially life-threatening, autoinflammatory skin disease, characterised by widespread eruption of sterile, visible pustules¹⁻⁴
- In the multicentre, randomised, double-blind, placebo-controlled Effisyil™ 1 study (NCT03782792) in patients presenting with a GPP flare, spesolimab treatment led to rapid pustular and skin clearance within 1 week^{4,5}
 - Primary endpoint (GPPGA pustulation subscore of 0; no visible pustules): 54% vs 6% (one-sided p<0.001)
 - Key secondary endpoint (GPPGA total score of 0 or 1; clear or almost clear skin): 43% vs 11% (one-sided p=0.0118)

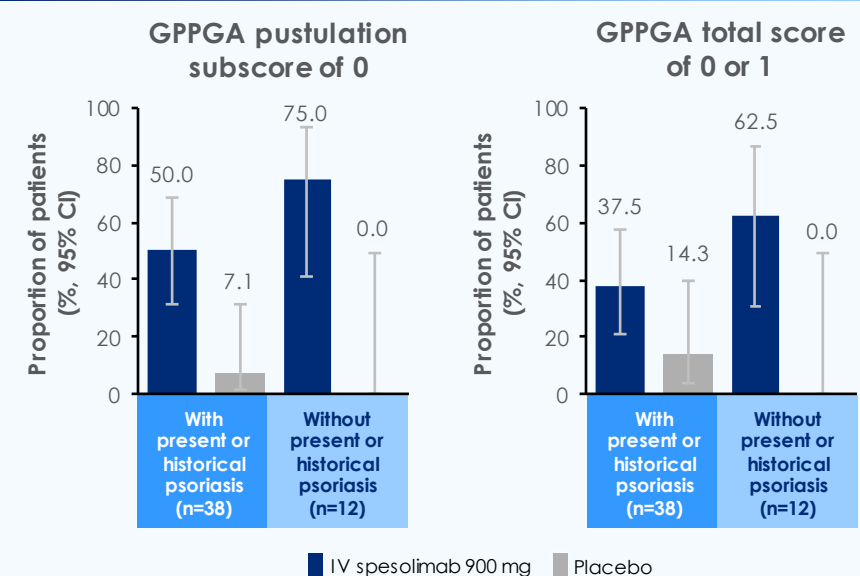
RESULTS

Baseline demographics and clinical characteristics		
Characteristic	With present or historical psoriasis (n=38)	Without present or historical psoriasis (n=12)
Mean age (SD), years	43.7 (11.3)	42.3 (8.2)
Female, n (%)	25 (65.8)	10 (83.3)
Race, n (%)*		
Asian	22 (57.9)	6 (50.0)
White	16 (42.1)	6 (50.0)
Pooled study site, n (%)		
USA	2 (5.3)	0
Japan	1 (2.6)	1 (8.3)
Asia (excluding Japan)	19 (50.0)	5 (41.7)
Europe	13 (34.2)	2 (16.7)
Africa	3 (7.9)	4 (33.3)
Mean BMI (SD), kg/m ²	27.3 (7.8)	24.8 (5.8)
Mean weight (SD), kg	73.5 (22.6)	63.3 (15.3)
IL36RN mutation, n (%)†	9 (23.7)	5 (41.7)
GPPGA total score, n (%)		
3	32 (84.2)	9 (75.0)
4	6 (15.8)	3 (25.0)
GPPGA pustulation subscore, n (%)		
2	9 (23.7)	2 (16.7)
3	16 (42.1)	6 (50.0)
4	13 (34.2)	4 (33.3)

Data for each subgroup include both treatment arms. *Race was reported by the patient. †One patient in the 'present or historical psoriasis' subgroup and 11 patients in the 'no present or historical psoriasis' subgroup who received placebo had missing data. Of 53 patients randomised to receive spesolimab or placebo, 46 had genetic testing.

Baseline characteristics and demographics were balanced between subgroups; however, a higher proportion of patients without present or historical psoriasis had an IL36RN mutation than those with present or historical psoriasis (41.7% vs 23.7%, respectively)

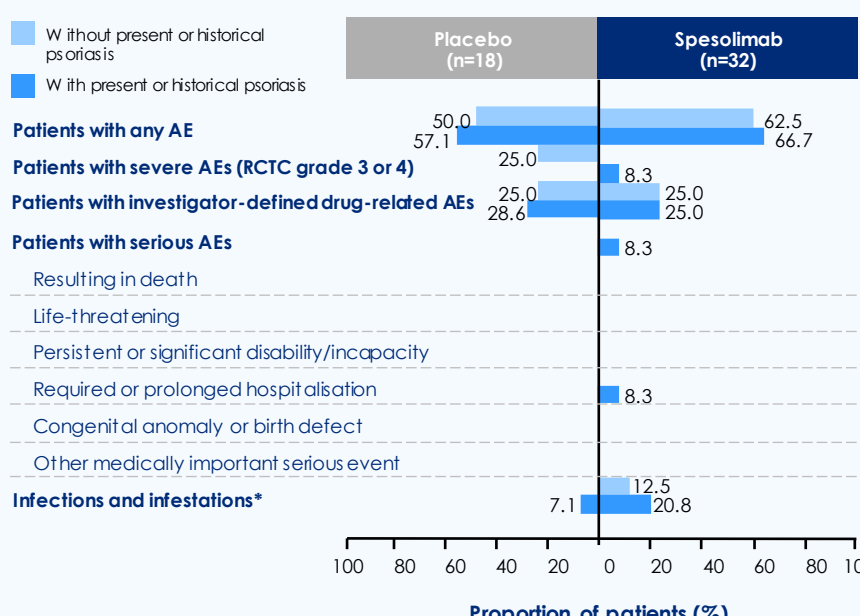
Primary and key secondary endpoints in patients by subgroup at Week 1



Two patients in the spesolimab arm and one patient in the placebo arm received another medication for GPP within the first week; one patient in the spesolimab arm discontinued treatment before completing Week 1. Missing values or any use of other medication for GPP within the first week of the trial were regarded as non-response for the analysis of these endpoints.

The efficacy of spesolimab by Week 1 was consistent between those with present or historical psoriasis at baseline and those without

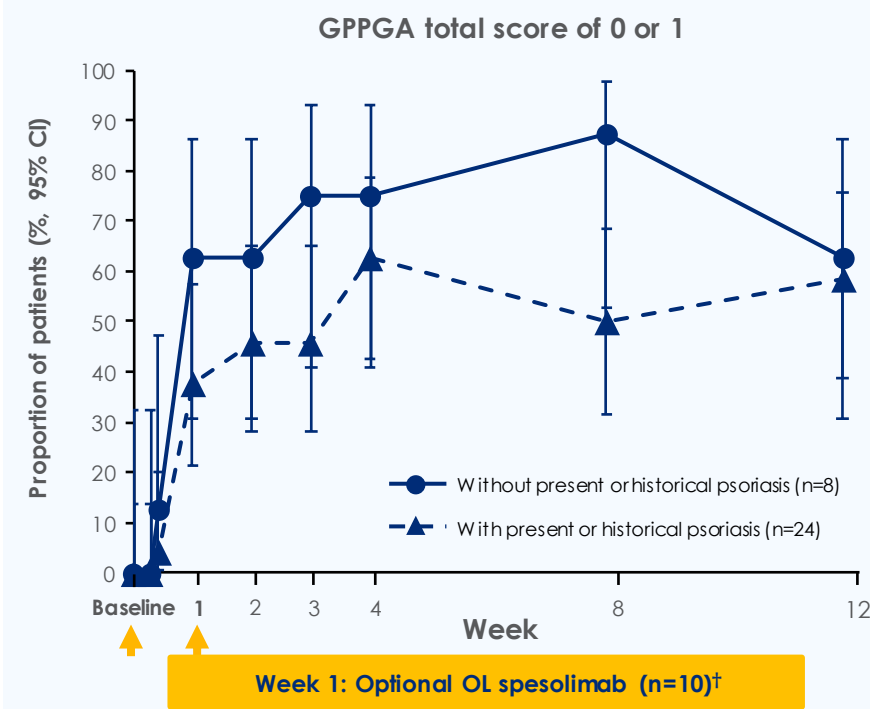
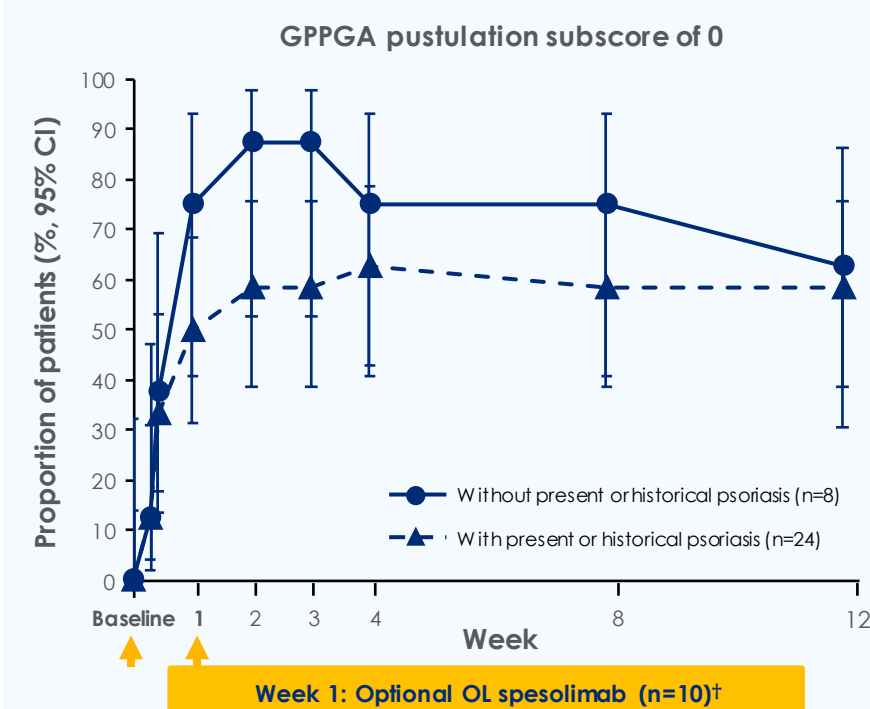
Proportion of patients experiencing AEs in both subgroups at Week 1



*Infections were more common in the spesolimab versus placebo arm; however, most cases were mild and uncomplicated, and were not indicative of opportunistic infection.

The proportion of patients who experienced an AE was similar in both subgroups

Proportion of patients treated with spesolimab* with a GPPGA pustulation subscore of 0 and GPPGA total score of 0 or 1 by subgroup



*Treatment effect in patients who received up to two doses of spesolimab at Day 1 (n=32) and an optional dose at Day 8 (n=10). n=8 with psoriasis, n=2 without plaque psoriasis. Missing values, and use of any other medication for GPP or spesolimab for the treatment of a new GPP flare were regarded as non-response for this analysis.

Following treatment with spesolimab, similar proportions of patients in both subgroups had no visible pustules/had clear skin over the course of the study

Abbreviations

AE, adverse event; BMI, body mass index; CI, confidence interval; GPP, generalized pustular psoriasis; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; IV, intravenous; OL, optional; RCTC, Rheumatology Common Toxicity Criteria; SD, standard deviation.

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