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The effect of the presence or absence of concomitant plaque psoriasis (PsO) at baseline on the efficacy of spesolimab in treating patients with a generalized pustular psoriasis (GPP) flare

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The efficacy and safety of spesolimab in the treatment of GPP flares is consistent between patients with and without concomitant plaque psoriasis

PURPOSE

To evaluate the efficacy of spesolimab treatment in patients with a GPP flare with and without concomitant plaque psoriasis.

INTRODUCTION

- GPP is a rare, potentially life-threatening, autoinflammatory skin disease, characterised by widespread eruption of sterile, visible pustules[1–4]
- 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[4,5]
  - Primary endpoint (GPPGA pustulation subscore of 0; no visible pustules): 54% versus 6% (one-sided p<0.001)
  - Key secondary endpoint (GPPGA total score of 0 or 1; clear or almost clear skin): 43% versus 11% (one-sided p=0.0118)

CONCLUSIONS

- Patients treated with spesolimab achieved rapid pustular and skin clearance, regardless of whether they did or did not have concomitant plaque psoriasis. These effects were sustained until the end of the study
- Spesolimab had an acceptable safety profile
- Spesolimab is a viable treatment option for patients with GPP, regardless of their plaque psoriasis status

METHODS

- Patients (N=53) were randomised (2:1) to IV spesolimab 900 mg or placebo at baseline and were followed for 12 weeks
- If disease worsening occurred during Week 1, patients were able to receive any other treatment for GPP any time after their first dose of spesolimab or placebo on Day 1 and before Day 8; this was considered as non-response for this analysis
- Scan the QR code at the bottom of this poster to see full details of the Effisayil 1 study design[4,5]

RESULTS

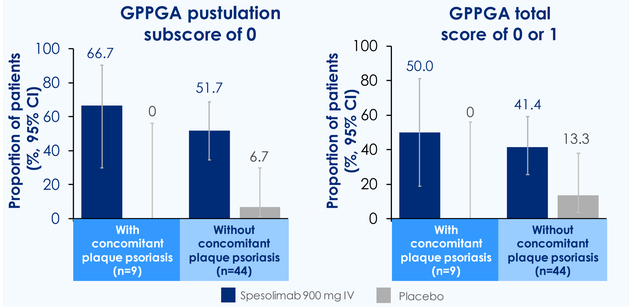
Baseline demographics and clinical characteristics

Characteristic	With concomitant plaque psoriasis (n=9)	Without concomitant plaque psoriasis (n=44)
Mean age (SD), years	39.8 (10.3)	43.7 (11.0)
Female, n (%)	4 (44.4)	32 (72.7)
Race, n (%)*		
Asian	6 (66.7)	23 (52.3)
White	3 (33.3)	21 (47.7)
Pooled study site, n (%)		
USA	1 (11.1)	2 (4.5)
Japan	0 (0)	2 (4.5)
Asia (excluding Japan)	6 (66.7)	19 (43.2)
Europe	2 (22.2)	14 (31.8)
Africa	0 (0)	7 (15.9)
Mean BMI (SD), kg/m²	28.2 (10.4)	26.7 (7.9)
Mean weight (SD), kg	78.6 (30.8)	70.7 (23.5)
***ILR36RN* mutation, n (%)†**	2 (22.2)	12 (27.3)
GPPGA total score, n (%)		
3	5 (55.6)	38 (86.4)
4	4 (44.4)	6 (13.6)
GPPGA pustulation subscore, n (%)		
2	1 (11.1)	10 (22.7)
3	2 (22.2)	21 (47.7)
4	6 (66.7)	13 (29.5)

Data for each subgroup include both treatment arms.
*Self-reported by the patients; †*ILR36RN* mutation status unknown in one (11.1%) patient with concomitant plaque psoriasis and in six (13.6%) patients without concomitant plaque psoriasis.

Baseline characteristics and demographics were generally balanced between patients with and without concomitant plaque psoriasis

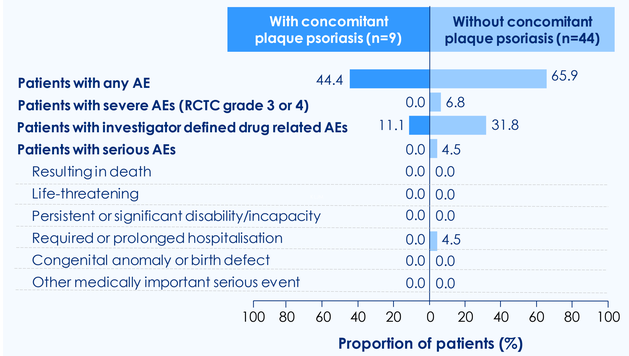
Primary and key secondary endpoints in patients by subgroup at Week 1



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 spesolimab arm discontinued 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.

Greater proportions of patients treated with spesolimab versus placebo achieved the primary and secondary endpoints by Week 1, regardless of whether they did or did not have concomitant plaque psoriasis

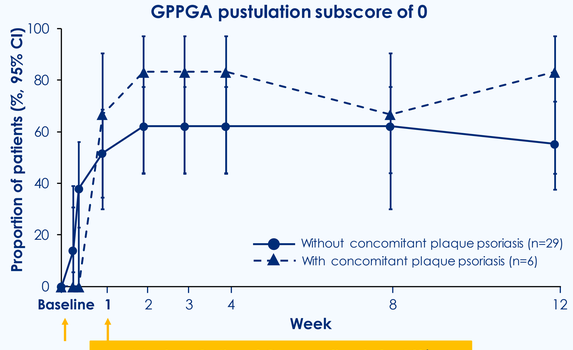
Proportion of patients experiencing AEs in both subgroups at Week 1



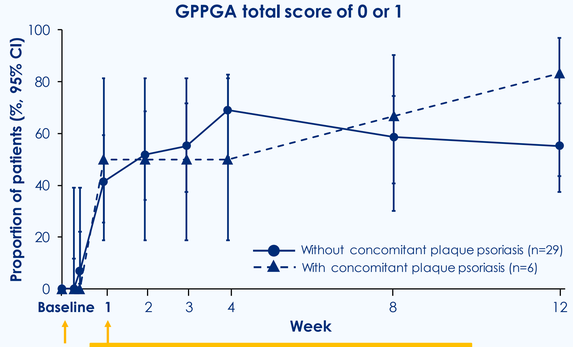
Data for each subgroup include both treatment arms.

Spesolimab had an acceptable safety profile

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



Week 1: Optional OL spesolimab (n=12)†



Week 1: Optional OL spesolimab (n=12)†

*Treatment effect in patients who received up to two doses of spesolimab: Day 1 (n=35) and optional dose at Day 8 (n=12); †n=2 with plaque psoriasis, n=10 without plaque psoriasis. Missing values, any use of 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 or 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 Global Assessment; *IL36RN*, interleukin-36 receptor gene; IV, intravenous; OL, open label; RCTC, Rheumatology Common Toxicity Criteria; SD, standard deviation.

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Disclosures & Acknowledgements
The study was supported and funded by Boehringer Ingelheim. **PvdK** declares receiving fees for consultancy service or lectureships from AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Eli Lilly, Janssen, LEO Pharma, Novartis and UCB. **YO** declares receiving grants or contracts from Eisai, Maruho and Shiseido Torii; and consulting fees from AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly, Janssen, JIMRO, Kyowa Kirin, LEO Pharma, Maruho, Novartis, Pfizer, Sanofi, Sun Pharmaceutical Industries, Taiho Pharmaceutical, Mitsubishi Tanabe, Torii Pharmaceutical and UCB. **LP** declares receiving perceived consultancy/ speaker's honoraria from and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer, Sandoz, Sanofi, and UCB. **JCP** declares paid activities as an advisor, speaker or consultant for Almirall, Boehringer Ingelheim, Janssen-Cilag, Novartis and Pfizer. **JS**, **CT** and **LL** are employees of Boehringer Ingelheim. **HB** declares receiving grants or contracts from Boehringer Ingelheim, Janssen, LEO Pharma, Novartis and Pfizer; consulting fees from AbbVie, Almirall, Biocad, Boehringer Ingelheim, Celgene, Dermavant, Eli Lilly, Janssen, Kyowa Kirin, LEO Pharma, Mylan, Novartis, UCB and Xion Pharmaceuticals; honoraria from AbbVie, Boehringer Ingelheim, Celgene and LEO Pharma; advisory board participation for Avillion; and meeting attendance support from Janssen, Novartis and UCB. The authors met criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE). The authors did not receive payment related to the development of the poster. Boehringer Ingelheim was given the opportunity to review the poster for medical and scientific accuracy, as well as intellectual property considerations. Geetha Vilventhraraja, BSc, of OPEN Health Communications (London, UK) provided writing, editorial and formatting support, which was contracted and funded by Boehringer Ingelheim.

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