CO179

Assessing the Real-World Effectiveness of Spesolimab in Generalized Pustular Psoriasis: A Systematic Literature Review

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Conclusions

- This systematic literature review of RWE studies found that 94% of patients with GPP treated with spesolimab achieved a positive clinical response
- Furthermore, spesolimab demonstrated the potential to provide significant symptom resolution, even in patients with complex clinical profiles and in those previously refractory to other biologic therapies
- Clinical response rates were similar in biologic-naïve and biologic-experienced patients and in patients with and without concomitant plaque psoriasis, suggesting consistent effectiveness across diverse patient subgroups

Objective

- The objective of the systematic literature review was to evaluate the effectiveness of spesolimab in clinical practice, with a particular focus on patients with previous non-GPP-specific biologic experience

Background

- GPP is an autoinflammatory, potentially life-threatening, chronic, systemic neutrophilic disease with a heterogeneous and unpredictable clinical course distinct from plaque psoriasis[1,2]
- Historically, treatment options for GPP have been limited and included conventional systemic therapies and biologics, many used off-label
- More recently, new targeted therapies have been developed against the IL-36 receptor, providing a GPP-specific targeted therapeutic approach
- The EFFISAYIL® 1 and 2 trials demonstrated that spesolimab is efficacious for the treatment and prevention of GPP flares[2,3]
- However, the effectiveness of spesolimab in real-world clinical practice, where patients often present with greater complexity, has not been studied

Key inclusion criteria

- Patients with GPP treated with spesolimab
- Adult and adolescent patients
- RWE studies

Key exclusion criteria

- Other diseases than GPP
- Pediatric patients (<12 years)
- Articles based on clinical trials
- Review articles

Methods

- A systematic review was conducted to collect relevant published RWE studies on patients with GPP treated with spesolimab

Search strategy and screening process

- Searches of PubMed® and Embase® were performed on 25 March 2026 in accordance with the PRISMA guidelines[4]
- Two reviewers independently conducted a preliminary screening of publications by assessing titles and abstracts against predefined eligibility criteria, followed by full-text review to confirm study inclusion (**Figure 1**)

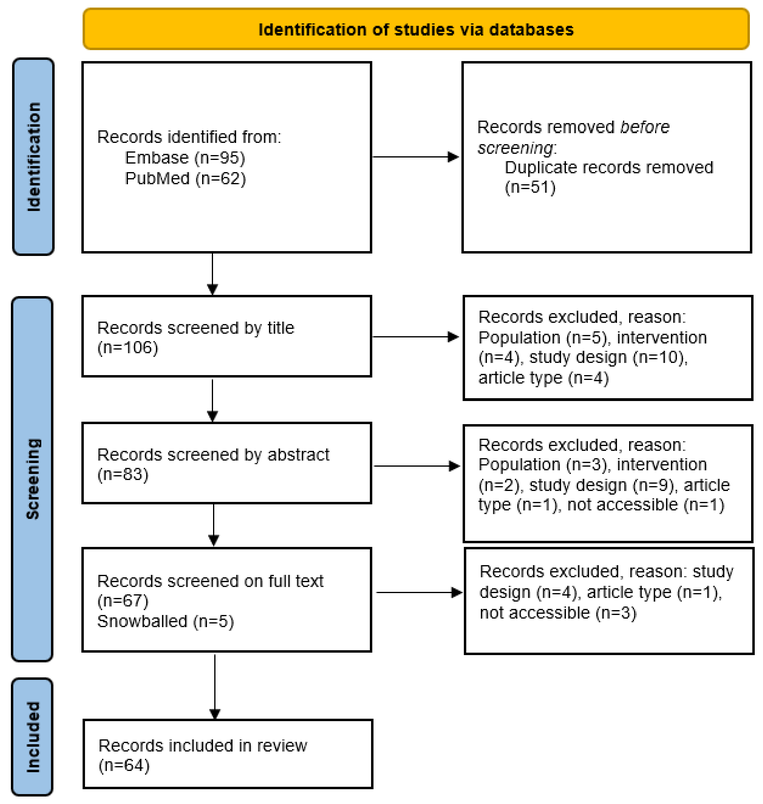
Eligibility criteria

- All observational studies and congress abstracts reporting on patients treated with spesolimab for GPP were included
- No restrictions were defined for year of publication

Statistical analysis and data presentation

- Treatment response was perceived as positive when studies described patients responding positively to spesolimab, being successfully treated with spesolimab, or reaching a GPPGA score of 0/1
- Data were presented with frequencies and percentages for categorical covariates including sex, age, relevant comorbidities, and number of previous biologic treatments to characterize the patient population
- Statistically significant differences were tested with chi^2-test and described with p-values with a 95% significance level

Figure 1 PRISMA flow chart of included studies[4]



Results

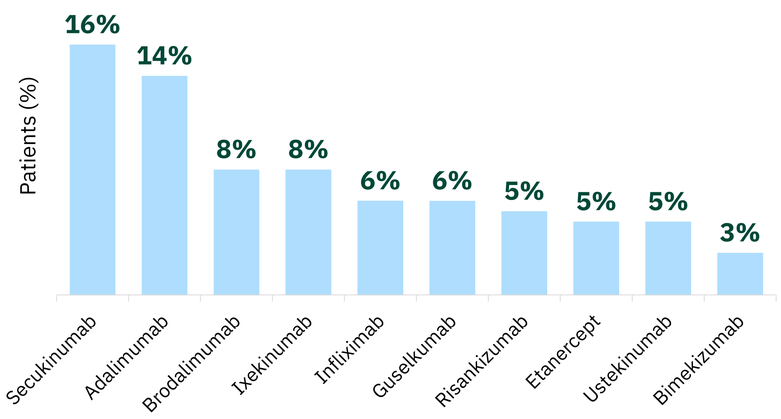
Study population, characteristics and data availability

- From the 64 included publications, a total of 153 patients with GPP treated with spesolimab were included [5-69]
- Individual level data on age, comorbidities and treatment history were available for 88 patients (57.5%)
- Among the included patients, 60% were female and 20% had concomitant plaque psoriasis (**Table 1**)

Prior treatment history

- Among patients with available treatment history, 61% of patients were biologic-naïve prior to spesolimab, 30% had been prescribed 1–2 biologic treatments, while 9% had previously received three or more biologic therapies to treat GPP, however, with limited efficacy (**Table 1**)
- A total of 14 different biologic treatments were reported in the included studies
  - Out of all patients, 16% were previously treated with secukinumab and 14% with adalimumab (**Figure 2**)

Figure 2 Proportion of patients treated with the most frequently reported biologic treatments*



*One patient may have been treated with multiple biologic treatments or none

Table 1 Baseline characteristics of patients

	Total population (N=153)	Biologic-experienced (n=34)	Biologic-naïve (n=54)
Sex, female, n (%)	92 (60)	21 (62)	30 (56)
Age, n (%)*			
<20	2 (2)	0 (0)	2 (6)
20-29	18 (20)	9 (26)	9 (26)
30-39	12 (14)	3 (9)	9 (26)
40-49	13 (15)	8 (24)	5 (15)
50-59	17 (19)	7 (21)	10 (29)
60-69	15 (17)	5 (15)	10 (29)
70+	11 (13)	2 (6)	9 (26)
Comorbidities, n (%)*			
Plaque psoriasis	30 (20)	7 (21)	18 (33)
Psoriasis	6 (4)	3 (9)	3 (6)
Psoriatic arthritis	15 (10)	6 (18)	1 (2)
Rheumatoid arthritis	2 (1)	2 (6)	0 (0)
Palmoplantar psoriasis	2 (1)	2 (6)	0 (0)
Number of previous biologic treatments, n (%)*			
0	54 (61)	0 (0)	54 (100)
1	16 (18)	16 (47)	0 (0)
2	10 (11)	10 (29)	0 (0)
3 or above	8 (9)	8 (24)	0 (0)

*Individual data on age and previous treatments were available for 88 (57.5%) patients

Treatment response to spesolimab

- Overall, 94% of patients treated with spesolimab experienced a positive effect, whereas only nine patients (6%) had limited or negative effect (**Figure 3**)
- Positive treatment effects were reported for multiple subpopulations.
  - No statistically significant difference in treatment effects of spesolimab was observed between biologic-naïve and biologic-experienced patients (p=0.49) (**Figure 4A**)
  - No difference in treatment effect was found between patients with and without plaque psoriasis (p=0.55) (**Figure 4B**)

Figure 3 Treatment effect of spesolimab treatment in patients with GPP (N=153)

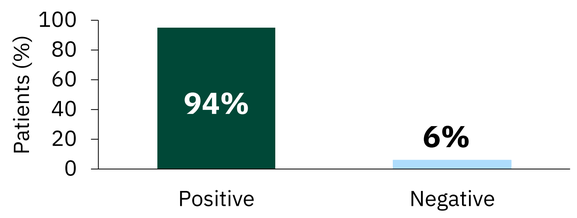
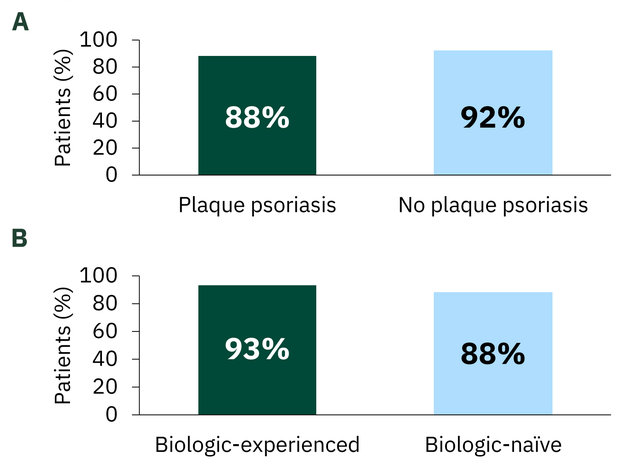


Figure 4 Positive treatment effect of spesolimab treatment in patients with GPP, by plaque psoriasis status and exposure to biologics (n=88)



Study limitations

- The effectiveness estimates were not adjusted for possible confounders
- Patient-level data was not available for all patients leading to incomplete data on several variables
- The literature review was based on data collected from multiple sources resulting in possible inconsistencies in data collection and data quality

Abbreviations GPP, Generalized pustular psoriasis; **GPPGA**, Generalized Pustular Psoriasis Physician Global Assessment, **RWE**, Real-World Evidence; **PRISMA,** Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

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