Real-world safety of spesolimab in generalized pustular psoriasis: Evidence from an expanded access program in Argentina

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Objectives: To provide early access to IV spesolimab via an EAP for patients with GPP experiencing a flare in Argentina
To report real-world safety and tolerability data on spesolimab use in the EAP

Synopsis

- Generalized pustular psoriasis (GPP) is a systemic, neutrophilic inflammatory disease associated with chronic symptoms and periods of flaring[1–3]
- GPP pathogenesis is driven by the interleukin (IL)-36 pathway;[4] skin biopsies from lesions of patients with GPP have been found to have significantly increased levels of IL-36 cytokines compared with non-lesional skin[5]
- Spesolimab is a first-in-class monoclonal antibody that targets the IL-36 receptor,[6] blocking IL-36 signaling and suppressing local and systemic inflammation[7]
- In the Phase 2, randomized, placebo-controlled EFFISAYIL 1 trial, spesolimab 900 mg intravenous (IV) treatment was associated with rapid pustular and skin clearance in patients experiencing a GPP flare, and was generally well tolerated[8]
- An expanded access program (EAP) was implemented in Argentina from 22 February 2023 to 10 January 2024, to provide early access to IV spesolimab for patients experiencing GPP flares who were not eligible for clinical trials and had no satisfactory authorized alternative treatment options
- IV spesolimab is now approved for the treatment of flares in adult patients with GPP in Argentina (approval date: 10 February 2024)[9]

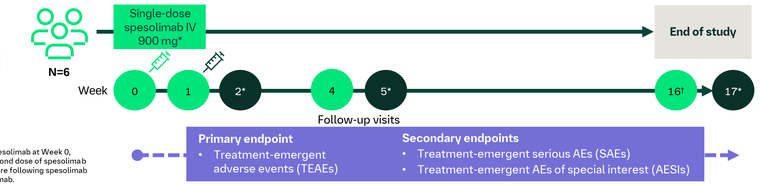
Methods

Study design

Study duration: 22 February 2023 to 10 January 2024

Inclusion criteria

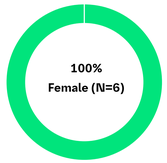
- 18–75 years old
- Diagnosed with GPP based on ERASPEN guidelines and experiencing a flare
- No satisfactory authorized alternative treatment available



*Optional second dose after 1 week for persistent flare symptoms. For patients who received one dose of spesolimab at Week 0, follow-up safety monitoring visits occurred at Week 1, Week 4, and Week 16; for patients who received a second dose of spesolimab at Week 1, follow-up visits occurred at Week 2, Week 5, and Week 17. †If a patient experienced a new GPP flare following spesolimab treatment after the 16-week follow-up period, they could re-enter the trial and be treated again with spesolimab.

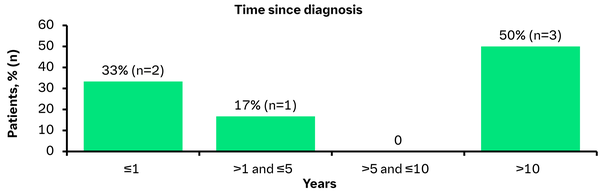
Results

Demographics and baseline characteristics



Mean age (±standard deviation [SD])
49.3 (11.5) years;
range 30–60 years

Mean body mass index (±SD)
28.1 (5.8) kg/m²

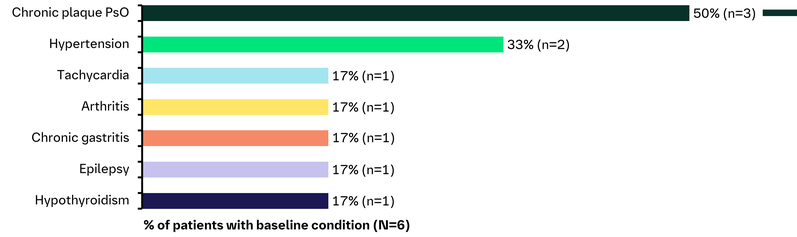


Comorbidities

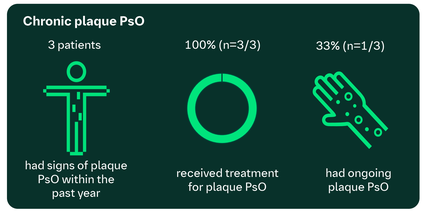
Mean follow-up (±SD) was 3.85 (0.11) months

Two patients received 1 dose, and 4 patients received 2 doses of spesolimab

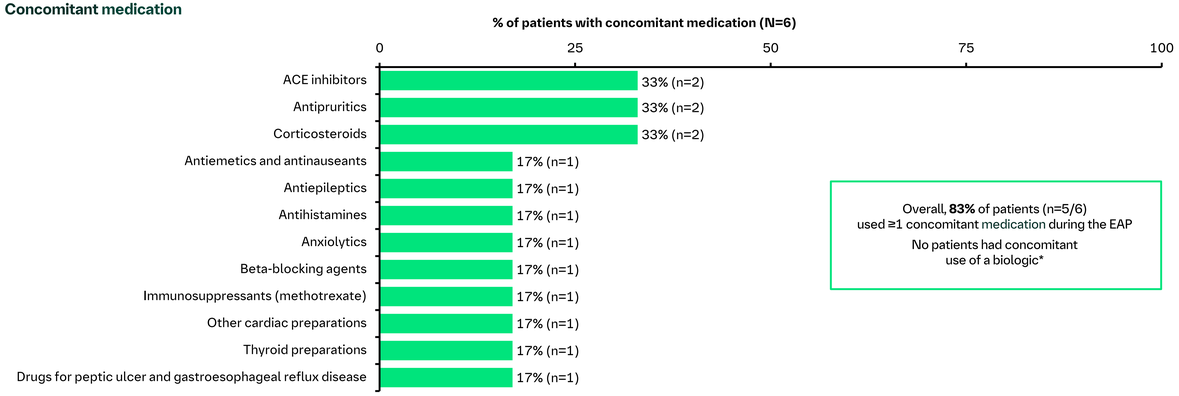
At baseline, **67%** of patients (n=4/6) had ≥1 comorbidity*



*Not including chronic plaque PsO, which was not reported as a comorbid condition at baseline but was reported within the last year and was ongoing in 3 patients (n=50%).



Concomitant medication



Overall, **83%** of patients (n=5/6) used ≥1 concomitant medication during the EAP
No patients had concomitant use of a biologic*

*Prior to this EAP, 1 patient discontinued ustekinumab (IL-12/IL-23 inhibitor).

Safety

Summary of AEs (N=6)	n	%
Patients with any AE	4	67
Patients with severe AEs (RCTC Grade 3 or 4)	0	0
Patients with investigator-defined, treatment-related AEs	1	17
Patients with AEs leading to discontinuation of trial drug	0	0
Patients with investigator-defined AESIs	0	0
Patients with SAEs	0	0

- **Four** patients (67%) had AEs, which were **mild** (influenza, catarrh, pruritus, rash, pain in extremity; each n=1) and **one** of these patients (17%) also had an AE of **moderate** intensity (headache)
- Two investigator-defined drug-related AEs (pruritus and rash) were reported in 1 patient (17%); the hypersensitivity event (rash) was non-serious
- There were no reports of SAEs, AESIs, or AEs that led to discontinuation or death

Conclusion

- Spesolimab showed a favorable safety profile in a real-world population of patients with GPP, including patients with comorbidities and those taking concomitant medication
- There were no AEs leading to discontinuation of spesolimab or death
- Findings were comparable with those reported in the Phase 2 randomized controlled trial in patients with GPP flares (EFFISAYIL 1);[8] however, the small sample size in this analysis must be considered when interpreting the findings

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Disclosures

MLG is a speaker for Boehringer Ingelheim and Pfizer; and an investigator for Amgen, Boehringer Ingelheim, BMS, Lilly, Novartis, Merck, MSD, and Pfizer.
ML is a speaker for Boehringer Ingelheim and AbbVie. **RV** declares no conflict of interest. **NP, RSS, AC, ND, GV, LS, AW,** and **XD** are employees of Boehringer Ingelheim.

Abbreviations

ACE, angiotensin-converting enzyme; **AE**, adverse event; **AESI**, adverse event of special interest; **EAP**, expanded access program; **ERASPEN**, European Rare and Severe Psoriasis Expert Network; **GPP**, generalized pustular psoriasis; **IL**, interleukin; **IV**, intravenous; **plaque PsO**, plaque psoriasis; **RCTC**, Rheumatology Common Toxicity Criteria; **SAE**, serious adverse event; **SD**, standard deviation; **TEAE**, treatment-emergent adverse event.

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Data sharing statement

To ensure independent interpretation of clinical study results and enable authors fulfill their role and obligations under the ICMJE criteria, Boehringer Ingelheim grants all external authors access to relevant clinical study data. In adherence with the Boehringer Ingelheim Policy on Transparency and Publication of Clinical Study Data, scientific and medical researchers can request access to clinical study data, typically, one year after the approval has been granted by major Regulatory Authorities or after termination of the development program. Researchers should use the https://vivli.org/ link to request access to study data and visit https://www.mystudywindow.com/msw/datasharing for further information.

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