Real-world experience with spesolimab in Chinese patients with GPP

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Objective: To present real-world safety and efficacy data on the use of spesolimab in patients with GPP in an EAP conducted in China

Synopsis

- Generalized pustular psoriasis (GPP) is a chronic, systemic, neutrophilic inflammatory disease[1,2]
- GPP has a heterogeneous and unpredictable clinical course associated with chronic symptoms and periods of flaring, which can be life threatening[2,3]
- Spesolimab is an anti-interleukin-36 receptor monoclonal antibody approved in China for the treatment of GPP flares in adults (intravenous [IV] formulation [December 2022])[4] and for the reduction of occurrence of GPP flare in adults and adolescents from 12 years of age with a body weight of ≥40 kg (subcutaneous formulation [March 2024])[5]
- In EFFISAYIL® 1 (a randomized, placebo-controlled trial for the treatment of GPP flares), patients treated with a single dose of IV spesolimab 900 mg had rapid pustular and skin clearance[6]
- In a subgroup analysis of Chinese patients from EFFISAYIL® 1, more patients who received spesolimab had lesion clearance than those on placebo at Week 1, with an acceptable safety profile, consistent with the overall trial population[7]
- An expanded access program (EAP) was implemented in China (12 sites) from 23 May 2022 to 17 July 2023 to provide early access to spesolimab for patients experiencing GPP flares who were not eligible for clinical trials and had no satisfactory authorized alternative treatment options

Methods

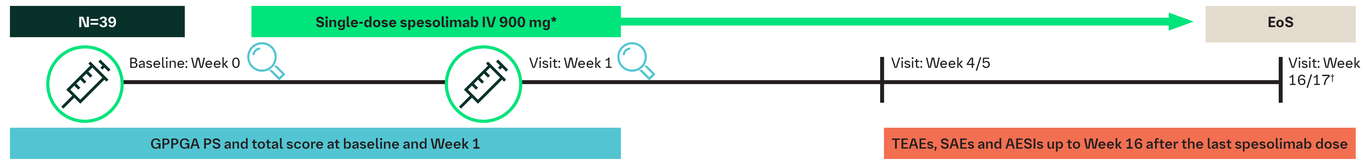
Enrolled patients

- 18–75 years old
- Diagnosed with GPP based on European Rare and Severe Psoriasis Expert Network guidelines
- No satisfactory authorized alternative therapy available
- Not eligible for clinical trials

Procedure

- Patients received a 900 mg dose of spesolimab IV for flare treatment, with an optional second dose after 1 week for persistent flare symptoms
- Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore (PS) and total score at baseline and Week 1 after administration of spesolimab were recorded
- Treatment-emergent adverse events (TEAEs), serious AEs (SAEs) and AEs of special interest (AESIs) were recorded up to Week 16 after the last spesolimab dose

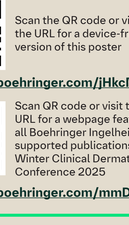
Study design



*Optional second dose after 1 week for persistent flare symptoms. †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.
EoS, end of study.

Results

Demographics and baseline characteristics



Study duration: 23 May 2022 to 17 July 2023.
Mean (± standard deviation [SD]) follow-up: 3.7 (0.1) months

N=39

Male (n=16)
Female (n=23)

Mean age (±SD): 39.3 (14.6) years; range: 18–65 years

Mean body mass index (±SD): 22.9 (3.7) kg/m²

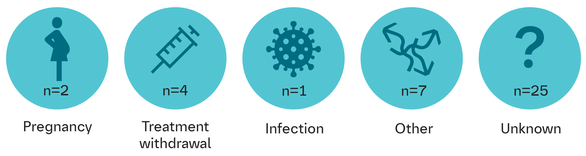
N=12*

Male (n=7)
Female (n=5)

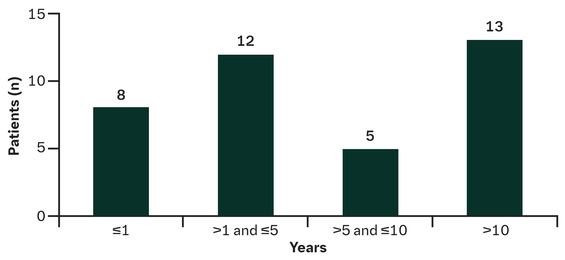
Mean age (±SD): 40.8 (15.4) years; range: 18–59 years

Mean body mass index (±SD): 24.7 (4.2) kg/m²

Flare triggers



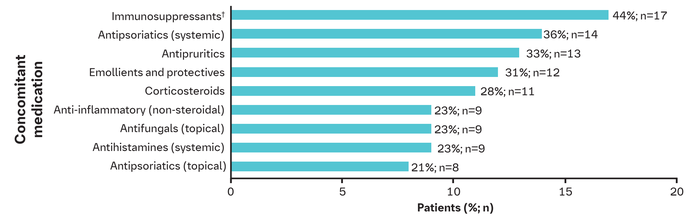
Time since diagnosis†



*12 patients had available GPPGA scores at baseline. †Missing data for one patient.

Concomitant medication

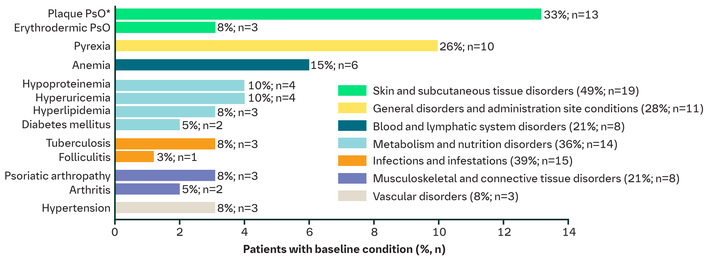
- Thirty-six patients (92%) reported the use of ≥1 concomitant medication* for GPP and/or other comorbidities
- Use of biologic therapy was reported among patients receiving immunosuppressants, interleukin-17 inhibitor (ixekizumab [13%; n=5], secukinumab [8%; n=3]) and/or tumor necrosis factor inhibitor (adalimumab [3%; n=1])



*Medications started prior to trial treatment or started within treatment phase are included.
†Some patients used more than one immunosuppressant, including biologic therapy (23%; n=9) and non-biologic therapy (28%; n=11).

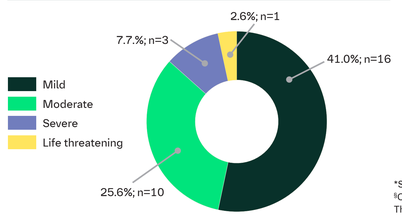
Comorbidities

- At baseline, 36 patients (92%) had at least one comorbidity
- Eighteen patients (46%) reported signs of chronic plaque psoriasis (PsO)* in the past year: mild (6%; n=1), moderate (72%; n=13) and severe (22%; n=4)
- Sixteen patients (89%) received treatment for their chronic plaque PsO



*At baseline, n=13 patients reported plaque PsO as a comorbidity as part of their medical history. Patients were also asked, "Within the last year, have there been signs of chronic plaque PsO?" (n=18 responded "yes"). This more specific question was designed to record whether patients had recently active chronic plaque PsO.

Thirty patients (77%) experienced TEAEs, which were mostly mild (n=16; 41.0%) or moderate (n=10; 25.6%)



Three patients (one female and two males) had severe AEs (Rheumatology Common Toxicity Criteria v.2.0 Grade 3 or 4), SAEs or AESIs

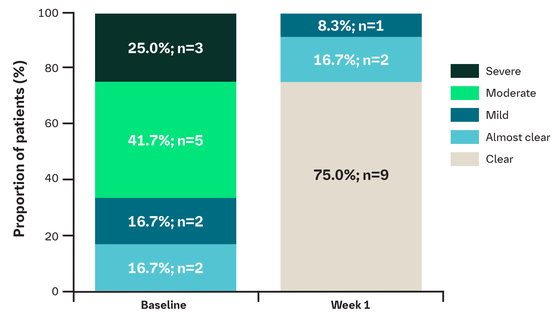
*Severe AE (Rheumatology Common Toxicity Criteria v.2.0 Grade 3 or 4). †SAE. ‡AESI.
§On Day 3, one patient developed lung infection that led to respiratory failure on Day 7. The patient required a 4-day hospitalization but recovered.

- Fourteen patients (35.9%) had investigator-defined drug-related AEs
- No AEs led to discontinuation or death

Most common AEs (>5% of patients)	n	%
Infections and infestations		
COVID-19	10	25.6
Upper respiratory tract infection	4	10.3
Nasopharyngitis	2	5.1
Pneumonia	2	5.1
Urinary tract infection	2	5.1
Blood and lymphatic system disorders		
Anemia	3	7.7
Metabolism and nutrition disorders		
Hypoproteinemia	4	10.3
Hyperuricemia	3	7.7
Hypokalemia	3	7.7
Skin and subcutaneous tissue disorders		
Pruritus	4	10.3
Rash	2	5.1
Urticaria	2	5.1
General disorders		
Pyrexia	6	15.4

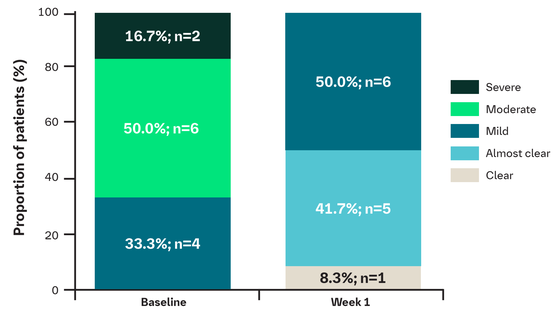
GPPGA PS after Week 1 of spesolimab (n=12*)

After 1 week of treatment, nine patients (75%) had clear skin with no pustules (GPPGA PS=0)



GPPGA total score after Week 1 of spesolimab (n=12*)

After 1 week of treatment, six patients (50%) achieved a GPPGA total score of 0 or 1, indicating clear or almost clear skin



*12 patients had available GPPGA scores at baseline.

Conclusions

- In a heterogeneous real-world population of patients with GPP in China, spesolimab was safe and well tolerated and provided rapid improvement of skin symptoms by Week 1
- The rapid improvement in skin symptoms observed in this analysis is consistent with the Phase 2a randomized controlled EFFISAYIL® 1 trial in patients with GPP flares, as well as a subgroup analysis of Chinese patients from EFFISAYIL® 1[6,7]
- In contrast to the EFFISAYIL® 1 trial, which required patients to have a GPPGA score of ≥3,[6] this analysis included patients with a GPPGA total score of ≥2 at baseline, highlighting the efficacy of treatment with spesolimab in a broader range of patients
- As previously reported, spesolimab has demonstrated a favorable safety profile in a real-world population of patients with GPP, with safety findings consistent with the context of the EAP (COVID-19 pandemic) and comparable with those reported in the EFFISAYIL® 1 trial[6,8]

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References

1. Rivera-Díaz R, et al. *Dermatol Ther (Heidelb)* 2023;13:673–88;
2. Puig L, et al. *J Eur Acad Dermatol Venereol* 2023;37:737–52;
3. Bhutani T and Farberg AS. *Dermatol Ther (Heidelb)* 2024;14:241–360;
4. Spesolimab [package insert]. Boehringer Ingelheim Investment Co., Ltd; Shanghai, China: December 2022;
5. Spesolimab [package insert]. Boehringer Ingelheim Investment Co., Ltd; Shanghai, China: March 2024;
6. Bachelez H, et al. *N Engl J Med* 2021;385:2431–40;
7. Tsai T-F, et al. *J Dermatol* 2023;13:3097–110;
8. Morita A, et al. EADV 2024. Poster presentation. P0997.

Abbreviations

AE, adverse event; **AESI**, adverse event of special interest; **EAP**, expanded access program; **EoS**, end of study; **GPP,** generalized pustular psoriasis; **GPPGA**, Generalized Pustular Psoriasis Physician Global Assessment; **IV**, intravenous; **PS**, pustulation subscore; **PsO**, psoriasis; **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 to 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.

Disclosures

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