Generalized pustular psoriasis (GPP) control is limited on traditional small-molecule therapy as measured by the GPPGA and DLQI:

Baseline data from the EFFISAYIL® 2 trial

Arash Mostaghimi,[1] Joseph F. Merola,[2] Alice B. Gottlieb,[3] Douglas DiRuggiero,[4] Jason Guercio,[5] Ming Tang,[6] Christian Thoma,[7] Mark G. Lebwohl[3]

[1]Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [2]UT Southwestern Medical Center, Dallas, TX, USA; [3]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [4]Skin Cancer & Cosmetic Dermatology Center, Rome, GA, USA; [5]Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA; [6]Boehringer Ingelheim (China) Investment Co. Ltd, Shanghai, China; [7]Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany

Objective

- Determine the GPP burden as measured by GPPGA and DLQI score at baseline in patients prior to randomization in EFFISAYIL® 2, stratified by baseline small-molecule medication

Conclusions

- Despite treatment with traditional small-molecule therapy prior to randomization, many patients entering EFFISAYIL® 2 still demonstrated incomplete skin clearance (GPPGA=1), and had DLQI scores of >5, reflecting a moderate effect on quality of life
- These findings suggest that patients would benefit from approved, targeted GPP therapy to reduce the clinical burden of GPP

Scan the QR code or visit URL for a device-friendly version of this poster https://go.boehringer.com/3hS4z

Scan the QR code or visit URL to view all Boehringer Ingelheim-supported presentations at WCH 2025 https://go.boehringer.com/mmD9e

Introduction

- GPP is a chronic, inflammatory, potentially life-threatening skin disease characterized by chronic symptoms and episodic flares of widespread skin pustulation[1]
- Spesolimab, an anti-interleukin-36 receptor monoclonal antibody, is approved to treat GPP in adults and pediatric patients aged ≥12 years and weighing ≥40 kg[2]
- EFFISAYIL® 2 (NCT04399837) was a randomized, multicenter, parallel-group, double-blind, placebo-controlled Phase IIb trial of spesolimab in patients with GPP[1]

Methods

- All patients in EFFISAYIL® 2 were aged 12–75 years, and had a documented history of GPP and a GPPGA total score of 0 or 1 at screening and randomization[1]
- Most patients were treated with systemic small-molecule medications before randomization
- In this analysis, GPP burden prior to randomization was measured in patients stratified by baseline medication use, including medications received by ≥5 patients or no medication
- GPP burden was assessed by the proportion of patients with a total GPPGA score of 1, and the mean (SD) DLQI score at baseline
- The GPPGA is an assessment of the burden of the skin symptoms of GPP (**Table 1**)[3]
- The DLQI is a 10-item questionnaire that reports the impact of dermatological diseases on patients' QoL based on 6 domains (symptoms and feelings, work and school, personal relationships, treatment, leisure, and daily activities; **Table 2**)[4]

Table 1. Components of the GPPGA score

Score	Erythema	Pustules	Scaling
0 (clear)	Normal or post-inflammatory hyperpigmentation	No visible pustules	No scaling or crusting
1 (almost clear)	Faint, diffuse pink, or slight red	Low-density occasional small discrete pustules (noncoalescent)	Superficial focal scaling or crusting restricted to periphery of lesions
2 (mild)	Light red	Moderate-density grouped discrete small pustules (noncoalescent)	Predominantly fine scaling or crusting
3 (moderate)	Bright red	High-density pustules with some coalescence	Moderate scaling or crusting covering most or all lesions
4 (severe)	Deep fiery red	Very-high-density pustules with pustular lakes	Severe scaling or crusting covering most or all lesions

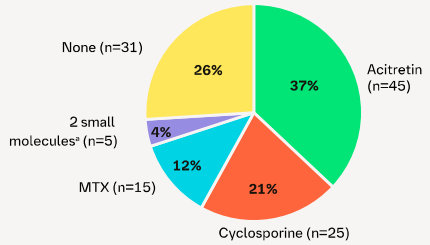
Table 2. DLQI total score definition

DLQI total score	Meaning
0–1	No effect on patient's life
2–5	Small effect on patient's life
6–10	Moderate effect on patient's life
11–20	Very large effect on patient's life
21–30	Extremely large effect on patient's life

Patients

- A total of 121 patients were included in this analysis (**Figure 1**); 74% had received small-molecule therapy prior to randomization

Figure 1. Baseline small-molecule medications (n=121)



[a]Included acitretin, MTX, and cyclosporine

- In each group, most patients were female; mean age 30–42 years, and mean BMI 23–27 kg/m²; the majority of patients were Asian, except in the MTX group (**Table 3**)

Table 3. Patient baseline characteristics

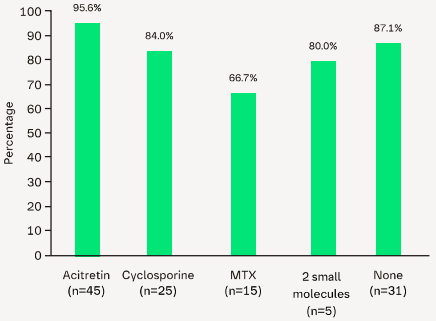
	Acitretin (n=45)	Cyclo-sporine (n=25)	MTX (n=15)	2 small molecules (n=5)	None (n=31)
Female, n (%)	28 (62.2)	16 (64.0)	9 (60.0)	4 (80.0)	18 (58.1)
Race, n (%)					
Asian	36 (80.0)	14 (56.0)	5 (33.3)	5 (100)	18 (58.1)
White	9 (20.0)	11 (44.0)	10 (66.7)	0 (0)	13 (41.9)
Mean age (SD), y	41.7 (14.6)	40.2 (17.2)	36.1 (11.8)	30.2 (4.8)	42.0 (19.1)
Mean BMI (SD), kg/m²	26.2 (7.5)	27.0 (8.2)	28.9 (11.7)	23.4 (3.7)	26.8 (6.6)
Time since first diagnosis, n (%)					
≤1 y	3 (6.7)	5 (20.0)	0 (0)	0 (0)	7 (22.6)
2–5 y	7 (15.6)	12 (48.0)	8 (53.3)	1 (20.0)	6 (19.4)
6–10 y	10 (22.2)	4 (16.0)	6 (40.0)	1 (20.0)	7 (22.6)
>10 y	25 (55.6)	4 (16.0)	1 (6.7)	3 (60.0)	11 (35.5)
Mean PSS score (SD)	4.5 (3.3)	3.9 (3.6)	4.2 (2.8)	3.2 (1.3)	4.4 (3.9)

Results

Baseline GPPGA total score

- Despite treatment with different traditional small-molecule therapies prior to entering EFFISAYIL® 2, a majority of patients in each baseline treatment group did not have clear skin (GPPGA=1) at baseline (**Figure 2**)

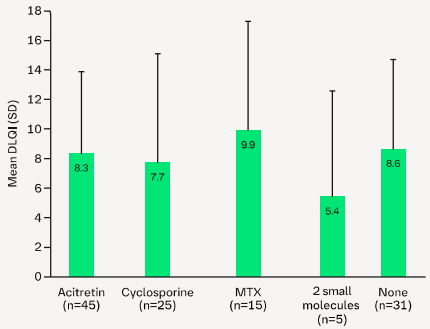
Figure 2. Proportion of patients with baseline GPPGA total score of 1



Baseline DLQI score

- All groups had a mean baseline DLQI score of >5, indicating at least a moderate effect on quality of life (**Figure 3**)

Figure 3. Mean baseline DLQI score in each group



Presented at: Winter Clinical Hawaii, Waikoloa Village, HI, USA; February 14–19, 2025

Abbreviations
BMI, body mass index; DLQI, Dermatology Life Quality Index; GPP, generalized pustular psoriasis; GPPGA, Generalized Pustular Psoriasis Physician's Global Assessment; MTX, methotrexate; PSS, Psoriasis Symptom Scale

References
1. Morita A, et al. Lancet. 2023;402:1541–51.
2. EFFISAYIL® prescribing information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761244s003lbl.pdf. (accessed January 13, 2024).
3. Burden AD, et al. BJD. 2023;189:138–40.
4. Finlay AY and Khan G. Clin Exp Dermatol. 1994;19:210–6.

Disclosures
AM has received consulting fees from AbbVie, ACOM Health, Biosiz, Boehringer Ingelheim, Concert, Digital Diagnostics, Eli Lilly, Equillium, Hims & Hers Health, and Pfizer; equity from ACOM Health, Figure 1, and Hims & Hers Health; licensing/royalties from Concert and Pfizer; and research funding from Aclaris, Concert, Eli Lilly, and Incyte. JFM is a consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Incyte, Janssen, LEO Pharma, Moonlake, Novartis, Pfizer, Sanofi, Regeneron, Sun Pharma, and UCB. ABG receives research/educational grants from Bristol Myers Squibb, Janssen, Moonlake, and UCB Pharma (all paid to Mount Sinai School of Medicine); and has received honoraria as an advisory board member and consultant for Amgen, Eli Lilly, Highlights Therapeutics, Janssen, Novartis, Sanofi, SunPharma, Takeda, Teva, UCB, and Xolotech (stock options for XA). DD has been a consultant and/or speaker for AbbVie, Ancuta, Amgen, Dermavant, Eli Lilly, Galderma, Janssen, Leo Pharma, Novartis, Sanofi/Regeneron, and UCB. JG, MT, and CT are employees of Boehringer Ingelheim. MGL is an employee of Mount Sinai and has received research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly, Incyte, Ionzyme, Janssen Research & Development, LLC, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for Almirall, AltruBio, Anaptysbio, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres Therapeutics, Bracket Biotech, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, EPI, Ionmenus, Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Searengy, Strata, Takeda, Trevi, and Verrica.

Acknowledgments
The study was supported and funded by Boehringer Ingelheim. The authors meet 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 this presentation. Boehringer Ingelheim was given the opportunity to review the presentation for medical and scientific accuracy, as well as intellectual property considerations. Hayley White, PhD, of Envision Pharma Group, provided writing, editorial, and formatting support, which was contracted and funded by Boehringer Ingelheim.

Boehringer Ingelheim