Spesolimab decreases generalized pustular psoriasis (GPP) body surface area (BSA) over time:

Results from the EFFISAYIL® 2 trial

Bruce E. Strober,[1] Joseph F. Merola,[2] Alice B. Gottlieb,[3] Arash Mostaghimi,[4] Jenny Hsiao,[5] Jason Guercio,[6] Ming Tang,[7] Christian Thoma,[8] Mark G. Lebwohl[3]

[1]Department of Dermatology, Yale University School of Medicine, New Haven, and Central Connecticut Dermatology, Cromwell, CT, USA; [2]Department of Dermatology and Department of Medicine, Division of Rheumatology, UT Southwestern Medical Center, Dallas, TX, USA; [3]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [4]Department of Dermatology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [5]Ronald Reagan UCLA Medical Center, Santa Monica, CA, USA; [6]Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA; [7]Boehringer Ingelheim (China) Investment Co. Ltd, Shanghai, China; [8]Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany

Objective

- To evaluate the efficacy of spesolimab on GPP BSA over time in patients enrolled in EFFISAYIL® 2

Conclusions

- Continuous treatment with s.c. spesolimab improved BSA, reducing the affected area from 13% to 5% at the end of the trial
- These findings suggest a role of spesolimab in improving area of involvement as measured by BSA

Scan QR code or visit URL for a webpage featuring all Boehringer Ingelheim-supported publications at Fall Clinical Dermatology Conference 2024 https://go.boehringer.com/QMa

Scan QR code or visit URL to view the e-poster https://go.boehringer.com/hD1wr

Introduction

- GPP is a chronic inflammatory, and potentially life-threatening skin disease characterized by episodic flares of widespread skin pustulation. Most patients experience chronic skin symptoms between flares, which can lead to significant disease burden[1]
- Spesolimab, an anti-interleukin-36 receptor monoclonal antibody, is approved in the United States as an i.v. or s.c. formulation to treat GPP in adults and pediatric patients ≥12 years of age and weighing at least 40 kg[2]
- EFFISAYIL® 2 (NCT04399837) evaluated the efficacy and safety of s.c. spesolimab in GPP. The study showed spesolimab (300 mg s.c. q4w after a 600 mg s.c. loading dose) reduced the risk of a GPP flare by 84%, and was significantly superior to placebo in preventing flares[1]
- Here, we report the effects on GPP BSA over time in patients treated with the US FDA-approved spesolimab dosing regimen (300 mg s.c. q4w after a 600 mg s.c. loading dose) in EFFISAYIL® 2

Methods

- Patients from the high-dose spesolimab group of EFFISAYIL® 2 were evaluated in this subgroup analysis (**Figure 1**)
- The average total BSA involvement was determined at baseline, Week 4, Week 16, and Week 48 (**Figure 2**)

Figure 1. Patients in EFFISAYIL® 2

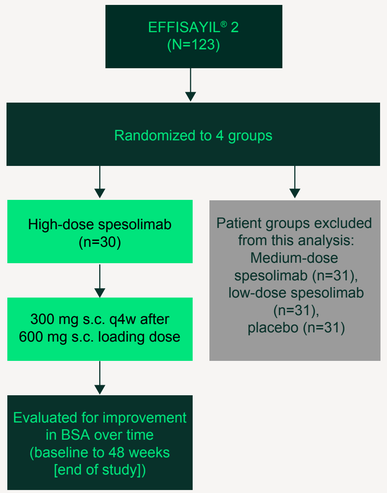
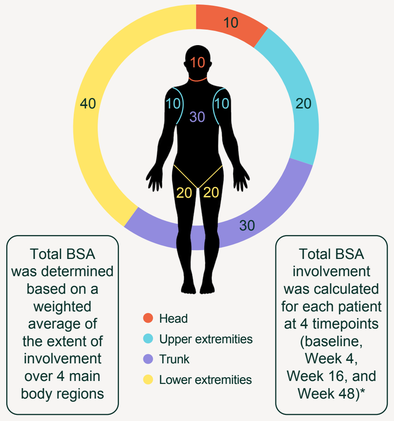


Figure 2. Assessment of body surface area



Total BSA was determined based on a weighted average of the extent of involvement over 4 main body regions

Total BSA involvement was calculated for each patient at 4 timepoints (baseline, Week 4, Week 16, and Week 48)*

*Data collected closest to the given time points were used by including the effect of potential i.v. spesolimab treatment and subsequent open-label s.c. spesolimab treatment in patients who experienced a flare. The data were analyzed as observed and by LOCF.

Results

- The average age of patients in this group was 40 years, 60% were female, and all patients were Asian (70%) or White (30%) (**Table 1**)

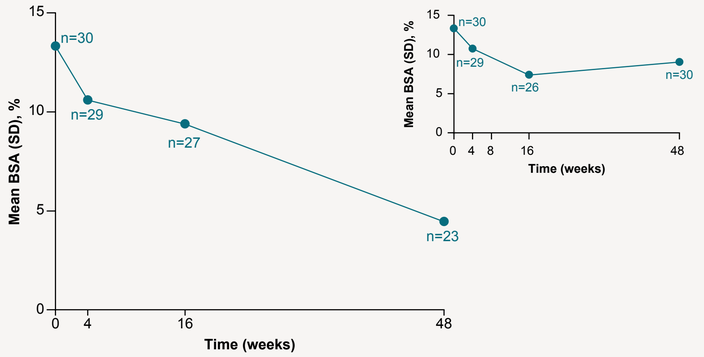
Table 1. Baseline patient characteristics

	High-dose spesolimab (300 mg s.c. q4w*) n=30
Mean age (SD), years	40.2 (16.4)
Female, n (%)	18 (60)
Race, n (%)	
Asian	21 (70)
White	9 (30)
Mean BMI (SD), kg/m²	25.6 (7.3)
Mean GPPASI total score (SD)	3.92 (4.4)
GPPGA total score, n (%)	
0	3 (10)
1	27 (90)
Mean PSS total score (SD)	5.3 (3.8)
Mean historical number of flares per year (SD)	2.4 (1.9)
Concurrent plaque PsO at baseline, n (%)	7 (23)

*Following a 600 mg s.c. loading dose

- Total BSA improved continuously with high-dose spesolimab treatment, decreasing from 13.3% at baseline, to 10.6% at Week 4, 9.4% at Week 16, and 4.5% at Week 48 (**Figure 3**)
- Data were also analyzed with LOCF to account for missing values (i.e. for the 3 patients who had flare events, and those who discontinued the trial prematurely). Even after imputation, BSA improved by Week 48 compared with baseline (**Figure 3, inset**)

Figure 3. Mean BSA involvement in patients receiving high-dose spesolimab over time, as observed, and by LOCF (inset)



Poster presented at: Fall Clinical Dermatology Conference, Las Vegas, NV, USA; October 24–27, 2024

Originally presented at: European Academy of Dermatology and Venereology 2024, Amsterdam, Netherlands, September 25–28, 2024

Abbreviations
BMI, body mass index; BSA, body surface area; FDA, Food and Drug Administration; GPP, generalized pustular psoriasis; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; GPPASI, Generalized Pustular Psoriasis Area and Severity Index; i.v., intravenous; LOCF, last observation carried forward; PsO, psoriasis; PSS, Psoriasis Symptom Scale; q4w, every 4 weeks; q12w, every 12 weeks; s.c., subcutaneous

References
1. Morita A, et al. *Lancet*. 2023;402:1541–51.
2. SPEVIGO® prescribing information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761244s003lbl.pdf (accessed Aug 8, 2024).

Disclosures
BES is a consultant for and receives honoraria from AbbVie, Alamar, Alumis, Almirall, Amgen, Arcutis, Arena, Aristea Therapeutics, Asana, Boehringer Ingelheim, Immunic Therapeutics, Kanggu Biopharmaceuticals, Bristol Myers Squibb, Connect Biopharma, Dermavant Sciences, Evelo Biosciences, Janssen, LEO Pharma, Eli Lilly, Maruho, Meiji Seika Pharma, Mindera Health, Protagonist, Nimbus, Novartis, Pfizer, UCB, Sun Pharma, Regeneron, Sanofi-Genzyme, Union Therapeutics, Ventyx Biosciences, and ∨Tv Therapeutics; has stock options in Connect Biopharma and Mindera Health; has acted as a speaker for AbbVie, Arcutis, Dermavant Sciences, Eli Lilly, Incyte, Janssen, Regeneron, and Sanofi-Genzyme; is an investigator for and receives consulting fees as Scientific Co-Director of the CorEvitas Psoriasis Registry; and receives payment as Editor-in-Chief of the *Journal of Psoriasis and Psoriatic Arthritis*. **JFM** is a consultant and/or investigator for AbbVie, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Eli Lilly, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, Sun Pharmaceuticals, and UCB. **ABG** has received research/educational grants from Highlights Therapeutics, Bristol Myers Squibb, Janssen, and UCB Pharma (all paid to Mount Sinai School of Medicine); and received honoraria as an advisory board member and consultant for Amgen, Anaptys Bio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dice Therapeutics, Eli Lilly, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB, and Xbiotech (stock options for RA). **AM** has received consulting fees from AbbVie, ACOM Health, Bioniz, Boehringer Ingelheim, Concert, Digital Diagnostics, Eli Lilly, Equillium, Hims & Hers Health, and Pfizer; equity from ACOM Health and Hims & Hers Health; licensing/royalties from Concert and Pfizer; and research funding from Aclaris, Concert, Eli Lilly, and Incyte. **JH** has been an advisor for AbbVie, Aclaris, Boehringer Ingelheim, Incyte, Novartis, and UCB; a speaker for AbbVie, Boehringer Ingelheim, Novartis, Sanofi Regeneron, and UCB; and an investigator for Amgen, Boehringer Ingelheim, and Incyte. **JG**, **MT**, and **CT** are employees of Boehringer Ingelheim. **MGL** is an employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Janssen, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for Almirall, Altru Bio Inc., Anaptys Bio, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres Therapeutics, Brickell Biotech, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, Corevitas, Dermavant Sciences, EPI, Evommune, 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, Seanergy, Strata, Takeda, Trevi, and Verrica

Acknowledgments
The study was supported and funded by Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI). 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 poster. Jia Gao, PharmD, and Hayley White, PhD, of Elevate Scientific Solutions provided writing and editorial support, which was contracted and funded by BIPI. BIPI was given the opportunity to review the poster for medical and scientific accuracy as well as intellectual property considerations.

Boehringer Ingelheim